# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION Washington, DC 20549

# FORM 10-K

|  | FURM 10-K  |
|--|--|
| (Mark One)   |  |
|  | R 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934<br>scal year ended December 31, 2018<br>OR  |
| ☐ TRANSITION REPORT PURSUANT TO SECTION 1  | 3 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  |
| For the transition   | period from to   |
| Comm   | nission File Number: 001-37625   |
| Voyager<br>(Exact Name of  | Therapeutics, Inc. of Registrant as Specified in Its Charter)  |
| Delaware<br>(State or Other Jurisdiction of<br>Incorporation or Organization)  | 46-3003182<br>(IRS Employer<br>Identification No.)   |
| 75 Sidney Street,<br>Cambridge, Massachusetts  | 02139  |
| (Address of Principal Executive Offices)   | 0215 <del>3</del><br>(Zip Code)  |
| (Registran   | (857) 259-5340<br>t's Telephone Number, Including Area Code)   |
| Indicate by check mark if the registrant is a well-known seasoned issu   | ner, as defined in Rule 405 of the Securities Act. <b>Yes</b> □ <b>No</b> ⊠  |
| Indicate by check mark if the registrant is not required to file reports p   | pursuant to Section 13 or Section 15(d) of the Act. <b>Yes No S</b>  |
| Indicate by check mark whether the registrant: (1) has filed all reports preceding 12 months (or for such shorter period that the registrant was received to $\mathbf{No}$ $\square$             | required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the juired to file such reports), and (2) has been subject to such filing requirements for the past 90 days.   |
|  | teractive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of  |
| Indicate by check mark if disclosure of delinquent filers pursuant to Ir contained, to the best of registrant's knowledge, in definitive proxy or inform 10-K. $\Box$                            | tem 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be<br>ormation statements incorporated by reference in Part III of this Form 10-K or any amendment to this   |
| Indicate by check mark whether the registrant is a large accelerated ficompany. See the definitions of "large accelerated filer," "accelerated filer Act.  | ler, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange        |
| Large accelerated filer □ Non-accelerated filer □  | Accelerated filer  Smaller reporting company  ⊠  |
|  | Emerging growth company  ant has elected not to use the extended transition period for complying with any new or revised   |
| Indicate by check mark whether the registrant is a shell company (as   | defined in Rule 12b-2 of the Act). <b>Yes</b> $\square$ <b>No</b> $\boxtimes$  |
| The aggregate market value of Common Stock held by non-affiliates 2018, the last business day of the registrant's most recently completed sec Nasdaq Global Select Market as of such date).      | of the registrant computed by reference to the price of the registrant's Common Stock as of June 29, ond fiscal quarter, was approximately \$442.0 million (based on the last reported sale price on the |
| As of February 22, 2019, there were 32,616,999 shares of the registra  | nt's common stock, par value \$0.001 per share, outstanding.   |
|  | S INCORPORATED BY REFERENCE  |
| Portions of the registrant's definitive Proxy Statement relating to its 2 Report on Form 10-K where indicated. Such Proxy Statement is expected of the fiscal year to which this report relates. | 019 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual to be filed with the U.S. Securities and Exchange Commission not later than 120 days after the end         |
|  |  |
|  |  |

|                   |   | Page |
|-------------------|---|------|
| PART I.           |   |      |
| Item 1.           | <u>Business</u>   | 4    |
| Item 1A.          | Risk Factors  | 60   |
| <u>Item 1B.</u>   | <u>Unresolved Staff Comments</u>  | 122  |
| Item 2.           | <u>Properties</u>   | 122  |
| <u>Item 3.</u>    | <u>Legal Proceedings</u>  | 122  |
| <u>Item 4.</u>    | Mine Safety Disclosures   | 122  |
| PART II.          |   |      |
| <u>Item 5.</u>    | Market for Registrant's Common Equity, Related Stockholder Matters and Issuer         |      |
|                   | <u>Purchases of Equity Securities</u>   | 122  |
| <u>Item 6.</u>    | Selected Financial Data   | 123  |
| <u>Item 7.</u>    | Management's Discussion and Analysis of Financial Condition and Results of Operations | 125  |
| Item 7A.          | Quantitative and Qualitative Disclosures about Market Risk                            | 142  |
| <u>Item 8.</u>    | Financial Statements and Supplementary Data   | 143  |
| <u>Item 9.</u>    | Changes in and Disagreements with Accountants on Accounting and Financial Disclosure  | 143  |
| Item 9A.          | Controls and Procedures   | 143  |
| Item 9B.          | Other Information   | 144  |
| PART III.         |   |      |
| Item 10.          | Directors, Executive Officers and Corporate Governance                                | 144  |
| Item 11.          | Executive Compensation  | 144  |
| Item 12.          | Security Ownership of Certain Beneficial Owners and Management and Related            |      |
|                   | Stockholder Matters   | 144  |
| <u>Item 13.</u>   | Certain Relationships and Related Transactions, and Director Independence             | 145  |
| <u>Item 14.</u>   | Principal Accountant Fees and Services  | 145  |
| PART IV.          |   |      |
| Item 15.          | Exhibits, Financial Statement Schedules   | 145  |
| <u>Item 16.</u>   | Form 10-K Summary   | 145  |
| <u>Signatures</u> |   | F-37 |
|                   |   |      |
|                   |   |      |

# **Forward-Looking Statements**

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words "anticipate," "believe," "estimate," "expect," "intend," "may," "might," "plan," "predict," "project," "target," "potential," "contemplate," "anticipate," "goals," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- our plans to develop and commercialize our product candidates based on adeno-associated virus, or AAV, gene therapy;
- · our ability to identify and optimize product candidates and novel AAV gene therapy capsids;
- our ongoing and planned clinical trials and related timelines, including our ability to continue to advance VY-AADC
  as a treatment for Parkinson's disease through the ongoing Phase 1b clinical trial and the RESTORE-1 Phase 2
  clinical trial, and our preclinical development efforts and studies;
- formulation changes to our product candidates may require us to conduct additional clinical studies to bridge our modified product candidates to earlier versions;
- the timing of and our ability to submit applications for, and obtain and maintain regulatory approvals for our product candidates, including our ability to file Investigational New Drug applications for our programs including VY-SOD102 for the treatment of a monogenic form of amyotrophic lateral sclerosis, VY-HTT01 for the treatment of Huntington's disease, and VY-FXN01 for the treatment of Friedreich's ataxia;
- · our estimates regarding expenses, future revenues, capital requirements, and needs for additional financing;
- · our ability to continue to develop our gene therapy platform;
- our ability to develop a manufacturing capability compliant with current good manufacturing practices for our product candidates;
- · our ability to access, develop, and obtain regulatory clearance for devices to deliver our AAV gene therapies to critical targets of neurological disease;
- · our intellectual property position and our ability to obtain, maintain and enforce intellectual property protection for our proprietary assets;
- · our estimates regarding the size of the potential markets for our product candidates and our ability to serve those markets:
- · the rate and degree of market acceptance of our product candidates for any indication once approved;
- · our strategic collaborations with Sanofi Genzyme Corporation, or Sanofi Genzyme; AbbVie Biotechnology Ltd and AbbVie Ireland Unlimited Company, or collectively AbbVie, and Neurocrine Biosciences, Inc., including the possibility and timing of Sanofi Genzyme or AbbVie exercising their respective options to certain of our programs as specified in the applicable collaboration agreements;

- our plans and ability to raise additional capital, including through equity offerings, debt financings, collaborations, strategic alliances, and licensing arrangements;
- · our competitive position and the success of competing products that are or become available for the indications that we are pursuing;
- the impact of government laws and regulations including in the United States, the European Union, and other important geographies such as Japan;
- · our ability to maintain consistency with results from our ongoing Phase 1b clinical trial and our separate Phase 1 clinical trial focused on posterior trajectory in future clinical trials; and
- · our ability to enter into future collaborations, strategic alliances, or licensing arrangements.

These forward-looking statements are only predictions and we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements. You should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in "Part I, Item 1A - Risk Factors" that could cause actual future results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to the Annual Report on Form 10-K with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by applicable law.

# PART I

#### ITEM 1. BUSINESS

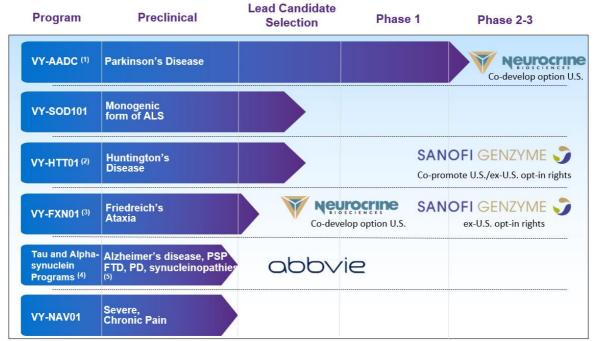
We are a clinical-stage gene therapy company focused on developing life-changing treatments for patients suffering from severe neurological diseases. We focus on neurological diseases where we believe an adeno-associated virus, or AAV, gene therapy approach that either increases or decreases the production of a specific protein can slow or reduce the symptoms experienced by patients, and therefore have a clinically meaningful impact. We have built a gene therapy platform that we believe positions us to be a leading company at the intersection of AAV gene therapy and severe neurological disease. Our gene therapy platform enables us to engineer, optimize, manufacture and deliver our AAV-based gene therapies that have the potential to provide durable efficacy following a single administration.

Additionally, we are working to identify novel AAV capsids, which are the outer viral protein shells that enclose the genetic material of the virus payload. Our team of experts in the fields of AAV gene therapy and neuroscience first identifies and selects severe neurological diseases that are well-suited for treatment using AAV gene therapy. We then engineer and optimize AAV vectors for delivery of the virus payload to the targeted tissue or cells. Our manufacturing process employs an established system that we believe will enable production of high quality AAV vectors at commercial-scale. In addition to our capsid optimization efforts, we leverage novel delivery paradigms, established routes of administration, and advances in dosing techniques to optimize delivery of our AAV gene therapies to target tissues, regions and cell types that are critical to the disease of interest. We believe we can achieve this directly, with targeted infusions to discrete regions of the brain or spinal cord, or systemically, in conjunction with our novel capsids.

Our business strategy focuses on discovering, developing, manufacturing and commercializing our gene therapy programs. As part of this strategy, we have developed core competencies specific to AAV gene therapy development and manufacturing and are beginning to build our commercial infrastructure. This business strategy also includes business development activities that may include in-licensing activities or partnering certain programs in specific geographies

with collaborators, as we have demonstrated through our collaborations, including those with Sanofi Genzyme, AbbVie, and Neurocrine. Since our inception, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio, determining which neurological diseases to pursue, advancing our product candidates including delivery and manufacturing, and conducting preclinical studies and clinical trials. We do not have any product candidates approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through private placements of redeemable convertible preferred stock, public offerings of our common stock, our collaboration with Sanofi Genzyme, or the Sanofi Genzyme Collaboration, which commenced in February 2015 and our collaboration with AbbVie focusing on tau-related diseases, or the AbbVie Tau Collaboration, which commenced in February 2018. Additionally, we recently entered into collaborations with Neurocrine, or the Neurocrine Collaboration, which we expect to commence in the first half of 2019, and with AbbVie focusing on pathological species of alpha-synuclein, or the AbbVie Alpha-Synuclein Collaboration.

Our pipeline of gene therapy programs is summarized in the table below:



(1) Voyager has option to co-commercialize U.S., or grant Neurocrine commercial rights (2) Sanofi Genzyme has ex-U.S. options and option to co-promote in the U.S. (3) Voyager has option to co-commercialize U.S., or grant Neurocrine commercial rights; Sanofi Genzyme maintains ex-U.S. options (4) Tau program in collaboration with AbbVie (5) PSP = Progressive Supranuclear Palsy, FTD = Frontotemporal Dementia, PD=Parkinson's disease

Our pipeline consists of programs for severe neurological indications, including Parkinson's disease; a monogenic form of amyotrophic lateral sclerosis, or ALS; Huntington's disease; Friedreich's ataxia; tau-related diseases including Alzheimer's disease, frontotemporal dementia, or FTD, and progressive supranuclear palsy; or PSP, Alpha-synuclein related diseases for Parkinson's disease and other synucleinopathies; and severe, chronic pain. We may seek orphan drug designation, breakthrough therapy designation, or other expedited review processes for certain of our product candidates in the United States, Europe, and Japan.

Our most advanced clinical candidate, VY-AADC for the treatment of Parkinson's disease, is being evaluated for safety and efficacy of escalating doses in an open-label, Phase 1b clinical trial. We have completed enrolling the Phase 1b trial of VY-AADC and continue to monitor results. Preliminary data from Cohorts 1 through 3 from this trial were reported beginning in late 2016 and most recently in November 2018.

In December 2018, we announced randomization of the first patient in our RESTORE-1 Phase 2, randomized, double-blind, placebo-surgery controlled trial evaluating the safety and efficacy of VY-AADC for the treatment of Parkinson's disease in patients with motor fluctuations that are refractory to medical management. The RESTORE-1 Phase 2 trial will enroll patients who have been diagnosed with Parkinson's disease for at least four years, are not responding adequately to oral medications, and have at least three or more hours of OFF time during the day as measured by a validated self-reported patient diary. Patients who meet the eligibility criteria will be randomized (1:1) to one-time administration of VY-AADC (for a total dose of up to  $2.5 \times 10^{12}$  vector genomes, or vg) or placebo surgery.

We are pursuing additional product candidates in the preclinical stages of development, including treatment programs for ALS, Huntington's disease, Friedreich's ataxia, tau-related neurodegenerative diseases and the treatment of severe, chronic pain. If preclinical studies prove successful, we plan to file investigational new drug, or IND, applications for our ALS and Huntington's disease programs during 2019.

In late 2017, we initiated additional preclinical studies to further optimize our ALS program's therapeutic approach, including exploration of additional routes of administration and novel AAV capsids in large animal models. VY-SOD102, our clinical candidate for the treatment of a monogenic form of ALS, is composed of an adeno-associated virus capsid and a proprietary transgene that selectively knocks down, or reduces, levels of SOD1 mRNA. VY-SOD102 has the potential to durably reduce the levels of toxic mutant SOD1 protein in the spinal cord to slow the progression of disease. In late 2018, we presented data on VY-SOD102 administered with a novel delivery paradigm comprising a one-time, intraparenchymal infusion after laminectomy to the cervical spinal cord of the mini-pig, which has a spinal cord similar in length and diameter to the human spinal cord. This delivery approach yielded safe and significant reduction of SOD1 at 4 weeks post-dosing at the site of the infusion and throughout the spinal cord, most notably in the cervical and thoracic regions critical for respiratory function. Further preclinical studies are underway with VY-SOD102 which, if successful, will support a potential filing of an IND application in 2019.

In 2017, we selected VY-HTT01 as our clinical candidate for the treatment of Huntington's disease. Recent preclinical delivery studies have further optimized the dosing paradigm to support filing of a potential IND application. VY-HTT01 is composed of an adeno-associated virus capsid (AAV1) and proprietary transgene that harnesses the RNA interference pathway to selectively knock down, or reduce, levels of HTT mRNA. In late 2018, we presented results demonstrating significant reduction of HTT mRNA at five weeks post-dosing in adult non-human primates using a magnetic resonance imaging, or MRI, guided surgical delivery of VY-HTT01 and a novel delivery paradigm targeting both the putamen and thalamus. Targeting the thalamus in addition to the putamen leverages more extensive and more preserved neuronal pathways to the cortex than delivery to the putamen alone. This novel dosing paradigm with VY-HTT01 resulted in safe and significant suppression of HTT in the striatum and in cortical neurons, which are critical in the progression of disease. Further preclinical studies are underway with VY-HTT01 which, if successful, will support a potential filing of an IND application in 2019.

Additional preclinical studies are underway including steps to optimize a lead clinical candidate for the treatment of Friedreich's ataxia. Additionally, we are collaborating with AbbVie on the research and development of specified vectorized antibody compounds comprised of an AAV or other viral capsid and a virus vector genome that encodes one or more antibodies that target and bind to a tau protein. We are also conducting proof-of-concept studies on our VY-NAV01 program for the treatment of severe, chronic pain.

In January 2019, we announced the Neurocrine Collaboration focused on the development and commercialization of our VY-AADC gene therapy program for Parkinson's disease and VY-FXN01 gene therapy program for Friedreich's ataxia, as well as rights to two programs to be determined. Agreements related to the Neurocrine Collaboration including the collaboration and license agreement are subject to certain conditions, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and other customary closing conditions. We expect our work to commence under the Neurocrine Collaboration in the first half of 2019. In February 2019, we announced the AbbVie Alpha-Synuclein Collaboration to develop and commercialize vectorized antibodies directed at pathological species of alpha-synuclein for the potential treatment of Parkinson's disease and other diseases characterized by the abnormal accumulation of misfolded alpha-synuclein protein, or synucleinopathies.

In addition to the programs described above, we continue to evaluate additional severe neurological diseases that could be treated using AAV gene therapy through application of either a gene replacement or a gene knockdown approach and are also actively exploring additional potential treatment methods that can utilize an AAV vector.

Finally, we developed our own real-time, intra-operative, MRI compatible device, the Variable Trajectory Array Guide, or V-TAG $^{\text{TM}}$ , that can be used with other neuro-navigational systems for the administration of drug to the putamen and other surgical procedures to avoid blood vessels and reduce the risk of potential hemorrhage during surgery and to maximize drug coverage of the putamen. In July 2018, the Center for Devices and Radiological Health, or the CDRH, of the FDA provided 510(k) clearance for V-TAG. We are currently working with a collaborator on process development and manufacturing of the device. Investigators have used an alternative MRI-compatible device called the ClearPoint\* System in our Phase 1b clinical trial of VY-AADC and Phase 1 posterior trajectory trial. We expect to use both our own V-TAG and the ClearPoint System in our RESTORE-1 Phase 2 clinical trial.

# Sanofi Genzyme Collaboration

In February 2015, we entered into a strategic collaboration with Sanofi Genzyme to leverage our combined expertise and assets to develop AAV gene therapies for certain severe neurological diseases. Under the agreement, we received \$65.0 million in upfront cash, a \$30.0 million upfront equity investment, and an in-kind commitment of \$5.0 million, totaling \$100.0 million. At the inception of the agreement, we were eligible to receive up to \$745.0 million in option and milestone payments while retaining U.S. commercial rights to most programs. Under the terms of the collaboration, we granted Sanofi Genzyme an exclusive option (i) to license, develop and commercialize ex-U.S. rights to the VY-AADC program, VY-FXN01, VY-HTT01, and a future program to be designated by Sanofi Genzyme, which we refer to collectively as the Split Territory Programs; (ii) to license, develop and commercialize worldwide rights to VY-SMN101; and (iii) to cocommercialize VY-HTT01 in the United States. Each of Sanofi Genzyme's options to a Split Territory Program is triggered following the completion of the first proof-of-principle human clinical study, or POP Study, on a program-by-program basis.

In October 2017, Sanofi Genzyme notified us that it had decided not to exercise its option for the ex-U.S. rights to VY-AADC for Parkinson's disease. As a result, we are no longer entitled to receive \$45.0 million and \$60.0 million of regulatory and commercial milestone payments from Sanofi Genzyme, respectively, related to the Parkinson's program under the Sanofi Genzyme Collaboration. If we use certain Sanofi Genzyme technology in VY-AADC, Sanofi Genzyme is entitled to receive low-single-digit royalty payments based on a percentage of net sales by us, and we may be obligated to make certain regulatory milestone payments to a third-party licensor.

#### AbbVie Tau Collaboration

In February 2018, we entered into an exclusive collaboration and option agreement with AbbVie for the research, development, and commercialization of AAV and other virus-based gene therapy products for the treatment of diseases of the central nervous system and other neurodegenerative diseases related to defective or excess aggregation of tau protein in the human brain, including Alzheimer's disease. Under the terms of the agreement, we received an upfront payment of \$69.0 million and may receive future option fees, development and regulatory milestone payments and royalties. Under the terms of the agreement, we will perform specified research, preclinical, and Phase 1 development activities regarding vectorized antibodies directed against tau, after which AbbVie may select one or more vectorized antibodies to proceed into INDenabling studies and clinical development. We will be responsible for the research, IND-enabling studies, and Phase 1 clinical trial activities and costs. Following the completion of Phase 1 clinical development, AbbVie has an option to license the vectorized tau antibody program and would then lead further clinical development and global commercialization for the product candidates pursuant to the agreement. We may earn up to \$215.0 million in option exercise fees for such preclinical and Phase 1 development activities. In addition to the upfront payment and the potential option exercise payments, we are eligible to receive up to \$895.0 million in development and regulatory milestones for each vectorized tau antibody compound. We are also eligible to receive tiered, escalating royalties in a range, subject to certain specified exceptions, from a high-single digit to a mid-to-high teen percentage of the global net sales of the vectorized antibodies for tauopathies, including Alzheimer's disease and other neurodegenerative diseases. We also have an option to share in the costs of clinical development for higher royalty rates. Under the terms of the agreement, each party will own the entire right, title and interest in and to all know-how and

patent rights first made or invented solely by it or its affiliates or its or their sublicensees in the course of the collaboration, with certain specified exceptions. We have also agreed to grant AbbVie a worldwide license to certain know-how and patent rights developed by us or jointly by the parties arising from the collaboration.

## Neurocrine Collaboration

In January 2019, we entered into the Neurocrine Collaboration Agreement for the research, development and commercialization of four programs including our Parkinson's disease program, or AADC Program, our Friedreich's ataxia program, or FA Program, and two programs, or the Discovery Programs. The Neurocrine Collaboration Agreement is not yet effective and remains subject to customary closing conditions, including certain antitrust approvals, that have not been satisfied as of the date of this Annual Report on Form 10-K. Under the terms of the agreement, we will receive an upfront payment of \$165.0 million, inclusive of \$50.0 million for the sale of 4,179,728 shares of our common stock, and may receive future development and regulatory milestone payments and royalties. We will use commercially reasonable efforts to develop the products in each of these programs. Neurocrine will be responsible for all costs incurred by us in conducting these activities for each program, in accordance with an agreed budget.

Under the terms of the agreement for the AADC Program, Neurocrine will fund the clinical development of the RESTORE-1 Phase 2 clinical trials for VY-AADC. After the data readout of the RESTORE-1 Phase 2 trial, we have the option to either: (1) co-commercialize VY-AADC with Neurocrine in the U.S. under a 50/50 cost- and profit-sharing arrangement and receive milestones and royalties based on ex-U.S. sales, or (2) grant Neurocrine full global commercial rights in exchange for milestone payments and royalties based on global sales. Under the terms of the agreement for the FA Program, Neurocrine will fund the development through the Phase 1 clinical trial of VY-FXN01. After the data readout of the Phase 1 trial, we have the option to either: (1) co-commercialize VY-FXN01 with Neurocrine in the U.S. under a 60/40 cost- and profit-sharing arrangement, or (2) grant Neurocrine full worldwide commercial rights in exchange for milestone payments and royalties based on global sales, subject to Sanofi Genzyme's option to commercialize the FA Program in countries outside the United States. Under the terms of the agreement for the two Discovery Programs, Neurocrine will fund the development of those programs and we have the right to earn milestone payments and royalties based on global sales.

In addition to the upfront payment, we are eligible to receive aggregate development milestone payments under (i) the AADC Program of up to \$170.0 million, (ii) the FA Program of up to \$195.0 million, and (iii) each of the Discovery Programs of up to \$130.0 million each. We may also be entitled to receive aggregate commercial milestone payments for each collaboration product of up to \$275.0 million, subject to an aggregate cap on commercial milestone payments across all programs of \$1.1 billion. We are also eligible to receive royalties, based on future net sales of the collaboration products. Such royalty percentages, for net sales in and outside the United States, as applicable, range (i) for the AADC Program, from the mid-teens to thirty and the low-teens to twenty, respectively; (ii) for the FA Program, from the low-teens to high-teens and high-single digits to mid-teens, respectively; and (iii) for each Discovery Program, from the high-single digits to mid-teens and mid-single digits to low-teens, respectively.

# AbbVie Alpha-Synuclein Collaboration

In February 2019, we entered into an exclusive collaboration and option agreement with AbbVie for the development and commercialization of vectorized antibodies directed against pathological species of alpha-synuclein for the potential treatment of Parkinson's disease and other diseases characterized by the abnormal accumulation of misfolded alpha-synuclein protein, or synucleinopathies. Under the terms of this agreement, we will receive and upfront payment of \$65.0 million and may receive future option fees, development, regulatory, and commercial milestone payments, and royalties. Under the terms of the agreement, we and AbbVie have agreed to collaborate on the research and development of specified vectorized antibody compounds, or research compounds, comprised of an AAV or other viral capsid and a virus vector genome that encodes one or more antibodies that target and bind to the alpha-synuclein protein. The collaboration is comprised of a research period and a development period. We are obligated to conduct research activities directed to constructing one or more virus vectors that encode antibodies designated by AbbVie. We are obligated to use diligent efforts to conduct antibody engineering and other research activities to create the Research Compounds and to develop product candidates containing or comprised of such Research Compounds, which we refer to as Product Candidates. We are solely responsible for the costs and expenses during the research period. During a

specified portion of the Research Period, AbbVie may exercise one or more of its exclusive development options to select up to a total of four Research Compounds and their corresponding Product Candidates to proceed to the development period, after which AbbVie may exercise its option to license such Product Candidates following Phase 1 results, for which we may earn up to \$245.0 million in option exercise payments in aggregate. In addition to the upfront payment and the potential option exercise payments, we are eligible to receive up to \$727.5 million in development and regulatory milestones for each Licensed Compound. We are also eligible to receive tiered, escalating royalties, in the mid-single-digit percentage range on aggregate net sales of Licensed Products on a Licensed Compound by Licensed Compound basis, as well as up to \$500.0 million in commercial milestones based on aggregate annual net sales thresholds of Licensed Products. The royalties are subject to potential reductions for biosimilar market penetration, patent claim expiration, and other provisions, subject to specified limits. Subject to certain exceptions, each of AbbVie and the Company has agreed to be financially responsible for all payments owed to a third party with which it has contracted for any use of in-licensed intellectual property under the Collaboration Agreement.

# Mission and Strategy

Our mission is to become the world leader in AAV gene therapy focused on treating severe neurological diseases by developing transformative therapies. Our strategy to achieve this mission is to:

• Optimize and advance VY-AADC for the treatment of Parkinson's disease. We continue to evaluate the dosing and delivery of VY-AADC to determine the optimal and safe dose to achieve meaningful clinical benefit for patients with Parkinson's disease. The November 2018 interim results from the ongoing Phase 1b clinical trial include data from all 15 patients treated in Cohorts 1, 2 and 3 (five patients in each Cohort) including data from patients in Cohort 1 at three years, Cohort 2 at two years and Cohort 3 at 18 months. The results continue to demonstrate durable improvements across multiple measures of patients' motor function after a one-time administration of the gene therapy, as evidenced by the patients' diaries, the Unified Parkinson's Disease Rating Scale, or UPDRS, UPDRS-II and UPDRS-III, and quality of life assessments. The average measure of motor function by UPDRS, or UPDRS-III, on medication score was 13.5 and UPDRS-III off medication score was 37.1, the average measure of activities of daily living by UPDRS, or UPDRS-II. The update of results from the ongoing Phase 1b clinical trial of VY-AADC include a 2.1-hour mean improvement in good ON time from baseline to three years for patients in Cohort 1, a 2.7-hour mean improvement from baseline to 2 years in Cohort 2, and a mean improvement of 1.7 hours from baseline to eighteen months in Cohort 3.

For the RESTORE-1 Phase 2 clinical trial, we have selected a dose of up to 2.5 x 10<sup>12</sup> vector genomes, which is defined as a maximum total bilateral dose. This dose is between the up-to-maximum total vector genome doses administered in Cohorts 2 and 3 from the Phase 1b trial when considering the higher volume administered with the posterior trajectory and vector produced using the baculovirus system. Having selected a dose for the RESTORE-1 Phase 2 trial between the two highest dose Cohorts from the Phase 1b trial, we have performed a combined analysis of the outcomes from the ten patients in Cohorts 2 and 3. Results from the combined ten patients in Cohorts 2 and 3 demonstrated mean increases from baseline in good ON time of 2.4 hours per day at 12 months, the timepoint for the primary endpoint in the RESTORE-1 Phase 2 trial, and 2.6 hours per day at 18 months, the latest timepoint measured for both Cohorts. Of the combined ten patients in Cohorts 2 and 3, seven patients would have met the eligibility criteria for the RESTORE-1 Phase 2 trial based on limits in severity of dyskinesia and minimum OFF time at baseline. For these seven patients, the RESTORE-1 Phase 2 trial relevant group, the mean improvements in good ON time were 2.8 hours at 12 months and 2.5 hours at 18 months. These results were achieved with clinically meaningful and sustained reductions in daily oral levodopa and trial.

**Build and advance a pipeline of gene therapy programs focused on severe neurological diseases.** Beyond our clinical-stage program for Parkinson's disease, we have a deep pipeline of AAV gene therapy programs in various stages of preclinical development. We plan to file two additional INDs for our preclinical

programs in 2019. We believe that our leadership position in AAV gene therapy for severe neurological diseases and our gene therapy platform provide us with the necessary capabilities to evaluate and capitalize on external opportunities. As such, we plan to opportunistically expand our pipeline through acquisition, in-licensing or other strategic transactions.

- Continuously invest in our AAV gene therapy platform. We plan to continuously invest in our gene therapy platform to maintain our leadership in AAV gene therapy for neurological diseases. Specifically, we intend to further develop and enhance our gene therapy platform by focusing on (i) vector engineering and optimization; (ii) manufacturing; and (iii) dosing and delivery techniques. We plan to continue generating novel AAV vectors by engineering and optimizing vectors best suited to a targeted disease. We have built an onsite, state-of-the-art process research and development facility to enable the manufacturing of high quality AAV gene therapy vectors at laboratory scale. We expect to utilize established and novel techniques for dosing and delivery of our AAV gene therapies to the central nervous system, or CNS.
- Establish a leadership position in commercial-scale, high quality AAV manufacturing. We believe that manufacturing capacity and expertise are critical to successfully treating patients using gene therapy. We have established relationships with multiple current good manufacturing practices, or cGMP, contract manufacturers. Previously, through one of our collaborations, with MassBiologics, an FDA-licensed manufacturer affiliated with the University of Massachusetts Medical School, we initiated cGMP production activities. More recently, we announced additional agreements with Brammer Bio and with Fujifilm Diosynth Biotechnologies, established contract manufacturers that specialize in gene therapy and AAV vectors. We are using the baculovirus/Sf9 AAV production system, a technology for producing AAV vectors at scale in insect-derived cells, originally invented and developed by several current and former members of our production team while at the National Institutes of Health, or NIH, which we continue to improve upon. We believe that having oversight through these key relationships over our own commercial manufacturing process is critical to ensuring quality product with commercial yields.
- Retain commercialization rights to our programs. We hold worldwide rights for our ALS, and severe, chronic pain programs. We have retained co-development and co-commercialization rights for our Parkinson's disease and Friedreich's ataxia programs under our Neurocrine Collaboration and for our Huntington's disease program under our Sanofi Genzyme Collaboration, respectively. As these and other programs advance through late-stage clinical development, we intend to build our own sales and marketing infrastructure and leverage our partnerships to support our programs where we have retained commercialization rights. These collaborations also represent an important advance in our strategy to leverage our AAV gene therapy platform and programs through collaborative partnerships with biopharmaceutical companies that bring complementary expertise, capabilities, and experience, in addition to capital.
- Expand our intellectual property portfolio. We seek to have an industry leading intellectual property portfolio. To that end, we seek patent rights for various aspects of our programs, including vector engineering and construct design, our production process, and all features of our clinical products including compositions and methods of delivery. We expect to continue to expand our intellectual property portfolio by aggressively seeking patent rights for promising aspects of our gene therapy platform and product candidates.

# **AAV Gene Therapy for Neurological Diseases**

Gene therapy is an approach whereby gene expression is directly altered in patients to address the underlying cause or predominant manifestations of disease. We believe that the targeted nature of gene therapy may enable powerful treatment options and provide these patients with meaningful and durable benefits.

While AAV gene therapy can potentially be harnessed for multiple treatment methods, we are currently focused on gene replacement and gene knockdown approaches. Gene replacement is intended to restore the expression of a protein that is not expressed, expressed at abnormally low levels or functionally mutated with loss of function. Gene knockdown, or gene silencing, is intended to reduce the expression of a pathologically mutated protein that has detrimental effects.

Our gene therapy approach uses AAV vectors which we believe are ideal vectors for gene therapy for several reasons:

**Broad Applicability.** AAV is able to transduce, or transfer a therapeutic gene, into numerous cell types including target cells in the CNS.

**Safety.** AAV is believed to be safe and is not known to cause any disease in humans. No vector-related serious adverse effects, or SAEs, have been reported in the more than 1,500 patients, including over 200 patients for neurological indications, treated with AAV gene therapy to date.

**Does Not Readily Integrate.** AAV does not readily integrate into the genome of the target cell, reducing the potential for oncogenesis, or the induction of cancer.

**Scalability.** AAV is able to be manufactured at commercial quality and scale.

We believe that neurological diseases are well-suited for treatment with AAV gene therapy for the following reasons:

**Validated Targets.** Many neurological diseases are caused by well-defined mutations in genes and these genes represent genetically validated drug targets for AAV gene therapy.

**Targeted Delivery.** Advances in delivery techniques allow for direct delivery of AAV vectors to discrete regions in the brain or broader delivery throughout the spinal cord via the cerebrospinal fluid, or CSF.

**Durable Expression.** Long-term gene expression may be achievable in the CNS following one-time dosing and transfer of the therapeutic gene with an AAV vector. Neurons in the CNS are terminally differentiated, or no longer divide, eliminating the potential for cell division to dilute expression of the therapeutic gene. Repeated or continual dosing with direct injection of drugs into the CNS is complex, therefore a one-time AAV gene therapy has significant advantages.

**Immune Privileged Site.** There is a reduced risk of harmful immune response or reduced efficacy due to localized delivery in a self-contained system.

While we are currently focused on gene replacement and gene knockdown approaches, we are also actively exploring additional potential treatment methods that can utilize an AAV vector, including the direct delivery of monoclonal antibodies to the CNS (such as in our collaborations with AbbVie), as well as gene editing to correct or delete a gene in the cell genome.

# The Voyager Gene Therapy Platform

We have built a gene therapy platform that we believe positions us to be the leading company at the intersection of AAV gene therapy and severe neurological diseases. Our team of experts in the fields of AAV gene therapy and neuroscience first identifies and selects severe neurological diseases that are well-suited for treatment using AAV gene therapy. We then engineer and optimize AAV vectors for delivery of the virus payload to the targeted tissue or cells. Finally, we leverage established routes of administration and advances in dosing techniques to optimize delivery of our AAV gene therapies to target cells that are critical to the disease of interest either directly to discrete regions of the brain,

or, more broadly, to the spinal cord region. We believe that optimizing each of these parameters is a key factor for overall program success. We expect that our current and future pipeline programs will make use of technological advances generated with our gene therapy platform.

Disease Selection

We assess potential product programs based upon the following criteria:

**Unmet Need.** There is a significant unmet medical need for the indication and substantial commercial potential.

**Target Validation.** There is strong evidence that expression of a specific gene, or lack thereof, is causing, or critical to, the disease state.

**Delivery Using AAV.** There is strong evidence supporting the ability to target the relevant tissue and cells using an AAV vector to achieve sufficient target gene expression.

**Clinical Readouts.** The clinical impact of an AAV gene therapy can be clearly measured, including through well-accepted clinical endpoints and the use of both existing and novel biomarkers.

**Scalability of Manufacturing.** Sufficient AAV vector to supply late-stage clinical development and commercialization can be manufactured.

In addition to the criteria above, we also look for groups of diseases where our knowledge can be transferred. For instance, we believe that some of the delivery parameters and imaging techniques that are employed in our VY-AADC program can be applied to AAV gene therapy delivery for Huntington's disease or other diseases where direct, targeted delivery to the brain is warranted.

Vector Engineering and Optimization

We have advanced or intend to advance our multiple preclinical programs towards selection of lead clinical candidates using AAV vectors that we believe are best suited for each of our programs either through use of our existing capsids, through exercising a non-exclusive worldwide commercial license to capsid sequences covered by third parties, or by engineering or optimizing novel capsids. The key components of an AAV vector include: (i) the capsid; (ii) the therapeutic gene, or transgene; and (iii) the promoter, or the DNA sequence that drives the expression of the transgene.

Members of our team have co-discovered many of the known naturally occurring AAV capsids and have also created promising genetically engineered AAV capsids. Genetically engineered capsids have yielded vectors with desirable properties, such as higher biological potency and enhanced tissue specificity. We believe that there is an opportunity to further optimize AAV capsids to confer desired characteristics relating to properties such as tissue specificity and immunogenicity. We have a significant effort dedicated to designing and screening for novel AAV capsids using a number of different scientific approaches. We believe that the information generated by this work will enhance our ability to rationally design AAV capsids with specific properties for particular therapeutic applications. In September 2016, we announced a co-exclusive worldwide license agreement with the California Institute of Technology, or Caltech, related to novel AAV capsids. The license agreement covers all fields of use and includes novel AAV capsids that have demonstrated enhanced blood-brain barrier penetration for the potential treatment of neurological diseases following systemic administration of an AAV gene therapy vector.

With respect to the target DNA delivered through AAV gene therapy, we are selecting promoters that we believe have the appropriate activity and tissue, selectively for our specific gene therapy programs. We are also designing transgenes to provide optimal expression once delivered to the targeted cells.

Manufacturing at Commercial Quality and Scale

The ability to produce high quality AAV vectors at commercial-scale is a critical success factor in AAV gene therapy. While at the NIH, former members of our production team invented and developed a baculovirus/Sf9 AAV production system, which we use and have continued to improve. This system has a number of attributes that we believe will enable high quality commercial-scale manufacturing, including:

**High Yield.** A single manufacturing run at 500-liter scale can yield many thousands of doses of an AAV gene therapy.

**High Purity.** A relatively high percentage of AAV vectors contain the therapeutic DNA, reducing the number of empty capsids compared to alternative manufacturing approaches. In addition, the baculovirus/Sf9 system eliminates the risk of introducing mammalian cell derived impurities.

**Scalability.** This process has been reproduced at volumes ranging from 0.02 liters to 250 liters. We believe the existing process is scalable to substantially higher volumes.

We have built a state-of-the-art process research and development production facility for manufacturing research-grade AAV vectors onsite at our Cambridge, Massachusetts headquarters. We have also established multiple contract manufacturing relationships with companies specializing in the manufacture of gene therapy and AAV vectors.

Optimized Delivery and Route of Administration

Identifying the optimal route of administration and delivery parameters for AAV gene therapy, such as infusion volume, flow rate, vector concentration and dose and formulation for a specific disease, are critical to achieving safe and effective levels of transgene expression in the targeted location in the CNS. We aim to develop clinically feasible protocols that yield reproducible results across patients. For our Parkinson's disease and Huntington's disease programs, we are pursuing direct injection into the brain, called intraparenchymal injection. For our ALS SOD1 and Friedreich's ataxia programs, we are evaluating multiple routes of administration including injection into the CSF within the cerebrospinal space, called intrathecal injection, as well as intravenous injection, intraparenchymal injection, and other delivery alternatives.

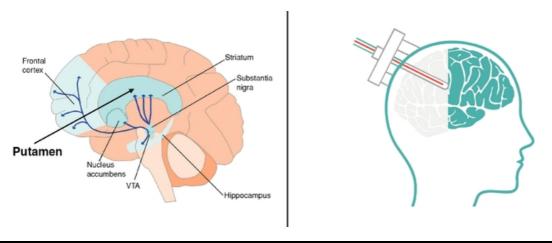
# VTAG<sup>™</sup> Intraparenchymal Injection to the Brain

The surgical approach that we are using for VY-AADC is similar, in some respects, to the stereotactic approach used for deep brain stimulation, or DBS, a marketed device-based treatment for Parkinson's disease. One primary difference with our approach is the ability to assist the physician in visualizing the delivery of VY-AADC to the putamen using real-time, intra-operative, magnetic resonance imaging, or MRI, to avoid specific blood vessels to reduce the risk of potential hemorrhages during the surgical procedure and to maximize the coverage of the putamen.

Investigators in the Phase 1b clinical trial of VY-AADC and the separate Phase 1 posterior trialectory trial use the real-time, intra-operative, MRI system called the ClearPoint System® from MRI Interventions, Inc. However, not all neuro-surgical units within the United States utilize this system and may employ other neuro-navigational systems that are not compatible with real-time MRI imaging.

Consequently, we developed the Voyager Trajectory Array Guide, or V-TAG<sup>TM</sup>, as our own device for use as a real-time, intra-operative, MRI-compatible device that can be used with other neuro-navigational systems for this and other surgical procedures. We received 510(k) clearance from the FDA in July 2018. We are currently working with a collaborator on process development and manufacturing of the device. We believe that our experience gained from our VY-AADC program, including the use of V-TAG, can be applied to AAV gene therapy delivery for our Huntington's disease program and possibly other projects as well.

# **Overview of Intraparenchymal Delivery**



Courtesy of: Okinawa Institute of Science and Technology.

# **Overview of Our Pipeline**

We have leveraged our gene therapy platform to assemble a pipeline of novel AAV gene therapies for the treatment of severe neurological diseases with high unmet medical need. Depending on the disease, our current AAV gene therapies will use either a gene replacement or gene knockdown approach. Our goal is to address the underlying cause or the predominant manifestations of a specific disease by significantly increasing or decreasing expression of the relevant proteins at targeted sites within the CNS.

# Parkinson's Disease Program: VY-AADC

Disease and VY-AADC Overview

Parkinson's disease is a chronic, progressive and debilitating neurodegenerative disease that affects approximately 1 million people in the United States and 6 million people worldwide. Parkinson's disease is characterized by a loss of dopamine and its function. Dopamine is a chemical "messenger" that is produced in the brain and is involved in the control of movement. Some chemicals, like dopamine, are made from other chemicals by proteins called enzymes. Dopamine is made in the brain when the enzyme AADC (aromatic l-amino acid decarboxylase) converts the chemical levodopa to dopamine. Levodopa, AADC, and dopamine are each present at normal levels in healthy people.

When dopamine levels decrease in the brain and there is no longer enough to control movement, the motor symptoms of Parkinson's disease including tremors, slow movement or loss of movement, rigidity, and postural instability, may occur. When this happens, a doctor may prescribe a levodopa medication, which is converted into dopamine by AADC in substantially the same way that naturally occurring levodopa is converted to dopamine.

As Parkinson's disease worsens, there is less AADC enzyme in parts of the brain where it is needed to convert levodopa to dopamine. Therefore, the amount of dopamine that is produced from each dose of levodopa medicine may be reduced. When this happens, patients' motor function may worsen and a less predictable response to medications may occur.

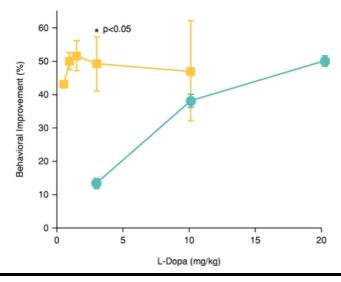
Our investigational gene therapy VY-AADC is designed to put the AADC enzyme into brain cells where it can convert levodopa to dopamine. To do this, the AADC gene is delivered inside a transporter called "adeno-associated

viral vector," which we refer to as AAV, much like a letter that carries the instructions the brain needs to make the AADC enzyme with the AAV as the envelope that carries the letter.

Preclinical studies conducted by Krystof Bankiewicz, M.D., Ph.D., one of our co-founders, and his colleagues at the University of California San Francisco, or UCSF, evaluated the safety, efficacy and pharmacological activity of AAV2-AADC gene therapy, a gene therapy substantially similar to VY-AADC, delivered directly to the putamen in a non-human primate model of Parkinson's disease. Overall, the procedure and vector were well-tolerated with no serious toxicity issues.

Positron emission tomography, or PET, imaging with tracers specific for AADC enzyme activity demonstrated a significant and sustained increase of activity in the brain region where the vector had been delivered. Increased responsiveness to levodopa was also evidenced by significant behavioral improvements observed post-treatment with the gene therapy compared to pre-treatment. In five animals, the mean improvement in behavior was determined at various doses of levodopa both one month before treatment, as a baseline measure for comparison purposes, and then again six months after treatment. A strong PET signal was observed in all five animals following treatment, confirming delivery of AADC into the putamen. Animals were significantly more sensitive to levodopa six months following treatment with the gene therapy when compared to baseline, as shown below.

# Behavioral Response to Various Doses of levodopa Pre- and Post-Treatment with AAV2-AADC in Non-Human Primates(1)



Adapted by permission from Macmillan Publishers Ltd; Forsayeth et al, Molecular Therapy (2006), 14 (4); 571-577, copyright 2006. Blue line represents

Adapted by petrilission from Machinian Publishes Edit, Prosagellet at, Molecular Tielespecies (2006), 14 (4), 371–377, Copyright 2000. But line represents base line measurements and yellow line represents six months post-treatment measurements.

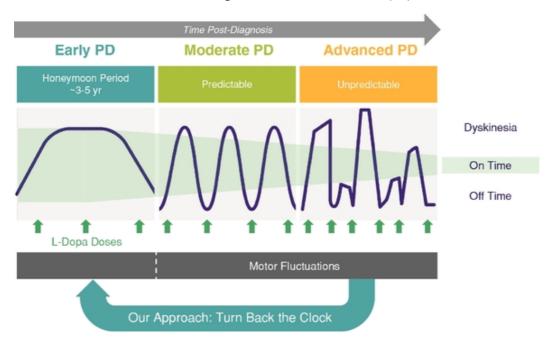
A result is considered to be statistically significant when the probability of the result occurring by random chance, rather than from the efficacy of the treatment, is sufficiently low. The conventional method for measuring the statistical significance of a result is known as the "p-value," which represents the probability that chance caused the result (e.g., a p-value = 0.001 means that there is a 0.1% or less probability that the difference between the control group and the treatment group is purely due to random chance).

The results of these preclinical studies provided support for the initiation of clinical trials.

# Previous Phase 1 Clinical Trials

The UPDRS is a standard and widely used four-part clinical rating scale for Parkinson's disease that evaluates cognitive, functional, and motor deficits, as well as medication-related complications. UPDRS Part III measures motor function by physician examination. The UPDRS is conducted when patients are taking their Parkinson's disease medications (referred to as "on" medication) and when patients are not taking their Parkinson's disease medications (referred to as "off" medication). In addition, a patient-completed Hauser diary records the patient's motor response over the course of several days as ON time when they have good mobility with or without non-troublesome dyskinesia, or uncontrolled, involuntary movement; OFF time when they have poor mobility; and ON time with troublesome dyskinesia when they have uncontrolled movements. As shown in the figure below, diary ON time decreases, while OFF time and dyskinesias increase as patients progress from the early honeymoon period into later stages of Parkinson's disease.

# Overview of Progression of Parkinson's Disease (PD)



In a completed open-label Phase 1 clinical trial conducted at UCSF, VY-AADC was delivered directly to the putamen of Parkinson's disease patients. The primary endpoints of this trial were safety and tolerability of VY-AADC. These endpoints were met as VY-AADC was well-tolerated and no treatment related SAEs were reported. Furthermore, pharmacologic activity of VY-AADC was observed. This trial was completed prior to our involvement in the program.

The Phase 1 clinical trial at UCSF was conducted in a total of 10 patients with Parkinson's disease. Two doses of VY-AADC were tested,  $9\times10^{10}$  vector genomes, or vg, and  $3\times10^{11}$  vg, with five patients per dose Cohort. The infusion volume was  $100\mu$  per putamen, or  $200\mu$  per patient. Patients in both Cohorts treated with VY-AADC showed modest improvements in motor fluctuations. At six months following treatment, diary OFF time was observed to be reduced by an average of approximately three hours and a corresponding increase in diary ON time without dyskinesias was also observed. In addition, at six months following treatment, an approximately 30% improvement in UPDRS total score both on-medication and off-medication UPDRS Total score, was observed, as shown in the table below.

# Summary of UPDRS Results from Phase 1 Trial(1)

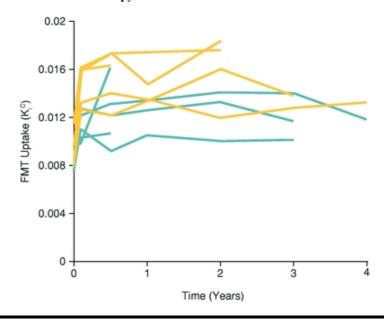
|                  | Off medications |          |          |         | On medications |          |          |         |
|------------------|-----------------|----------|----------|---------|----------------|----------|----------|---------|
|                  | Baseline        | 6 months | % Change | p Value | Baseline       | 6 months | % Change | p Value |
| Total UPDRS      |                 |          |          |         |                |          |          |         |
| Low-dose cohort  | 69.6            | 49.6     | -28      | 0.04    | 32.6           | 21.8     | -33      | 0.024   |
| High-dose cohort | 62.4            | 41.3     | -33      | 0.001   | 29.7           | 20.5     | -31      | 0.08    |
| Combined cohorts | 66              | 45.5     | -31      | 0.0008  | 31.2           | 21.2     | -32      | 0.004   |

(1) Christine et al, Neurology (2009), 73: 1662-1669. The row titled "Low-dose Cohort" represents data from the five patients treated with 9 X 10<sup>10</sup> vg of VY-AADC01. The row titled "Combined Cohorts" represents data from all ten patients treated with VY-AADC01. The data in the columns under the header "Off medications" represents periods during which patients' medications were not working as measured by a patient's total UPDRS score at baseline, before treatment with VY-AADC01, and at six months following treatment with VY-AADC01, along with percent change from baseline to six months and the corresponding p-value. The data in the columns under the header "On medications" represents periods during which patients' medications were working as measured by a patient's total UPDRS score at baseline, before treatment with VY-AADC01, along with percent change from baseline to six months and the corresponding p-value. A result is considered to be statistically significant when the probability of the result occurring by random chance, rather than from the efficacy of the treatment, is sufficiently low. The conventional method for measuring the statistical significance of a result is known as the "p-value," which represents the probability that chance caused the result (e.g., a p-value = 0.001 means that there is a 0.1% or less probability that the difference between the control group and the treatment group is purely due to random chance). Because of the small size of this trial, the p-values may not be reliable or repeatable, and may not be duplicated in future trials.

While no gene therapy related SAEs were reported, three patients experienced minor hemorrhages related to the surgical procedure. Two of the hemorrhages were asymptomatic, noticed only on imaging, and one was symptomatic with the patient making an almost complete recovery. Nevertheless, the stereotactic injection protocol used in the surgical procedure was modified to avoid specific blood vessels and no further hemorrhages were reported. In our ongoing Phase 1b clinical trial, we implemented the use of real-time, intra-operative MRI guidance. The use of this intra-operative MRI guidance is a significant advancement in vector delivery.

The 10 patients in this Phase 1 clinical trial were followed for up to four years after treatment, and a durable, dose-dependent expression of AADC enzyme activity was observed. Patients treated with both doses of the gene therapy had an increased PET signal, or uptake of the [18F]fluoro-L-m-tyrosine tracer indicative of AADC enzyme activity that persisted for up to four years. Patients treated with the high dose gene therapy had a greater PET signal on average when compared to the low dose Cohort.

Long-Term AADC Expression as Measured by PET Imaging in Patients Treated with High and Low Doses of AAV Gene Therapy in a Previous Phase 1 Clinical Trial (1)



(1) Mittermeyer et al, *Human Gene Therapy* (2012), 23: 377-381. The publisher for this copyrighted material is Mary Ann Liebert, Inc. publishers. Blue lines represent patients treated with the low dose and yellow lines represent patients treated with the high dose.

A similar Phase 1 clinical trial was conducted at Jichi Medical University, or JMU, in Japan using the same vector that was used in the UCSF trial. The primary endpoint of this trial was safety of the treatment. This endpoint was met as the treatment was well-tolerated and no treatment related SAEs were reported. Six patients were treated in this trial and an enhanced PET signal was observed in a subset of patients monitored 96 weeks following treatment. A second, open-label Phase 1/2 trial is currently being conducted at JMU. The primary endpoint of this trial is also safety. This trial is using lower infusion volumes and total doses compared to our ongoing Phase 1b and Phase 2 clinical trials. Importantly, the JMU trial is not using real-time, intra-operative MRI guidance.

While the prior UCSF and JMU clinical results were encouraging and provided evidence of long-term AADC enzyme expression, the magnitude of the clinical benefits observed did not exceed placebo effects observed in previous surgical therapy trials in Parkinson's disease patients, and the UCSF and JMU trials were not blinded. Further, based on post-operative imaging and our current work using real-time, intra-operative MRI monitoring, we estimate that less than 10% of the putamen volume was covered by the infusion in these trials, which reflects suboptimal distribution of the gene therapy vector in the putamen. We believe that by further optimizing the delivery, dose and infusion volume to substantially increase the coverage of the putamen, a more substantial clinical benefit can be achieved.

# Voyager VY-AADC Phase 1b Trial

In 2014, UCSF initiated an open-label Phase 1b clinical trial to optimize the development of VY-AADC. The IND for the Phase 1b trial was filed by UCSF in July 2013 and was transferred to us in October 2015. In November 2017, we completed enrolling this open-label, dose-escalating Phase 1b trial of VY-AADC. The trial included 15 patients with Parkinson's disease and was designed to evaluate the safety and efficacy of escalating doses of VY-AADC. In this trial, one-time administration of VY-AADC led to improvements in patients' motor function, and patients were able to reduce their daily levodopa and other Parkinson's disease medications. To date, administration of VY-AADC has been well-tolerated. In patients treated in this trial, there have been no vector-related serious adverse events reported.

Patients in three Cohorts of five patients each were treated with a single administration of ascending doses of VY-AADC administered under MRI guidance to the putamen, a region of the brain associated with impaired motor function in Parkinson's disease. The primary endpoints of this trial are safety and tolerability of the treatment. This trial incorporates three key design features:

- Use of real-time, intra-operative MRI system during surgery to assist the physician in visualizing the delivery of VY-AADC to the putamen and to avoid specific blood vessels during the surgical procedure, with the goal of reducing the risk of hemorrhages.
- Larger infusion volumes designed to increase coverage of the putamen with VY-AADC.
- · Higher concentrations of VY-AADC vector compared to the previously completed UCSF Phase 1 trial.

Secondary endpoints of this trial, which are being used to assess the potential pharmacologic activity of VY-AADC, include UPDRS, AADC PET imaging, quality of life, a patient-completed Hauser diary monitoring good ON time without troublesome dyskinesia, and a behavioral test using intravenous levodopa treatment to measure changes in a patients' sensitivity to levodopa as well as endpoints to measure motor functions.

In November 2018, we updated interim results from the ongoing, open-label Phase 1b clinical trial of VY-AADC for the treatment of Parkinson's disease. Interim results include data from all 15 patients treated in Cohorts 1, 2 and 3 (five patients in each Cohort) including data from patients in Cohort 1 at three years, Cohort 2 at two years and Cohort 3 at 18 months. Cohort 1 patients received a single administration of VY-AADC at a concentration of  $8.3\times10^{11}$  vg per milliliter, or vg/ml, using an infusion volume of up to 450  $\mu$ L per putamen, or up to 900  $\mu$ L per patient, for a total dose of  $7.5\times10^{11}$  vg. Cohort 2 patients received a single administration of VY-AADC at a concentration of  $8.3\times10^{11}$  vg/ml, using an infusion volume of up to 900  $\mu$ L per putamen, or up to 1.800  $\mu$ L per patient, for a total dose of  $1.5\times10^{12}$  vg. Cohort 3 patients received a three-fold higher vg concentration of  $2.6\times10^{12}$  with the same infusion volumes of VY-AADC similar to those received by Cohort 2 patients (up to 900  $\mu$ L per putamen), for a total dose of up to  $4.5\times10^{12}$  vg.

Administration of VY-AADC has been well-tolerated in all fifteen patients treated in the three Cohorts with no reported vector-related SAEs. Fourteen of the 15 patients were discharged from the hospital within two days following surgery. As previously reported, one patient experienced two SAEs: a pulmonary embolism or blood clot in the lungs, and related heart arrhythmia or irregular heartbeat. Investigators determined that these SAEs were most likely related to immobility during the administration of the product; consequently, deep vein thrombosis prophylaxis has been added to the clinical trial protocol.

Key findings from this trial to date include:

- The use of real-time, MRI-guided delivery and increasing infusion volumes resulted in progressively greater coverage of the putamen, 21% mean coverage of the volume of the putamen with VY-AADC in Cohort 1, 34% mean coverage in Cohort 2, and 42% mean coverage in Cohort 3.
- · VY-AADC treatment resulted in a 13% increase, a 56% increase, and a 79% increase in mean putaminal AADC enzyme activity in Cohort 1, 2, and 3, respectively, at six months relative to baseline as measured by <sup>18</sup>F-Dopa PET scan. Coverage of the putamen and AADC enzyme activity were highly correlated (r=0.84, p=0.0002).
- One-time administration of VY-AADC resulted in reduced daily doses of oral levodopa and related medications. Six months after VY-AADC administration, patients in Cohort 1 had a reduction in levodopa equivalent daily dose, or LED, of 15%, Cohort 2 had a LED reduction of 33%, and Cohort 3 had a LED reduction of 42%. LED reductions were maintained through last follow up in Cohort 2 (24 months) and Cohort 3 (18 months).

Patients enrolled in Cohorts 1, 2 and 3 were:

- · On average, 58 years of age with a Parkinson's disease diagnosis for an average of 10 years.
- · Candidates for surgical intervention including deep-brain stimulation due to disabling motor complications despite treatment with optimal anti-Parkinsonian medication.
- · At baseline, the average patient diary ON time without troublesome dyskinesia was 10.5 hours and, average diary OFF time was 4.6 hours; both diary measures were normalized to a 16-hour waking day.
- · Average UPDRS-III (motor function) on medication score was 13.5 and UPDRS-III off-medication score was 37.1; average UPDRS-II (activities of daily living) on medication score was 3.9 and UPDRS-II off medication score was 16.5. Patients in Cohort 3 entered the trial with more severe dyskinesia at baseline than patients in Cohorts 1 and 2 based on the Unified Dyskinesia Rating Scale, with a mean score of 30.2 for Cohort 3 compared with a mean score of 19.2 and 17.4 for Cohorts 1 and 2, respectively.
- At baseline, patients were treated with optimal levels of multiple dopaminergic medications including, in many
  cases, amantadine for the treatment of dyskinesia, or uncontrolled or involuntary movements. Patients' average
  amount of Parkinson's disease medications at baseline was 1,526 mg of oral LEDs per day.

The results continue to demonstrate durable improvements across multiple measures of patients' motor function after a one-time administration of the gene therapy, as evidenced by the patients' diaries and UPDRS-III, and quality of life assessments. The update of results from the ongoing Phase 1b trial of VY-AADC include a 2.1-hour mean improvement in good ON time from baseline to three years for patients in Cohort 1, a 2.7-hour mean improvement from baseline to two years in Cohort 2, and a mean improvement of 1.7 hours from baseline to 18 months in Cohort 3 as shown in the table below.

| sood ON time: hour<br>inprovement from baseline (SE) | Baseline          | 12-months        | 18-months | 2-years          | 3-years   |
|--|-------------------|------------------|-----------|------------------|-----------|
| Cohort 1, n=5  | 10.5 (1.0)        | 1.6 (0.4)        | n/a 1     | 2.3 (0.4)        | 2.1 (0.6) |
| Cohort 2, n=5  | 10.6 (0.8)        | 3.3 (0.6)        | 3.5 (1.1) | <b>2.7</b> (1.4) | -         |
| Cohort 3, n=5  | 10.3 (0.7)        | <b>1.5</b> (0.5) | 1.7 (1.1) | -                | -         |
| Cohorts 2-3, n=10                                    | 10.5 (0.5)        | 2.4 (0.5)        | 2.6 (0.8) | -                | -         |
| Cohorts 2-3 and Phase 2 trial eligible, n=7          | <b>10.1</b> (0.5) | 2.8 (0.6)        | 2.5 (1.0) | -                |           |

For the RESTORE-1 Phase 2 clinical trial, we have selected a dose of up to 2.5 x 10<sup>12</sup> vg, which is defined as a maximum total bilateral dose. This dose is between the up-to-maximum total vector genome doses administered in Cohorts 2 and 3 from the Phase 1b trial when considering the higher volume administered with the posterior trajectory and vector produced using the baculovirus system. Having selected a dose for the RESTORE-1 Phase 2 trial between the two highest dose Cohorts from the Phase 1b trial, we have performed a combined analysis of the outcomes from ten patients in Cohorts 2 and 3. Results from the combined ten patients in Cohorts 2 and 3 demonstrated mean increases from baseline in good ON time of 2.4 hours per day at 12 months, the timepoint for the primary endpoint in the RESTORE-1 Phase 2 trial, and 2.6 hours per day at 18 months, the latest timepoint measured for both Cohorts as shown in the table below. Of the combined ten patients in Cohorts 2 and 3, seven patients would have met the eligibility criteria for the RESTORE-1 Phase 2 trial based on limits in severity of dyskinesia and minimum OFF time at baseline. For these seven patients, the RESTORE-1 Phase 2 trial relevant group, the mean improvements in good ON time were 2.8 hours at 12 months and 2.5 hours at 18 months. These results were achieved with clinically meaningful and sustained reductions in daily oral levodopa and related medications.

| OFF time and ON time w/ troublesome<br>dyskinesia hour per day (SE) | Baseline         | 12-months         | Mean % change from baseline (1) | 18-months         | Mean %<br>change<br>from<br>baseline<br>(1) |
|---|------------------|-------------------|---------------------------------|-------------------|---|
| Cohorts 2-3, n=10   | <b>5.5</b> (0.5) | <b>-2.4</b> (0.5) | -46%                            | <b>-2.6</b> (0.8) | -47%  |
| Cohorts 2-3 and Phase 2 trial eligible,<br>n=7                      | <b>5.9</b> (0.5) | <b>-2.8</b> (0.6) | -46%                            | <b>-2.5</b> (1.0) | -39%  |

# Voyager Phase 1 Posterior Trajectory Clinical Trial

In a separate Phase 1 clinical trial, we have changed the trajectory for administration of VY-AADC to a posterior, or back of the head, approach into the putamen, compared to a transfrontal, or top of the head, delivery approach used in Cohorts 1 through 3 of the ongoing Phase 1b clinical trial described above. A posterior approach better aligns the infusion of VY-AADC with the anatomical structure of the putamen, which reduces the number of trajectories needed and potentially reduces the total procedure time and increases the total coverage of the putamen. Administration of VY-AADC with this posterior approach has been well-tolerated in the eight patients treated with no reported SAEs. Most patients were discharged from the hospital the day after surgery. This trial utilized the same dose concentration as Cohort 3 of our Phase 1b clinical trial at a higher volume, yielding a total dose of up to  $9.0 \times 10^{12}$  vg compared with a total dose of up to  $4.5 \times 10^{12}$  vg in Cohort 3. As we announced in July 2018, interim results suggest that the posterior approach is associated with greater average putaminal coverage (approximately 50%), reduced total procedure times compared with the transfrontal approach by two to three hours, and improvements in patients' motor function at six months, which were consistent with improvements achieved from patients in Cohorts 2 and 3 at the same time point in our Phase 1b trial with VY-AADC. We have determined that the posterior approach is the preferred surgical route of administration for the RESTORE-1 Phase 2 clinical trial.

We continue to follow patients from Cohorts 1 through 3 in the Phase 1b clinical trial of VY-AADC and patients in the Phase 1 posterior trajectory trial, and plan to report updated results from these trials from time to time.

Voyager VY-AADC RESTORE-1 Phase 2 and RESTORE-2 Phase 3 Clinical Trials

In December 2017, we submitted an IND for VY-AADC which has become effective. As part of this IND, the chemistry, manufacturing, and controls section included data demonstrating comparability between VY-AADC using our baculovirus/Sf9 manufacturing process and VY-AADC produced using a mammalian cell system consisting of triple-transfection of HEK293 cells, which was used in our two Phase 1 clinical trials. Both were produced under good manufacturing practice or GMP. Our baculovirus/Sf9 manufacturing process is designed for production of AAV vectors at clinical and commercial scale, with the potential for increased yields and efficient scalability compared with mammalian-based systems. We have demonstrated that this production platform change resulted in comparable vector quality and activity. We are using VY-AADC manufactured in our baculovirus/Sf9 system in our global RESTORE-1 Phase 2 clinical trial and the planned RESTORE-2 Phase 3 clinical trial. In June 2018, the FDA granted RMAT designation for our VY-AADC gene therapy treatment, which provides for an enhanced level of interactions between the company sponsor and the FDA throughout the development program. The designation was based on our Phase 1b clinical data with VY-AADC. Previously, the FDA also granted fast-track designation for VY-AADC.

In December 2018, we announced randomization of the first patient in RESTORE-1 Phase 2, randomized, double-blind, placebo-surgery controlled trial evaluating the safety and our efficacy of VY-AADC for the treatment of Parkinson's disease in patients with motor fluctuations that are refractory to medical management. The RESTORE-1 Phase 2 trial will enroll patients who have been diagnosed with Parkinson's disease for at least four years, are not responding adequately to oral medications, and have at least three or more hours of OFF time during the day as measured by a validated self-reported patient diary. Patients who meet the eligibility criteria will be randomized (1:1) to one-time

administration of VY-AADC (for a total dose of up to  $2.5 \times 10^{12}$  vg) or placebo surgery. In December 2018, we randomized the first patient in the RESTORE-1 Phase 2 clinical trial.

The primary endpoint of RESTORE-1 is good ON time, as measured by a validated self-reported patient diary at 12 months. Secondary endpoints include diary OFF time, other motor function UPDRS-II and UPDRS-III scores, assessments from the Parkinson's Disease Questionnaire (PDQ-39), and patient's global function as measured by the proportion of participants with improvement on the Clinical Global Impression, or CGI, score. The trial will also measure non-motor symptoms from the Non-Motor Symptom Scale, or NMSS, as well as safety.

Biomarker data include measurements of the coverage of the putamen, the specific region of the brain targeted with VY-AADC, and measurements of AADC enzyme expression and activity in the putamen measured by PET using fluorodopa F-18. Changes in patients' daily doses of oral levodopa and related medications will also be recorded.

In December 2018, we held a Type B meeting with the FDA to discuss the overall development program for VY-AADC. Based on the meeting discussion and subsequent written feedback from the FDA, we plan to submit a revised trial protocol that will include an increase in the target number of patients in the RESTORE-1 Phase 2 trial, resulting in 75 to 100 total patients in the trial, and to conduct a staggered-parallel RESTORE-2 Phase 3 trial of similar size and design to RESTORE-1. These updates incorporate guidance from the FDA from the Type B meeting to conduct two adequate and well-controlled clinical trials for a large patient population such as Parkinson's disease.

We expect that the RESTORE-1 Phase 2 trial will enroll 75 to 100 patients. Movement disorder specialists will identify and screen potential patients prior to referring to a surgical site for VY-AADC administration and provide clinical and safety follow-up after VY-AADC administration.

We expect patient enrollment to take 15 to 21 months from first patient enrolled, for the RESTORE-1 Phase 2 clinical trial. We plan to begin enrolling the RESTORE-2 Phase 3 clinical trial in the first half of 2020. We anticipate that, if positive, results from the RESTORE-1 Phase 2 clinical trial and the planned RESTORE-2 Phase 3 clinical trial could potentially form the basis for submission of a BLA, to the FDA for VY-AADC for the treatment of Parkinson's disease.

In January 2019, we entered into the Neurocrine Collaboration Agreement for the research, development, and commercialization of four programs including our Parkinson's disease program.

# ALS Program: VY-SOD102

Disease Overview

ALS is a fatal neurodegenerative disease that leads to muscle atrophy, spasticity and weakness as well as impaired speech, swallowing and breathing, with many patients requiring ventilator support as the disease progresses. The average age of onset of ALS is 55 years, and median survival is approximately three years after initial symptoms appear. It is estimated that there are approximately 20,000 patients in the United States who are living with the disease. Familial, or inherited, ALS accounts for approximately 10% of ALS cases, and an estimated 20% of familial ALS is caused by mutations in the superoxide dismutase 1, or SOD1, gene. Therefore, there are an estimated 400-800 patients in the United States with ALS caused by mutations in the SOD1 gene.

The normal function of the SOD1 protein is to catalyze the conversion of superoxide anion  $(O_2)$  to hydrogen peroxide  $(H_2O_2)$  and oxygen  $(O_2)$ . Mutations in SOD1 have been shown to lead to the formation of toxic aggregates of the SOD1 protein, resulting in the dysfunction and death of motor neurons. Patients with familial ALS caused by certain mutations in the SOD1 gene progress more rapidly than patients with other forms of ALS, although the reason for this more rapid progression is unknown.

There are currently only two FDA-approved treatments for ALS, Riluzole by Sanofi, which has been shown to have only modest efficacy, prolonging life by a few months, and Edaravone, which has been shown to slow decline of daily functioning.

# Our Treatment Approach

We believe that AAV gene therapy is an attractive approach to treating monogenic ALS caused by SOD1 mutations. Since the SOD1 gene mutations that cause ALS are toxic gain-of-function mutations, we believe that we can employ an AAV gene therapy approach that targets the knockdown of SOD1 gene expression. In addition, the primary target cells - motor neurons - reside within the spinal cord, which we believe can be effectively transduced with AAV gene therapy through intraparenchymal injection as well as other routes of administration. The mechanism of action of VY-SOD102 is knockdown of SOD1 expression in motor neurons, thereby potentially reducing the level of toxicity associated with mutated protein, and slowing functional decline and prolonging ventilator-independent survival.

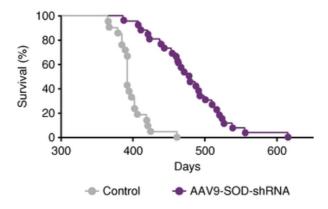
We believe that there is also the potential to leverage our approach for the treatment of other genetically defined forms of ALS.

# Preclinical Studies Targeting SOD1 for Monogenic ALS

Results from our preclinical studies using intraparenchymal delivery of AAV vector to the spinal cord support targeting mutant SOD1 for the treatment of monogenic ALS. In the mini-pig, used as an animal model as it has a spinal cord similar in size to the human spinal cord, significant knockdown of SOD1 expression was observed following intraparenchymal spinal cord injection of an AAV vector carrying a transgene designed to inhibit SOD1 expression. This novel delivery approach with VY-SOD102 reduced SOD1 mRNA in the spinal cord on average by 70% and 50% in the cervical and thoracic regions, respectively, both regions critical for respiratory function, and 82% near the site of cervical injection. In addition, VY-SOD102 reduced SOD1 mRNA by 22% in the lumbar region.

The knockdown of SOD1 has also been reported to provide significant survival benefits in animal models of ALS. As shown in the example below, mice with a SOD1 mutation treated with an AAV vector to knock down expression of the mutant human SOD1 gene extended median survival by 87 days compared to mice treated with a control vector.

# Improved Survival Post Knockdown of SOD1(1)



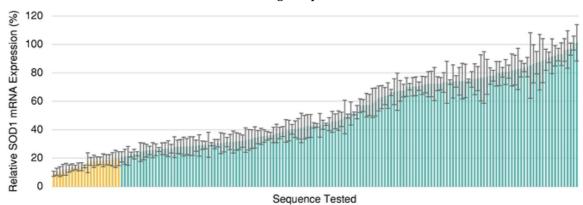
(1) Reprinted by permission from Macmillan Publishers Ltd: Foust et al, *Molecular Therapy* (2013), 21 (12); 2148-2159, copyright (2013). Purple line represents mice treated with AAV gene therapy, while gray line represents control mice.

These studies provide proof-of-principle for our approach to treating monogenic ALS due to SOD1 mutations with VY-SOD102.

# Our Program Status

In late 2016, we identified VY-SOD101 as a lead clinical candidate after screening a series of capsids, microRNA expression cassettes, (a segment of DNA that contains the sequence that targets SOD1 gene expression selectively for knockdown), and encoded payloads. We screened more than 100 RNAi sequences, each represented by a bar in the graph below, and successfully identified multiple, highly-potent RNAi sequences targeting SOD1, as highlighted by the yellow bars in the figure below:

# Overview of miRNA Target Sequences for Knockdown of SOD1



The most potent RNAi sequences targeting SOD1 gene expression were evaluated in multiple microRNA expression cassettes and with a number of vector genome configurations. We have completed the necessary experiments to evaluate these potential lead candidates based upon criteria that include safety, selectivity, potency, and efficiency and precision of microRNA processing.

In late 2017, we initiated additional preclinical studies to further optimize our ALS program's therapeutic approach, including exploration of additional routes of administration and novel AAV capsids in large animal models. Based on these studies, we selected VY-SOD102 as our lead candidate. VY-SOD102, our clinical candidate for the treatment of a monogenic form of ALS, is composed of an adeno-associated virus capsid and a proprietary transgene to selectively knock down levels of SOD1 mRNA. VY-SOD102 has the potential to durably reduce the levels of toxic mutant SOD1 protein in the spinal cord to slow the progression of disease. In late 2018 we presented data on VY-SOD102 administered with a novel delivery paradigm comprising a one-time, intraparenchymal infusion after laminectomy to the cervical spinal cord of the mini-pig, which has a spinal cord similar in length and diameter to the human spinal cord. This delivery approach yielded safe and significant reduction of SOD1 at four weeks post-dosing at the site of the infusion in the spinal cord, most notably in the cervical and thoracic regions critical for respiratory function. Further preclinical studies are underway with VY-SOD102 which, if successful, will support a potential filing of an IND application in 2019.

# Friedreich's ataxia Program: VY-FXN01

# Disease Overview

Friedreich's ataxia is a debilitating neurodegenerative disease resulting in poor coordination of legs and arms, progressive loss of the ability to walk, generalized weakness, loss of sensation, scoliosis, diabetes and cardiomyopathy as well as impaired vision, hearing and speech. The typical age of onset is 10 to 12 years, and life expectancy is severely reduced with patients generally dying of neurological and cardiac complications between the ages of 35 and 45.

According to the Friedreich's Ataxia Research Alliance, there are approximately 6,400 patients living with the disease in the United States. There are currently no FDA-approved treatments for the disease.

Friedreich's ataxia patients have mutations of the FXN gene that reduce production of the frataxin protein, resulting in the degeneration of sensory pathways and a variety of debilitating symptoms. Friedreich's ataxia is an autosomal recessive disorder, meaning that a person must obtain a defective copy of the FXN gene from both parents in order to develop the condition. One healthy copy of the FXN gene, or 50% of normal frataxin protein levels, is sufficient to prevent the disease phenotype. We therefore believe that restoring FXN protein levels to at least 50% of normal levels by AAV gene therapy might lead to a successful therapy.

# Our Treatment Approach

We are developing an AAV gene therapy approach that we believe will deliver a functional version of the FXN gene to the sensory pathways through intravenous injection. We think this approach has the potential to improve balance, ability to walk, sensory capability, coordination, strength and functional capacity of Friedreich's ataxia patients. Most Friedreich's ataxia patients produce low levels of the frataxin protein, which although insufficient to prevent the disease, exposes the patient's immune system to frataxin. This reduces the likelihood that the FXN protein expressed by AAV gene therapy will trigger a harmful immune response.

#### Preclinical Studies

We initially conducted preclinical studies in non-human primates and achieved high FXN expression levels within the target sensory ganglia, or clusters of neurons, along the spinal region following intrathecal injection. More recently, we conducted preclinical studies in non-human primates with intravenous injection and achieved target FXN expression levels within sensory ganglia and the heart. The levels of FXN expression observed using an AAV vector were, on average, greater than FXN levels present in control normal human brain tissue. FXN expression was also observed in the cerebellar dentate nucleus, another area of the CNS that is often affected in Friedreich's ataxia, and that is often considered difficult to target therapeutically.

# Our Program Status

VY-FXN01 is currently in preclinical development. We are in the process of identifying a lead candidate which will comprise an optimal capsid, promoter, and FXN transgene. We are completing several AAV capsid screening experiments to identify capsids that effectively distribute to disease target tissues in a desired manner following intravenous injection. Criteria for evaluating these capsids include safety, overall level of transgene expression achieved, distribution of transgene expression and the specific cell types transduced. In addition, we are optimizing the promoter for VY-FXN01. To evaluate the therapeutic potential of our vectors, we have conducted testing in a new genetic mouse model of Friedreich's ataxia. In this preclinical model of Friedreich's ataxia, our gene therapy candidates durably improved sensory function, and rescued the Friedreich's ataxia phenotype based on multiple functional tests. In physiological and behavioral assays, our gene therapy candidates demonstrated dose-dependent and durable responses for more than 10 months after a single administration, preventing central and peripheral disease progression. We also have a significant effort focused on better understanding the clinical course of Friedreich's ataxia and identifying potential clinical endpoints for future clinical trials.

Once we identify a lead candidate for this program, we plan to complete IND enabling studies to evaluate its safety and efficacy.

In January 2019, we entered into the Neurocrine Collaboration Agreement for the research, development, and commercialization of four programs including our Friedreich's ataxia program.

**Huntington's Disease Program: VY-HTT01** 

# Disease Overview

Huntington's disease is a fatal, inherited neurodegenerative disease that results in the progressive decline of motor and cognitive functions and a range of behavioral and psychiatric disturbances. The average age of onset is 39 years, with patients typically dying approximately 15 to 20 years following diagnosis. According to the Huntington's Disease Society of America, Huntington's disease affects approximately 30,000 patients in the United States. Huntington's disease is caused by mutations in the huntingtin, or HTT, gene. Huntington's disease is an autosomal dominant disorder, which means that an individual is at risk of inheriting the disease if only one parent is affected. More than 200,000 individuals in the United States are at risk for inheriting the mutant gene from an affected parent. While the exact function of the HTT gene in healthy individuals is unknown, it is essential for normal development before birth and mutations in the HTT gene ultimately lead to the production of abnormal intracellular huntingtin protein aggregates that cause neuronal cell death. Currently, there are no approved treatments targeting the underlying cause of the disease and only one drug, tetrabenazine, has been approved for the treatment of the specific motor symptoms of Huntington's disease.

# Our Treatment Approach

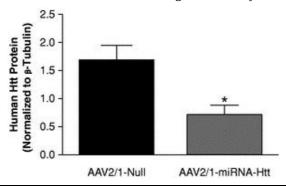
We believe that AAV gene therapy is an attractive approach to treating Huntington's disease. Since HTT mutations that cause Huntington's disease are toxic gain-of-function mutations, we believe that we can employ an AAV gene therapy approach designed to knock down expression of the HTT gene. In addition, the targeted cells for treatment primarily reside in discrete regions of the brain - the striatum and the cortex - that can be targeted with AAV gene therapy delivered directly into the brain. The mechanism of action of VY-HTT01 is knockdown of HTT expression in neurons in the striatum and cortex, thereby reducing the level of toxicity associated with mutated protein in these brain regions, and slowing the progression of cognitive and motor symptoms. We believe that we can use the same surgical approach for this program that has been used for VY-AADC delivery to the brain, allowing us to leverage prior clinical experience.

# Preclinical Studies

Our collaborators at Sanofi Genzyme have completed significant preclinical work focused on AAV gene therapy for Huntington's disease. Sanofi Genzyme's preclinical studies in a mouse model of Huntington's disease demonstrated the safety and efficacy of AAV gene therapy targeting the knockdown of the HTT gene in the CNS.

As shown in the figure below, using an AAV vector delivered directly to the CNS, HTT gene expression was observed to be reduced by over 50%, on average, in the treatment group as compared to the control group. No signs of toxicity were reported.

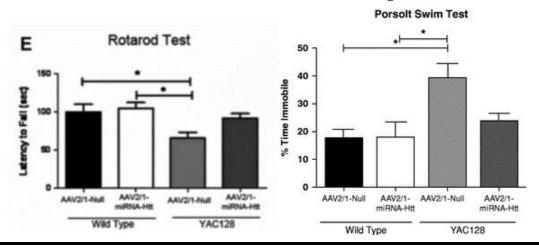
# Knockdown of HTT Following AAV Delivery(1)



(1) Stanek et al, *Human Gene Therapy* (2014); 25; 461-474. The publisher for this copyrighted material is Mary Ann Liebert, Inc. publishers. \* p<0.05

In addition, significant functional benefit was observed in the treatment group, as measured by the rotarod test to assess motor function, and the Porsolt Swim Test to measure depressive behavior in mice. In the figure below, both normal or wild type mice, and mice with the HTT mutation, or YAC128, were evaluated following treatment with either an AAV vector targeting the knockdown of the HTT gene, labeled as AAV2/1-miRNA-Htt below, or a negative control vector, labeled as AAV2/1-Null below. As expected, knocking down HTT in the control mice was observed to have no functional impact, whereas knocking down HTT in YAC128 mice was observed to have significant functional benefit.

# Reduction of Behavioral Deficits in an Animal Model of Huntington's Disease<sup>(2)</sup>



(2) Stanek et al, *Human Gene Therapy* (2014); 25; 461-474. The publisher for this copyrighted material is Mary Ann Liebert, Inc. publishers. p<0.05

# Our Program Status

VY-HTT01 is in preclinical development. Sanofi Genzyme's Huntington's disease gene therapy program was combined with our efforts in connection with entering into the Sanofi Genzyme Collaboration agreement in February 2015. Through our gene therapy platform, we also constructed and screened a series of microRNA expression cassettes and encoded payloads. Multiple rounds of optimization have resulted in potential candidates that are potent and selective for knocking down HTT. In addition, many construct configurations were evaluated toward the identification of one which would provide excellent yield and genome integrity for manufacturing scale-up in our baculovirus/Sf9 AAV manufacturing system in insect-derived cells.

We also conducted the necessary experiments to evaluate these potential lead candidates based upon criteria that include safety, selectivity, potency, and efficiency and precision of microRNA processing, leveraging the learnings from the VY-SOD101 program, including the miRNA cassettes and vector genome configurations that we designed for the VY-SOD101 program. In June 2017, we reported that we had selected a lead clinical candidate.

In preclinical studies, a single administration of VY-HTT01 was well-tolerated and resulted in robust and widespread knockdown of HTT messenger RNA at five weeks post-dosing in disease-relevant regions of the non-human primate central nervous system. The extent of HTT mRNA suppression (greater than 50%) and high precision and efficiency of primary microRNA processing in our preclinical studies supported the selection of our lead clinical candidate. Additionally, preclinical data in large mammals have demonstrated that a single intraputaminal administration results in robust knockdown of HTT in the putamen.

Recent preclinical delivery studies have further optimized the dosing paradigm. VT-HTT01 is composed of an adeno-associated virus capsid (AAV1) and proprietary transgene that harnesses the RNA interference pathway to selectively knock down, or reduce, levels of HTT mRNA. In late 2018, we presented results demonstrating significant

reduction of HTT mRNA at five weeks post-dosing in adult non-human primates using an MRI-guided surgical delivery of VY-HTT01 and a novel delivery paradigm targeting both the putamen and thalamus. Targeting the thalamus in addition to the putamen leverages more extensive and more preserved neuronal pathways to the cortex than delivery to the putamen alone. This novel dosing paradigm with VY-HTT01 resulted in safe and significant suppression of HTT in the striatum and in cortical neurons, which are critical in the progression of disease. A combined infusion of VY-HTT01 into the putamen and thalamus significantly reduced HTT mRNA by 68% in the caudate, 67% in the putamen, and 73% in the thalamus, on average, as measured from tissue punches, and by 32% on average, in laser captured cortical neurons, which was also supported by in situ hybridization for HTT mRNA. Further preclinical studies are underway with VY-HTT01 which, if successful, will support a potential filing of an IND application in 2019.

#### **Tau Program**

#### Disease Overview

In healthy individuals, tau is an abundant soluble cytoplasmic protein that binds to microtubules, which are key structural proteins in cells, to promote their stability and function. In Alzheimer's disease and other tauopathies, tau aggregates and forms insoluble tau-containing neurofibrillary tangles. The progressive spread of tau pathology along distinct anatomical pathways in the brain closely correlates with disease progression and severity in a number of tauopathies, including Alzheimer's disease, FTD, and PSP. In addition, mutations in the tau gene have been shown to cause inherited forms of tauopathies, including FTD and PSP. Because the extent of tau pathology in Alzheimer's disease and other tauopathies closely correlates with the severity of neurodegeneration, synapse loss, and cognitive deficits, attempts to prevent, reduce, or slow the development of tau pathology have become important therapeutic strategies for these diseases.

In previous preclinical studies in animal models, despite high weekly or biweekly systemic doses of anti-tau monoclonal antibodies administered over three to six months, only very low levels of antibody reached the brain, resulting in a modest reduction of tau pathology by  $\sim$ 40–50%. This incomplete and modest reduction in tau pathology following treatment with very high and frequent systemic doses of these antibodies may pose therapeutic challenges in humans with various tauopathies. To address these limitations, our AbbVie Tau Collaboration attempts to develop AAV gene therapies to deliver monoclonal antibodies to the brain directed against tau as potential new treatments for Alzheimer's disease and other tau-related neurodegenerative diseases.

# Our Program Status

The tau program is currently in the preclinical stage. We have agreed to collaborate with AbbVie on the research and development of specified vectorized antibody compounds comprised of an AAV or other viral capsid and a virus vector genome that encodes one or more antibodies that target and bind to a tau protein. During the research period of our collaboration, we and AbbVie agreed to each identify up to five potential antibodies for evaluation during the AbbVie Tau Collaboration. Under the agreement, up to three research antibodies may be selected as candidates for creation of research compounds. AbbVie has the right to select two of the three research antibodies. During a specified portion of the research period, AbbVie may exercise one or more of its exclusive development options to select up to a total of three research compounds and their corresponding product candidates to proceed to the development period.

# Severe, Chronic Pain Program: VY-NAV01

# Disease Overview

 ${
m Na_v}1.7$  is a sodium ion channel that is required for transmission of pain signals to the CNS. We believe that an AAV gene therapy approach targeting the knockdown of  ${
m Na_v}1.7$  in sensory neurons could be an effective treatment for certain forms of severe, chronic pain. A major challenge for the successful development of small molecules and antibodies targeting  ${
m Na_v}1.7$  has been the selective inhibition of  ${
m Na_v}1.7$  over closely related sodium channels such as  ${
m Na_v}1.5$  which are important for cardiac function. MicroRNAs, which work by harnessing the RNA interference pathway,

can achieve a high level of specificity for their messenger RNA targets, and can inhibit  $\rm Na_v 1.7$  selectively over other sodium channel subtypes. Such an approach could avoid the dose-limiting side effects associated with the non-selective profile of many current drugs used to treat severe, chronic pain, and also achieve a durable clinical benefit following a single administration of the therapy. VY-NAV01 leverages our extensive experience designing novel microRNA knockdown cassettes and delivering them using AAV, an approach that we are using for our ALS and Huntington's disease programs.

# Our Program Status

VY-NAV01 is currently in the research stage. We are in the process of conducting proof-of-concept studies to establish the level of  $\rm Na_v 1.7$  knockdown needed to relieve pain in animal models. We will then identify a lead candidate which will comprise an optimal capsid, promoter, and microRNA targeting  $\rm Na_v 1.7$ . We have also initiated proof-of-concept studies to evaluate knockdown of another sodium channel subtype implicated in chronic pain that may be combined with  $\rm Na_v 1.7$  knockdown. We are completing several AAV capsid screening experiments to identify capsids that effectively distribute to pain sensory neurons in a desired manner. We are comparing capsids in non-human primates following intrathecal and intravenous injection, and evaluating these capsids based upon multiple criteria including safety, overall level of transgene expression achieved, distribution of transgene expression and the specific cell types transduced.

#### **Future Programs**

We are evaluating additional severe neurological diseases that could be treated using AAV gene therapy through application of either a gene replacement or a gene knockdown approach.

# **Collaborations and License Agreements**

#### Sanofi Genzyme Collaboration

In February 2015, we entered into a strategic collaboration with Sanofi Genzyme to leverage our combined expertise and assets to develop AAV gene therapies for neurological diseases. Under the agreement, we retained U.S. rights to VY-AADC and VY-FXN01, as well as at least co-commercialization rights to VY-HTT01 in the United States. In October 2017, Sanofi Genzyme decided not to exercise its option for the ex-U.S. rights to VY-AADC, returning global rights to VY-AADC to us. VY-SOD102 is not included as part of the Sanofi Genzyme collaboration and we retain unencumbered worldwide rights to this program. Sanofi Genzyme maintains exclusive options to license, develop and commercialize (i) the Split Territory Programs outside the United States with an incremental option to co-commercialize VY-HTT01 in the United States, and (ii) VY-SMN101 worldwide. Sanofi Genzyme's option for the Split Territory Programs and VY-SMN101 is triggered following the completion of the first POP Study on a program-by-program basis. In November 2016, we and Sanofi Genzyme elected to deprioritize the development of VY-SMN101 for spinal muscular atrophy due to, among other things, the significant progress we have made in our other preclinical programs and the evolving competitive landscape.

Prior to any option exercise by Sanofi Genzyme, we will collaborate with Sanofi Genzyme in the development of products under each Split Territory Program and VY-SMN101 pursuant to a written development plan and under the guidance of an alliance joint steering committee, comprised of an equal number of our employees and Sanofi Genzyme employees.

We are required to use commercially reasonable efforts to develop products under each Split Territory Program and VY-SMN101 through completion of the applicable POP Study. During the development of our joint programs, our and Sanofi Genzyme's activities are guided by a Development Advisory Committee, which we refer to as the DAC. The DAC may elect to utilize certain Sanofi Genzyme technology relating to the VY-AADC program, the VY-HTT01 Program, or generally with the manufacture of Split Territory Program products. If we use certain Sanofi Genzyme technology in VY-AADC, Sanofi Genzyme is entitled to received low single digit royalty payments based on a

percentage of net sales by us, and we may be obligated to make certain regulatory milestone payments to a third-party licensor

We will be solely responsible for all costs incurred in connection with the development of Split Territory Programs and VY-SMN101 products prior to option exercise, subject to the following: (i) Sanofi Genzyme may agree to provide additional funds in return for agreed-upon payback or other agreed economic terms; (ii) we may request, and upon mutual agreement, Sanofi Genzyme will provide in-kind services valued at up to \$5.0 million; and (iii) expenses of certain activities under the VY-HTT01 development plan may be funded to the extent such activities are reimbursed through financial support that Sanofi Genzyme may receive from a disease foundation group.

Excluding the VY-AADC program, if we do not initiate a POP Study for a given Split Territory Program by December 31, 2026 (or for the Future Program by the tenth anniversary of the date the Future Program is nominated by Sanofi Genzyme), and Sanofi Genzyme has not terminated this agreement with respect to such Collaboration program, then Sanofi Genzyme shall be entitled, at its sole and exclusive remedy, to a credit of \$10.0 million for each such program against other amounts payable by Sanofi Genzyme under the Collaboration. However, if we do not initiate a POP Study by such date as a result of a regulatory delay or a force majeure event, such time period shall be extended for so long as such regulatory delay or force majeure event continues and we shall not be deemed to have failed to initiate a POP Study.

# Post-Option Exercise

Upon Sanofi Genzyme's exercise of its option to license a given product in a Split Territory Program, which we refer to as a Split Territory Licensed Product, we will have sole responsibility for the development of such Split Territory Licensed Product in the United States and Sanofi Genzyme shall have sole responsibility for development of such Split Territory Licensed Product in the rest of the world. We and Sanofi Genzyme will have shared responsibility for execution of ongoing development of such Split Territory Licensed Product that is not specific to either of our territories, including costs associated therewith.

A steering committee for each program will review and approve a written plan and budget for each relevant program. In addition, all development activities to be undertaken with respect to each Split Territory Licensed Product by or on behalf of either party will be set forth in a written development plan.

Sanofi Genzyme shall have the sole right to develop VY-SMN101 worldwide. Sanofi Genzyme shall be responsible for all of the development costs that occur after the option exercise date for VY-SMN101.

#### Commercialization

We shall be solely responsible, at our expense, for all commercialization activities relating to Split Territory Licensed Products in the United States. Sanofi Genzyme shall be solely responsible, at its expense, for all commercialization activities relating to Split Territory Licensed Products in the rest of the world. For VY-HTT01, if Sanofi Genzyme has exercised its option to co-commercialize VY-HTT01 in the United States, then Sanofi Genzyme will be the lead party responsible for all VY-HTT01 commercialization activities in the United States, and these activities will be set forth in reasonable detail in a written commercialization plan.

Sanofi Genzyme shall be solely responsible, at its expense, for all commercialization activities relating to VY-SMN101 worldwide. Sanofi Genzyme shall use commercially reasonable efforts to commercialize VY-SMN101 in each major market specified in the agreement where Sanofi Genzyme has obtained required governmental approvals.

#### Financial Terms

We received \$65.0 million in upfront cash, a \$30.0 million upfront equity investment and an in-kind commitment of \$5.0 million, totaling \$100.0 million. If Sanofi Genzyme exercises its option for a collaboration program,

Sanofi Genzyme is required to make an option exercise payment of \$20.0 million or \$30.0 million for each program. We are no longer entitled to receive the regulatory and commercial milestone payments from Sanofi Genzyme related to VY-AADC. Sanofi Genzyme shall pay us up to \$540.0 million across the remaining product programs upon the achievement of specified regulatory and commercial milestones.

In addition, to the extent any Split Territory Licensed Product or the VY-SMN101 Product is commercialized, we are entitled to receive tiered royalty payments ranging from the mid-single digits to mid-teens based on a percentage of net sales. Sanofi Genzyme is entitled to receive royalty payments from us related to sales of the Split Territory Licensed Products ranging from the low-single digits to mid-single digits, depending on whether we use Sanofi Genzyme technology in a Split Territory Licensed Product or the VY-SMN101 Product. If Sanofi Genzyme exercises its option to co-commercialize VY-HTT01 in the United States, we will share any profits or losses from VY-HTT01 product sales.

Term and Termination; Remedies

Our collaboration agreement with Sanofi Genzyme will continue in effect until the later of (i) the expiration of the last to expire of the option rights and (ii) the expiration of all payment obligations unless sooner terminated by us or Sanofi Genzyme.

We and Sanofi Genzyme have customary termination rights including the right to terminate for an uncured material breach of the agreement committed by the other party and Sanofi Genzyme has the right to terminate for convenience.

#### AbbVie Tau Collaboration

In February 2018, we entered into an exclusive collaboration and option agreement with AbbVie, or the AbbVie Tau Collaboration Agreement, for the research, development, and commercialization of AAV and other virus-based gene therapy products for the treatment of neurodegenerative diseases related to defective or excess aggregation of tau protein in the human brain, including Alzheimer's disease.

Under the AbbVie Tau Collaboration Agreement, we have agreed to collaborate with AbbVie on the research and development of specified vectorized antibody compounds comprised of an AAV or other viral capsid and a virus vector genome that encodes one or more antibodies that target and bind to a tau protein. The collaboration is comprised of a research period, a development period, and an exclusive license option.

Research Period and AbbVie Development Option

During the research period, each party has agreed to identify up to five antibodies for inclusion in the collaboration. Subject to certain conditions and exceptions, the parties will then select up to three antibodies, or the Research Antibodies, as candidates for creation of research compounds, or the Research Compounds, with AbbVie having the right to select two of the three Research Antibodies. We are obligated to use diligent efforts to conduct antibody engineering and other research activities to create Research Compounds and to develop product candidates containing or comprised of such Research Compounds. We will be solely responsible for the costs and expenses during the Research Period. During a specified portion of the Research Period, or the Development Option Period, AbbVie may exercise one or more of its exclusive development options, each of which we refer to as a Development Option, to select up to a total of three Research Compounds, or the Selected Research Compounds, and their corresponding product candidates, or the Selected Product Candidates, to proceed to the development period.

Development Period and AbbVie License Option

During the development period, we are obligated to use diligent efforts to conduct development activities, including IND-enabling and Phase 1 clinical trial activities, for the Selected Research Compounds and corresponding

Selected Product Candidates. We will be solely responsible for the costs and expenses during the development period. During a specified portion of the development period, or the License Option Period, AbbVie may exercise its exclusive license option, or the License Option, to further develop and commercialize all of the Research Compounds, or the Licensed Compounds, and corresponding product candidates, or the Licensed Products. Upon AbbVie's exercise of its License Option, we have agreed to grant to AbbVie an exclusive, worldwide license, with the right to sublicense, under certain of our intellectual property rights to develop and commercialize the Licensed Compounds and the Licensed Products for all human diagnostic, prophylactic and therapeutic uses. In addition, after AbbVie's exercise of the License Option, we have certain obligations to complete any remaining research and development activities that have not been completed for any Research Compounds and Product Candidates.

#### Governance

Our research and development activities will be conducted pursuant to the plans agreed to by the parties and overseen by a joint governance committee, or JGC, comprised of an equal number of representatives from each party. Prior to AbbVie's exercise of its License Option, we will have final decision-making authority within the JGC, subject to specified limitations; thereafter, AbbVie will have final decision-making authority, subject to specified limitations. Any material amendment to the research or development plans, however, must be mutually agreed to by the parties, which may be through the JGC.

# Commercialization

Under the AbbVie Tau Collaboration Agreement, AbbVie is required to use commercially reasonable efforts to develop and commercialize at least one Licensed Product in each of the United States, Japan, the United Kingdom, Germany, France, Italy and Spain. After exercise of the License Option, AbbVie is solely responsible for all development and commercialization activities relating to Licensed Compounds and Licensed Products at its sole cost and expense (subject to our obligation to complete any remaining research and development activities set forth in the agreed-upon plans), except that we may elect to share in AbbVie's development costs relating to a Licensed Product on an indication-by-indication basis in exchange for a specified increase in royalties. If we exercise this cost-sharing option, we may either reimburse AbbVie for AbbVie's applicable development costs or, in the case of certain budget overruns, AbbVie may instead deduct applicable development costs, up to a specified cap, from milestone and royalty payments owed by AbbVie to us.

#### Manufacturing

During both the research period and the development period, we will be solely responsible for the manufacture and supply of all pre-clinical and clinical requirements for the Research Compounds and Product Candidates. If AbbVie were to exercise its License Option, we would be required, at AbbVie's request, to effect a full transfer of the manufacturing process for each Licensed Compound and corresponding Licensed Product to AbbVie. Following such transfer, we have agreed to disclose, on a continuing basis, all modifications, enhancements and improvements to manufacturing processes for the Licensed Products, and AbbVie has agreed to grant to us a non-exclusive, royalty-free license to modifications to the manufacturing process made by AbbVie, in each case subject to specified limitations.

# Financial Terms

Under the terms of the AbbVie Tau Collaboration Agreement, AbbVie paid us an upfront payment of \$69.0 million in February 2018. AbbVie has also agreed to pay us within 30 days after the applicable exercise date: (1) upon AbbVie's exercise of a Development Option, (a) \$80.0 million for the first Selected Research Compound and its corresponding Selected Product Candidate and (b) \$30.0 million each for up to two additional Selected Research Compounds and their corresponding Selected Product Candidates, and (2) upon AbbVie's exercise of the License Option, a one-time payment of \$75.0 million. We will be eligible to receive (1) specified development and first-sale milestone payments for each Licensed Compound of up to an aggregate of \$550.0 million in the case of an Alzheimer's disease indication, up to \$230.0 million in the case of the first indication other than Alzheimer's disease, and \$115.0 million for subsequent non-Alzheimer's disease indication; and (2) tiered, escalating royalties, in a range from a high-

single digit to a mid-to-high teen (or, if we have exercised our cost-sharing option, low-twenties) percentage of aggregate net sales of Licensed Products on a Licensed Compound by Licensed Compound basis. The royalties are subject to potential reductions for biosimilar market penetration, patent claim expiration, and other provisions, subject to specified limits. For each Licensed Product, AbbVie may make a one-time request either to decrease its royalty payments to a specified low-single digit percentage or to terminate them altogether in exchange for a one-time payment by AbbVie at a fair market value to be negotiated by the parties. If the parties are not able to agree to the terms of such buy-down, the parties may seek a fair market value determination for the buy-down pursuant to dispute resolution procedures specified in the agreement.

# Intellectual Property

Under the terms of the AbbVie Tau Collaboration Agreement, each party will own the entire right, title and interest in and to all know-how and patent rights first made or invented solely by it or its affiliates or its or their sublicensees in the course of the collaboration, with certain specified exceptions. Also subject to specified exceptions, the parties will jointly own all rights, title and interest in and to all know-how and patent rights first made or invented jointly by such party or its affiliates or its or their sublicensees in the course of the collaboration. Regardless of whether AbbVie has exercised a Development Option or the License Option, we have agreed to grant AbbVie perpetual, exclusive or non-exclusive (as the case may be), worldwide licenses to certain know-how and patent rights developed by us or jointly by the parties arising from the collaboration.

# Exclusivity

During the term of the AbbVie Tau Collaboration Agreement, (1) neither party nor any of its respective affiliates is permitted to directly or indirectly exploit any vectorized antibody compound targeting a tau protein, which we refer to as Vectorized Antibody Exclusivity, and (2) neither we nor any of our affiliates is permitted to directly exploit any Research Antibody targeting a tau protein, which we refer to as Research Antibody Exclusivity, in each case subject to specified exceptions, including our conduct of basic research.

## **Termination**

Unless earlier terminated, the AbbVie Tau Collaboration Agreement will expire on the earliest to occur of the expiration of (1) the Development Option Period, without AbbVie's exercise of a Development Option; (2) the License Option Period, without AbbVie's exercise of its License Option; and (3) the last-to-expire royalty term with respect to all Licensed Products in all countries. Subject to a cure period, either we or AbbVie may terminate the AbbVie Tau Collaboration Agreement, in whole or, in the case of us, in part, subject to specified conditions, in the event of the other party's uncured material breach. Either we or AbbVie may also terminate, subject to specified conditions, for insolvency of the other party, certain failures or delays to obtain certain regulatory clearances of the collaboration, or a joint determination of scientific infeasibility by the parties. AbbVie may terminate the AbbVie Tau Collaboration Agreement (1) without cause, in its entirety or, after its exercise of the License Option, on a country-by-country basis, with 180 days' prior written notice or (2) for our non-compliance with certain anti-bribery or anti-corruption covenants. We may terminate the AbbVie Tau Collaboration Agreement, subject to specified conditions, if AbbVie or its affiliates challenge the validity or enforceability of certain of our, or jointly-held intellectual property rights.

Upon termination in certain cases, AbbVie has agreed to grant to us reversionary licenses to certain Licensed Compounds. In such case, we may be required to pay royalties to AbbVie in a range from a low to high single digit percentage of net sales of Licensed Products containing or comprised of such License Compound, subject to potential reduction in some cases. Additionally, upon termination in certain cases, the Vectorized Antibody Exclusivity and Research Antibody Exclusivity will survive until the third anniversary of the termination date. If the parties mutually agree to terminate for infeasibility or AbbVie terminates for our failure to deliver a final research or development report, neither us nor any of its affiliates may directly or indirectly exploit a vectorized antibody compound that targets or binds to a tau protein for 18 months after the termination date.

# Neurocrine Collaboration

In January 2019, we entered into the Neurocrine Collaboration Agreement for the research, development and commercialization of certain of our AAV gene therapy products. Under the Neurocrine Collaboration Agreement, upon the expiration or termination of applicable waiting periods and the receipt of any required approvals or clearances including antitrust clearance, we have agreed to collaborate on the conduct of four collaboration programs, which we refer to collectively as the Neurocrine Programs: the AADC Program for the treatment of Parkinson's disease, our FA Program for the treatment of Friedreich's ataxia including the development of the VY-FXN01 product candidate, which together with the AADC Program, we refer to as the Existing Programs, and two programs to be determined by us and Neurocrine at a later date, which we refer to as the Discovery Programs.

# Collaboration and Licenses

Under the terms of the Neurocrine Collaboration Agreement, subject to the rights retained by us thereunder, we have agreed to collaborate with Neurocrine on, and to grant, exclusive, royalty-bearing, non-transferable, sublicensable licenses to certain of our intellectual property rights, for all human and veterinary diagnostic, prophylactic, and therapeutic uses, for the research, development, and commercialization of gene therapy products, which we refer to as the Collaboration Products, under (i) the AADC Program, on a worldwide basis; (ii) the FA Program, in the United States and, upon expiration of Sanofi Genzyme's option to the FA Program pursuant to the Sanofi Genzyme Collaboration without exercise of such option, all countries in the world in which the Neurocrine Collaboration Agreement remains in effect with respect to the FA Program; and (iii) each Discovery Program, on a worldwide basis.

Pursuant to development plans to be agreed by the parties, which will be overseen by a joint steering committee, or JSC, we have operational responsibility, subject to certain exceptions, for the conduct of each Neurocrine Program prior to the Transition Event for each Program, as described below, and are required to use commercially reasonable efforts to develop the Collaboration Products. Neurocrine has agreed to be responsible for all costs incurred by us in conducting these activities for each Neurocrine Program, in accordance with an agreed budget. If we breach our development responsibilities or in certain circumstances upon a change in control of us, Neurocrine has the right but not the obligation to assume the activities under such Neurocrine Program.

Upon the occurrence of a specified event for each Neurocrine Program, or a Transition Event, Neurocrine has agreed to assume responsibility for development, manufacturing and commercialization activities for such Neurocrine Program from us and to pay milestones and royalties on future net sales as described further below. For each Existing Program, we have the option, or a Co-Co Option, to co-develop and co-commercialize such Neurocrine Program upon the occurrence of a specified event, or a Co-Co Trigger Event. Should we elect to exercise our Co-Co Option, we have agreed to enter into a cost- and profit-sharing arrangement with Neurocrine, or a Co-Co Agreement, whereby we have agreed to jointly develop and commercialize Collaboration Products for such Neurocrine Program, or Co-Co Products, and share in its costs, profits and losses, and we agree to forfeit certain milestones and royalties on net sales in the United States during the effective period of the applicable Co-Co Agreement. The Transition Events are (i) with respect to the AADC Program, our receipt of topline data for the ongoing RESTORE-1 Phase 2 clinical trial for VY-AADC; (ii) with respect to the FA Program, our receipt of topline data for the initial Phase 1 clinical trial for an Friedreich's ataxia program product candidate; and clinical trial for an Friedreich's ataxia program product candidate; and with respect to each Discovery Program, the preparation by us and the approval by Neurocrine of an investigational new drug application to be filed with the FDA by Neurocrine for the first development candidate in such Discovery Program. The Co-Co Trigger Events are (i) with respect to the AADC Program, our receipt of topline data for the ongoing RESTORE-1 Phase 2 clinical trial for VY-AADC and (ii) with respect to the FA Program, the achievement of milestones or metrics specified in the applicable development plan, as determined by the JSC.

Subject to exceptions specified in the Neurocrine Collaboration Agreement, profits and losses under our Co-Co Option are agreed to be allocated (i) 50% to Neurocrine and 50% to us for a Collaboration Product from the VY-AADC program and (ii) 60% to Neurocrine and 40% to us for a Collaboration Product from the FA Program; provided, however, that Neurocrine may elect, within a specified period following the acceptance for filing of a BLA from the FDA, to pay a \$35.0 million rate-shifting fee to us to change the allocation for the VY-AADC Program to 55% to Neurocrine and 45% to us. The parties have agreed that each Co-Co Agreement will provide us the right to terminate for any reason upon prior written notice to Neurocrine and Neurocrine the right to terminate in certain circumstances upon our change of control.

#### Governance

Our research and development activities under the Neurocrine Collaboration Agreement are to be conducted pursuant to plans agreed to by the parties, on a program-by-program basis, and overseen by the JSC, which is composed of an equal number of representatives from the parties. The JSC may delegate matters within its authority to subcommittees of the JSC. In addition, the Neurocrine Collaboration Agreement establishes working groups to handle specified matters on a subject matter-by-subject matter basis. If a working group or subcommittee cannot agree on a matter within its purview within a specified time, such matter is to be referred sequentially to the JSC and then the executive officers of the parties. If the executive officers are not able to resolve the matter, then (i) with respect to each Existing Program, subject to specified exceptions, (x) Neurocrine has the right to resolve such matter prior to our exercise of our Co-Co Option with regard to such Co-Co Product or if such Co-Co Option expires or goes unexercised and (y) following the timely exercise by us of our Co-Co Option, depending on the subject of such matter, either Neurocrine, in certain instances, or the parties jointly or the JSC, in other instances, would have the right to resolve such matter, and (ii) with respect to Discovery Programs, subject to specified exceptions, Neurocrine has the right to resolve such matter.

# Candidate Selection

The parties have committed, following the effective date of the Neurocrine Collaboration Agreement, to agree on a list of up to eight target genes, or Targets, from which Neurocrine has the right to nominate Targets for the two Discovery Programs. Each Target for the Discovery Programs must be approved by a consensus of the JSC or the executive officers.

# Manufacturing

Prior to the Transition Event for a Neurocrine Program, we are responsible for the manufacture of any Collaboration Products for the Program. Following the Transition Event, the parties shall negotiate the manufacturing and supply responsibilities, subject to the terms of any applicable Co-Co Agreement.

#### Financial Terms

Under the terms of the Neurocrine Collaboration Agreement, Neurocrine has agreed to pay us an upfront payment of \$115.0 million within five business days after the effective date, and \$50.0 million as an equity purchase of 4,179,728 shares to purchase our common stock. The Neurocrine Collaboration Agreement provides for aggregate development milestone payments from Neurocrine to us for Collaboration Products under (i) the AADC Program of up to \$170.0 million; (ii) the FA Program of up to \$195.0 million, and (iii) each of the two Discovery Programs of up to \$130.0 million per Discovery Program. We may be entitled to receive aggregate commercial milestone payments for each Collaboration Product of up to \$275.0 million, subject to an aggregate cap on commercial milestones across all Neurocrine Programs of \$1.1 billion.

Neurocrine has also agreed to pay us royalties, based on future net sales of the Collaboration Products. Such royalty percentages, for net sales in and outside the United States, as applicable, range (i) for the VY-AADC program, from the midteens to thirty and the low-teens to twenty, respectively; (ii) for the FA Program, from the low-teens to high-teens and high-single digits to mid-teens, respectively; and (iii) for each Discovery Program, from the high-single digits to mid-teens and mid-single digits to low-teens, respectively. On a country-by-country and program-by-program basis, royalty payments would commence on the first commercial sale of a Collaboration Product and terminate on the later of (a) the expiration of the last patent covering the Collaboration Product or its method of use in such country, (b) 10 years from the first commercial sale of the Collaboration Product in such country and (c) the expiration of regulatory exclusivity in such country, or the Royalty Term. Royalty payments may be reduced by up to 50% in specified circumstances, including expiration of patents rights related to a Collaboration Product, approval of biosimilar products in a given country or required payment of licensing fees to third parties related to the development and commercialization of any Collaboration Product. Additionally, the licenses granted to Neurocrine shall automatically

convert to fully paid-up, non-royalty bearing, perpetual, irrevocable, exclusive licenses on a country-by-country and product-by-product basis upon the expiration of the Royalty Term applicable to such Collaboration Product in such country.

### Intellectual Property

Under the terms of the Neurocrine Collaboration Agreement and subject to specified exceptions therein, each party owns the entire right, title and interest in and to all intellectual property rights made solely by its employees or agents in the course of the collaboration. The parties jointly own all rights, title and interest in and to all intellectual property rights made or invented jointly by employees or agents of both parties.

## Exclusivity

During the term of the Neurocrine Collaboration Agreement, neither party nor any of its respective affiliates is permitted to directly or indirectly exploit any AAV-based gene therapy products directed to a Target to which a Collaboration Product is directed, subject to specified exceptions, including the parties' conduct of basic research and our activities under the Sanofi Genzyme Collaboration.

#### **Termination**

Unless earlier terminated, the Neurocrine Collaboration Agreement expires on the later of (i) the expiration of the last to expire Royalty Term with respect to a Collaboration Product in all countries in the relevant territory or (ii) the expiration or termination of all Co-Co Agreements. Neurocrine may terminate the Neurocrine Collaboration Agreement in its entirety or on a program-by-program or country-by-country basis by providing at least (x) 180-day advance notice if such notice is provided prior to the first commercial sale of the Collaboration Product to which the termination applies or (y) one-year advance notice if such notice is provided after the first commercial sale of the Collaboration Product to which the termination applies. We may terminate the Neurocrine Collaboration Agreement, subject to specified conditions, if (i) Neurocrine fails to make the equity purchase of 4,179,728 shares of our common stock, for an aggregate purchase price of approximately \$50.0 million, or (ii) Neurocrine challenges the validity or enforceability of certain of our intellectual property rights. Subject to a cure period, either party may terminate the Neurocrine Collaboration Agreement in the event of a material breach by the other party in whole or in part, subject to specified conditions. Either party may also terminate the Neurocrine Collaboration Agreement if specified regulatory agencies seek to enjoin the transaction or if the parties are unable to obtain antitrust clearance within 180 days of the applicable antitrust filings.

Upon termination in certain cases, Neurocrine has agreed to grant to us licenses to certain Neurocrine intellectual property, subject to a negotiation between the parties to establish royalty rates for use of such intellectual property. In the event of a breach by us with respect to a Neurocrine Program, if such termination were to occur after a Transition Event, then (i) if a Co-Co Agreement is in effect with respect to such program, Neurocrine can terminate the Co-Co Agreement for such program and we would no longer have co-development and co-commercialization rights with respect to the Collaboration Product and (ii) subject to any license agreements, Neurocrine would no longer have any obligations with respect to any Collaboration Products resulting from such program.

# AbbVie Alpha-Synuclein Collaboration

In February 2019, we entered into an exclusive collaboration and option agreement, the AbbVie Alpha-Synuclein Collaboration Agreement, with AbbVie, for the research, development and commercialization of AAV and other virus-based gene therapy products directed against pathological species of alpha-synuclein for the potential treatment of indications including Parkinson's disease and other synucleinopathies.

# Collaboration and AbbVie Options

Under the AbbVie Alpha-Synuclein Collaboration Agreement, we and AbbVie have agreed to collaborate on the research and development of specified vectorized antibody compounds comprised of an AAV or other viral capsid

and a virus vector genome that encodes one or more antibodies that target and bind to the alpha-synuclein protein. The collaboration is comprised of a research period and a development period.

# Research Period and AbbVie Development Option

During the research period, we are obligated to conduct research activities directed to constructing one or more virus vectors that encode antibodies designated by AbbVie, or AbbVie Designated Antibodies, which initially are to be antibodies provided by AbbVie. We are obligated to use diligent efforts to conduct research activities to create research compounds and to develop product candidates containing or comprised of such research compounds. We are solely responsible for the costs and expenses during the research period. During a specified portion of the research period, AbbVie may exercise one or more of its exclusive development options to select up to a total of four research compounds and their corresponding Product candidates to proceed to the development period.

# Development Period and AbbVie License Option

During the development period, we are obligated to use diligent efforts to conduct development activities, including IND application-enabling and Phase 1 clinical trial activities, for the selected research compounds and corresponding selected product candidates. We are solely responsible for the costs and expenses during the development period. During a specified portion of the development period, AbbVie may exercise its exclusive license option to further develop and commercialize all of the research compounds and corresponding product candidates. Upon AbbVie's exercise of its license option, we have agreed to grant to AbbVie an exclusive, worldwide license, with the right to sublicense, under certain of our intellectual property rights to develop and commercialize the licensed compounds and the licensed products for all human diagnostic, prophylactic and therapeutic uses. In addition, after AbbVie's exercise of the license option, we have certain obligations to complete any remaining research and development activities that have not been completed for any research compounds and product candidates.

#### Governance

Our research and development activities are to be conducted pursuant to the plans agreed to by the parties and overseen by a joint governance committee, or the ASN JGC, comprised of an equal number of representatives from each of us and AbbVie. Prior to AbbVie's exercise of its License Option, we have final decision-making authority within the ASN JGC, subject to specified limitations; thereafter, AbbVie is entitled to final decision-making authority, subject to specified limitations. Any material amendment to the research or development plans, however, must be mutually agreed to by the parties, which may be through the ASN JGC.

## Commercialization

Under the AbbVie Alpha-Synuclein Collaboration Agreement, AbbVie is required to use commercially reasonable efforts to develop and commercialize at least one licensed product in each of the United States, Japan, the United Kingdom, Germany, France, Italy and Spain. After exercise of the license option, AbbVie is solely responsible for all development and commercialization activities relating to licensed compounds and licensed products at its sole cost and expense, subject to our obligation to complete any remaining research and development activities set forth in the agreed-upon plans.

# Manufacturing

During both the research period and the development period, we are solely responsible for the manufacture and supply of all pre-clinical and clinical requirements for the research compounds and product candidates. If AbbVie were to exercise its license option, we would be required, at AbbVie's request, to effect a full transfer of the manufacturing process for each licensed compound and corresponding licensed product to AbbVie. Following such transfer, we have agreed to disclose, on a continuing basis, all modifications, enhancements and improvements to manufacturing processes for the licensed products, and AbbVie has agreed to grant to us a non-exclusive, royalty-free license to modifications to the manufacturing process made by AbbVie, in each case, subject to specified limitations.

#### Financial

Under the terms of the AbbVie Alpha-Synuclein Collaboration Agreement, AbbVie has agreed to pay us an upfront payment of \$65.0 million within 15 business days of entry into the AbbVie Alpha-Synuclein Collaboration Agreement. AbbVie has also agreed to pay to us, within 30 days after the applicable exercise date: (1) upon AbbVie's exercise of a development option, (a) \$80.0 million for the first selected research compound and its corresponding selected product candidate and (b) \$30.0 million each for up to three additional selected research compounds and their corresponding selected product candidates, and (2) upon AbbVie's exercise of the license option, a one-time payment of \$75.0 million. We are eligible to receive (1) specified regulatory milestone payments for each licensed compound of up to an aggregate of \$450.0 million in the case of a Parkinson's disease indication and up to \$185.0 million in the case of the first indication other than Parkinson's disease and \$92.5 million for a subsequent non-Parkinson's disease indication; (2) specified commercial milestone payments for all licensed products for all indications up to an aggregate of \$500.0 million; and (3) tiered, escalating royalties, in the mid-single digit percentage range for aggregate net sales of licensed products on a licensed compound by licensed compound basis. The royalties are subject to potential reductions for biosimilar market penetration, patent claim expiration, and other provisions, subject to specified limits. Subject to certain exceptions, we and AbbVie have agreed to be financially responsible for all payments owed to a third party with which it has contracted for any use of inlicensed intellectual property under the AbbVie Alpha-Synuclein Collaboration Agreement.

# Intellectual Property

Under the terms of the AbbVie Alpha-Synuclein Collaboration Agreement, each party owns the entire right, title and interest in and to all know-how and patent rights first made or invented solely by it or its affiliates or its or their sublicensees in the course of the collaboration, with certain specified exceptions. Also subject to specified exceptions, the parties jointly own all rights, title and interest in and to all know-how and patent rights first made or invented jointly by such party or its affiliates or its or their sublicensees in the course of the collaboration. Regardless of whether AbbVie has exercised a development option or the license option, we have agreed to grant AbbVie perpetual, exclusive or non-exclusive (as the case may be), worldwide licenses to certain know-how and patent rights developed by the Company or jointly by the parties arising from the collaboration.

## Exclusivity

During the term of the AbbVie Alpha-Synuclein Collaboration Agreement, (1) neither party nor any of its respective affiliates is permitted to directly or indirectly exploit any vectorized antibody compound targeting the alpha-synuclein protein, or Vectorized Antibody Exclusivity and (2) neither us nor any of our affiliates is permitted to directly or indirectly exploit any AbbVie Designated Antibody, in each case subject to specified exceptions, including AbbVie's conduct of basic research.

#### **Termination**

Unless earlier terminated, the AbbVie Alpha-Synuclein Collaboration Agreement expires on the earliest to occur of the expiration of (1) the development option period, without AbbVie's exercise of a development option; (2) the license option period, without AbbVie's exercise of its license option; and (3) the last-to-expire royalty term with respect to all licensed products in all countries. Subject to a cure period, either party may terminate the AbbVie Alpha-Synuclein Collaboration Agreement, in whole or, in the case of us, in part, subject to specified conditions, in the event of the other party's uncured material breach. Either party may also terminate, subject to specified conditions, for insolvency of the other party, certain failures or delays to obtain certain regulatory clearances of the collaboration, or a joint determination of scientific infeasibility by the parties. AbbVie may terminate the AbbVie Alpha-Synuclein Collaboration Agreement (1) without cause, in its entirety or, after its exercise of the license option, on a country-by-country basis, with 180 days' prior written notice or (2) for our non-compliance with certain anti-bribery or anti-corruption covenants. We may terminate the AbbVie Alpha-Synuclein Collaboration Agreement, subject to specified conditions, if AbbVie or its affiliates challenge the validity or enforceability of certain of our or jointly-held intellectual property rights.

Upon termination in certain cases, the Vectorized Antibody Exclusivity and AbbVie Designated Exclusivity survives until the third anniversary of the termination date. If the parties mutually agree to terminate for infeasibility or AbbVie terminates for our failure to deliver a final research or development report, neither we nor any of our affiliates may directly or indirectly exploit a vectorized antibody compound that targets or binds to the alpha-synuclein protein for 18 months after the termination date

## License Agreement with University of Massachusetts

On January 30, 2014, we entered into a license agreement with the University of Massachusetts, or UMass, pursuant to which UMass granted us an exclusive, worldwide, royalty-bearing license to certain of its licensed patents to make, have made, use, offer for sale, sell, have sold and import certain licensed products in the field of human diseases that use gene therapy applications. Our license is subject to any rights that may be required to be granted to the government of the United States, and UMass reserves the right to use the licensed patents for education and research and, with our consent, for non-commercial patient care, without the payment of any compensation to us.

In consideration for rights granted to us under the agreement, we made an upfront payment of \$0.2 million to UMass. We are obligated to pay UMass (i) low-single digit royalty payments based on net sales of the licensed products, (ii) annual maintenance payments of \$30.0 thousand, which are creditable against royalties payable in such period, (iii) minimum aggregate annual royalty payments that are creditable against royalties payable in such period, with the minimum aggregate amount payable being in the low-six digits for each of the first four years of this agreement and a minimum aggregate amount payable being in the mid-six digits for each year, thereafter, (iv) milestone payments of up to \$1.8 million, per licensed product for the first five licensed products, based on the achievement of development and regulatory milestones and (v) a percentage of sublicensing income that decreases over time from low double digit percentages to a mid-single digit percentage. We also agreed to reimburse UMass approximately \$0.7 million for patent related expenses incurred by UMass as of the effective date of the agreement over a two-year period.

Under the agreement, we agreed to use commercially reasonable efforts to develop licensed products and to introduce such licensed products into the commercial market, and further agreed to certain development milestones.

The agreement will terminate on the date that is the later of (i) seven years after the first commercial sale of the last licensed product under the agreement or (ii) such time as there are no valid claims covering a licensed product. We have the right to terminate the agreement for any reason upon 90 days prior written notice, and we and UMass have the right to terminate the agreement if the other party fails to cure a written breach within 60 days of receiving written notice of such breach.

# MassBiologics and UMass Collaboration Agreement

On October 20, 2014, we entered into a Collaboration Agreement with UMass and MassBiologics, pursuant to which we shall (i) fund certain projects that will be conducted by UMass or MassBiologics, (ii) fund certain educational programs of UMass, including post-doctoral research at our laboratories beginning in 2015 and an annual lecture series beginning in 2015 and (iii) collaborate with MassBiologics to establish scalable processes for manufacturing recombinant AAV vector products using cGMP.

In November 2014, we agreed to the first project under this agreement whereby we funded approximately \$2.9 million over a 16-month period for certain research and development services performed by MassBiologics. The project commenced in January 2015 and completed during 2016. We and UMass and/or MassBiologics may agree to conduct other projects in the future, the terms of which will be agreed upon at such time.

This agreement will remain in effect for a period of five years and automatically renews for additional one-year periods. Either party has the right to terminate this agreement, once in each renewal period, for any reason upon providing the other party with 90 days written notice or in the event of a material breach of the agreement by the other party that is not cured within 60 days of written notice.

We will own all intellectual property rights generated under this agreement, either by our employees, UMass and/or MassBiologics employees, or jointly by our employees and UMass and/or MassBiologics employees, that cover AAV materials. We and UMass and/or MassBiologics, as applicable, will jointly own any intellectual property rights generated under this agreement jointly by our employees and the employees of UMass and/or MassBiologics, as applicable, that do not cover AAV materials.

# License Agreement with REGENX

In May 2014, we entered into a license agreement with REGENXBIO Inc., formerly known as ReGenX Biosciences, LLC, or REGENX, for the development and commercialization of gene therapies to treat ALS, Friedreich's ataxia and Huntington's disease. Under this license agreement, REGENX granted us a non-exclusive worldwide license to make, have made and use its technology solely for internal research and preclinical development for the identification of specific vectors that could be commercialized. Following identification, we have an option to obtain a non-exclusive worldwide license under the licensed intellectual property to a single specified AAV vector to make, have made, use, import, sell and offer for sale licensed products using the selected vector, which can be exercised for each of ALS, Friedreich's ataxia, or Huntington's disease. Under the terms of this license agreement, we paid REGENX an upfront fee of \$0.5 million, an extension fee of \$0.1 million and are required to pay an annual maintenance fee.

In November 2016, we exercised commercial options for the use of REGENX's NAV® Technology Platform, or NAV, vectors for the development and commercialization of gene therapies for specific neurological diseases. Upon exercise of the options, REGENX has granted us a non-exclusive worldwide commercial license, with rights to sublicense, to three specific NAV vector sequences covered by REGENX's NAV Technology Platform, each for the treatment of a specific neurological disease. In return for these rights, we paid upfront payments of \$1.05 million and have paid to REGENX an annual maintenance fee payment of five digits based on the number of disease indication options exercised. In addition, we will be required to pay to REGENX up to \$5.0 million in milestone fees per disease indication, mid- to high-single digit royalty percentages on net sales of licensed products, and low- to mid-single digit percentages of any sublicense fees that we receive from sublicensees for the licensed intellectual property rights.

Our license agreement with REGENX will expire upon the expiration, lapse, abandonment, or invalidation of the last claim of the licensed intellectual property to expire, lapse, or become abandoned or unenforceable in all the countries of the world

We may terminate the license agreement upon a specified number of days prior written notice. REGENX may terminate the license agreement if we, our affiliates, or sublicensees experience insolvency, if we are more than a specified number of days late in paying money due under the license agreement, or, effective immediately, if we or our affiliates commence any action against REGENX or its licensors to declare or render any claim of the licensed patent rights invalid or unenforceable. Either party may terminate the license agreement for material breach that is not cured within a specified number of days.

In February 2019, we provided notice to REGENX of our intent to terminate our commercial license. Upon the effective date of the termination, we are required to grant to REGENX a non-exclusive, perpetual, irrevocable, worldwide, royalty-free, transferable, sublicensable license to certain improvements made by us during the term of the license (including any intellectual property rights with respect thereto). This grant back will allow for REGENX's use of the improvements in the research, development or commercialization of products in any therapeutic indication.

# Competition

The biopharmaceutical industry is characterized by intense and dynamic competition to develop new technologies and proprietary therapies. Any product candidates that we successfully develop into products and commercialize may compete with existing therapies and new therapies that may become available in the future. While we believe that our gene therapy platform, product programs, product candidates and scientific expertise in the fields of gene therapy and neuroscience provide us with competitive advantages, we face potential competition from various

sources, including larger and better-funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as from academic institutions, governmental agencies and public and private research institutions.

We are aware of several companies focused on developing AAV gene therapies in various indications, including Abeona Therapeutics, Inc., Adverum Biotechnologies, Inc., Aevitas Therapeutics, Inc., Agilis Biotherapeutics, LLC, which was acquired by PTC Therapeutics, Inc. in 2018, Applied Genetic Technologies Corporation, Asklepios BioPharmaceutical, Inc., Audentes Therapeutics, Inc., AveXis, Inc., or AveXis which was acquired by Novartis in 2018, Axovant Sciences Ltd., GenSight Biologics SA, LogicBio Therapeutics, Inc., Lysogene SA, MeiraGTx Ltd., NightstaRx Ltd, Prevail Therapeutics, Inc., REGENXBio Inc., Sarepta Therapeutics, Inc., Solid Biosciences, Inc., uniQure NV, or uniQure, Pfizer, Inc., or Pfizer, and Spark Therapeutics, Inc., or Spark, as well as several companies addressing other methods for modifying genes and regulating gene expression. Any advances in gene therapy technology made by a competitor may be used to develop therapies that could compete against any of our product candidates.

We expect that VY-AADC will compete with a variety of therapies currently marketed and in development for Parkinson's disease, including DBS marketed by Medtronic plc, Abbott Laboratories (acquired from St. Jude Medical in 2017), and other medical device companies, DUOPA/Duodopa marketed by AbbVie Inc., as well as other novel, non-oral forms of levodopa in development, including Mitsubishi Tanabe Pharma's ND0612 (acquired from NeuroDerm in 2017), Acorda Therapeutics' inhaled levodopa, INBRIJA (CVT-301), and Sunovion Pharmaceuticals', or Sunovion's, sublingual apomorphine, APL-130277. Gene therapy competition for Parkinson's disease previously included AMT-090 or AAV-GDNF, but this was deprioritized by uniQure in 2016. Axovant Sciences Ltd. is developing a second generation LentiVector gene therapy, AXO-Lenti-PD (previously OXB-102, licensed from Oxford Biomedica in 2018). MeiraGTx is developing AAV-GAD, acquired from Vector Neurosciences, Inc. in 2018.

We expect that our preclinical programs will compete with a variety of therapies in development, including:

- VY-SOD102 for a monogenic form of ALS will potentially compete with IONIS-SOD1R<sub>x</sub> being developed by Ionis Pharmaceuticals, Inc., or Ionis, in collaboration with Biogen Inc., or Biogen, and a gene therapy being developed by AveXis;
- VY-FXN01 for Friedreich's ataxia will potentially compete with AAV gene therapies being developed by Pfizer and by Agilis Biotherapeutics, LLC (acquired by PTC Therapeutics, Inc. in 2018), and BMN 290 being developed by BioMarin Pharmaceutical Inc.;
- VY-HTT01 for Huntington's disease will potentially compete with IONIS-HTTR<sub>x</sub> being developed by Ionis in collaboration with F. Hoffmann-La Roche Ltd., or Roche, WVE-120101 and WVE-120102 being developed by WAVE Life Sciences in collaboration with Takeda Pharmaceuticals, a Zinc Finger Protein (ZFP) therapy being developed by Sangamo Therapeutics, Inc. in collaboration with Shire plc, and gene therapies being developed by uniQure and Spark;
- Our Tau program for tauopathies including Alzheimer's disease, PSP, and FTD will potentially compete with tau antibodies being developed by Roche Genentech Inc. in collaboration with AC Immune SA, Eli Lilly & Co., AbbVie Inc., Biogen, and several other companies, as well as an antisense oligonucleotide program being developed by Ionis in collaboration with Biogen; and
- · VY-NAV01 for severe, chronic pain will potentially compete with Na<sub>v</sub>1.7 inhibitors being developed by Biogen, Sunovion, Amgen, Inc., and Astellas Pharma Inc, and Na<sub>v</sub>1.8 inhibitors being developed by Vertex Pharmaceuticals, or Vertex.

In addition, companies that are currently engaged in gene therapy for non-neurological diseases could at any time decide to develop gene therapies for neurological diseases.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of product candidates and commercializing those product candidates. Accordingly, our competitors may be more successful than us in obtaining approval for product candidates and achieving widespread market acceptance. Our competitors' product candidates may be more effective, or more effectively marketed and sold, than any product candidate we may commercialize and may render our treatments obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We anticipate that we will face intense and increasing competition as new product candidates enter the market and advanced technologies become available. We expect any product candidates that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, and the availability of reimbursement from government and other third-party payers.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

#### **Manufacturing**

The manufacture of gene therapy products is technically complex, and necessitates substantial expertise and capital investment. Production difficulties caused by unforeseen events may delay the availability of material for our clinical studies. To meet the requirements of our current and planned future trials we have developed a proprietary manufacturing platform that provides a robust and scalable process for AAV production. We are using the baculovirus/Sf9 AAV production system, a technology for producing AAV vectors at scale in insect-derived cells. We focus on developing internal processes and capabilities to produce high-yield and high-quality gene therapies. The process has been successfully transferred to our contract manufacturing organizations where it is used in manufacturing of clinical materials in accordance with the FDA's cGMP. We have entered into agreements with Brammer Bio and Fujifilm Diosynth Biotechnologies to further expand our manufacturing capabilities to support the development of our gene therapy programs. We have also built an onsite, state-of-the-art process research and development facility to enable the manufacturing of high quality AAV gene therapy vectors at laboratory scale.

We presently contract with third parties for the manufacturing of our program materials. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. The use of contracted manufacturing and reliance on collaboration partners is relatively cost efficient and has eliminated the need for our direct investment in manufacturing facilities and additional staff early in development. Although we rely on contract manufacturers, we have personnel with manufacturing and quality experience to oversee our contract manufacturers.

## **Intellectual Property**

## Overview

We strive to protect the proprietary technology, inventions, and know-how to enhance improvements that are commercially important to the development of our business, including seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also rely on trade secrets and know-how relating to our proprietary technology platform, on continuing technological innovation and on in-licensing opportunities to develop, strengthen and maintain the strength of our position in the field of gene therapy that may be important for the development of our business. We additionally may rely on regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available.

Our commercial success may depend in part on our ability to: obtain and maintain patent and other protections for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid enforceable patents and intellectual property rights of third parties. Our ability to stop third parties from making, having made, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable licenses, patents or trade secrets that cover these activities. In some cases, these rights may need to be enforced by third-party licensors. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same.

We have 182 patent applications pending in the United States and foreign jurisdictions. At least 28 patent applications have been filed and are pending in the United States and foreign jurisdictions by or on behalf of universities which have granted us exclusive license rights to the technology. To date, 72 patents have issued to our licensors which have granted us exclusive license rights to the technology. To date, 148 patents have issued to our licensors which have granted us non-exclusive license rights to the technology with 64 applications pending. Our policy is to file patent applications to protect technology, inventions and improvements to inventions that are commercially important to the development of our business. We seek United States and international patent protection for a variety of technologies, including: research tools and methods, methods for transferring genetic material into cells, AAV-based biological products, methods of designing novel AAV constructs, methods for treating diseases of interest and methods for manufacturing our AAV-based products. We also intend to seek patent protection or rely upon trade secret rights to protect other technologies that may be used to discover and validate targets and that may be used to identify and develop novel biological products. We seek protection, in part, through confidentiality and proprietary information agreements. We are a party to various other license agreements that give us rights to use specific technologies in our research and development.

# **Company-Owned Intellectual Property**

#### Parkinson's Disease

We own four pending patent families with one issued patent and 35 patent applications directed to AAV constructs encoding the gene AADC for therapeutic uses. Patents that grant from these patent families are generally expected to start to expire in 2035, subject to possible patent term extensions.

#### ALS

We own four pending patent families with 19 patent applications directed to targeting SOD1 for the treatment of ALS, and we have an ownership interest in a fifth patent family with 2 patent applications directed to pharmaceutical compositions and methods for the treatment of ALS to protect our intellectual property arising from a funded grant from

The Amyotrophic Lateral Sclerosis Association. Patents that grant from these patent families are generally expected to start to expire in 2035, subject to possible patent term extensions.

#### Friedreich's Ataxia

We own two pending patent families with seven patent applications and we have an ownership interest in one pending patent family with two patent applications directed to AAVs encoding frataxin constructs for the treatment of Friedreich's ataxia. Patents that grant from these patent families are generally expected to start to expire in 2036, subject to possible patent term extensions.

#### Huntington's Disease

We own three pending patent families with 19 patent applications directed to pharmaceutical compositions and methods for targeting HTT for the treatment of Huntington's disease, and we have an ownership interest in a fourth patent family with one patent application directed to protect our work for additional pharmaceutical compositions and methods for targeting HTT for the treatment of Huntington's disease. Patents from this family are generally expected to start to expire in 2037, subject to possible patent term extensions.

# Tauopathies and Antibodies

We own five pending patent families directed to antibodies with 11 patent applications. The first patent family has four patent applications directed to assays for the detection of neutralizing antibodies. The next three patent families have six patent applications directed to vectorized antibodies and other therapies. The last patent family has one patent application directed to vectored augmentation of proteins. Patents from these families are generally expected to start to expire in 2036, subject to possible patent term extensions.

We also have one pending patent family with one patent application directed to pharmaceutical compositions and methods for the treatment of Alzheimer's Disease. Patents from this family are generally expected to start to expire in 2039, subject to possible patent term extensions.

# Neuropathic Pain

We own one pending patent family with two patent applications directed to pharmaceutical compositions and methods for the treatment of neuropathic pain. Patents from this family are generally expected to start to expire in 2039, subject to possible patent term extensions.

# Regulatable Expression

We own two pending patent families with four patent applications directed to regulatable expression control of AAV transgenes. Patents that grant from this patent family are generally expected to start to expire in 2036, subject to possible patent term extensions.

# Delivery

We own one pending patent family with five patent applications directed to the delivery of AAV gene therapies to the CNS. Patents that grant from this patent family are generally expected to start to expire in 2036, subject to possible patent term extensions

We own one pending patent family with one patent application directed to cannula delivery system and methods of use. Patents that grant from this patent family are generally expected to start to expire in 2039, subject to possible patent term extensions.

We have an ownership interest in two pending patent families directed to trajectory array delivery devices, including the V-TAG device and methods of use. Patents that grant from these patent families are generally expected to start to expire in 2037, subject to possible patent term extensions.

Engineering

We own seven pending patent families with 14 patent applications directed to AAV production and/or engineering of the capsid and we have an ownership interest in one patent family with one patent application directed to engineering of the capsid. Patents that grant from these patent families are generally expected to start to expire in 2035, subject to possible patent term extensions.

We own three patent families with 33 patent applications directed to engineering of the vector genome. Patents that grant from these patent families are generally expected to start to expire in 2035, subject to possible patent term extensions.

Production; Chemistry, Manufacturing, and Controls

We own 14 pending patent families with 22 patent applications directed to AAV production and CMC. Patents that grant from this patent family are generally expected to start to expire in 2035, subject to possible patent term extensions.

## Licensed Intellectual Property

We have obtained exclusive licenses and non-exclusive licenses to patents directed to both compositions of matter and methods of use.

We have licensed six families of patents and patent applications, in the exclusive field of gene therapy for human diseases, directed to RNAi constructs as vector payloads, their design and use in the treatment of neurological disorders from the University of Massachusetts. These families of patents and applications are pending and/or granted in the United States and other territories and comprises 67 granted patents and 15 applications. Patents have been granted in the United States, Canada, Europe, Israel, Japan, Korea and Australia. Nationalization for some members has taken place in Germany, Spain, France, Great Britain, Italy, and Netherlands. Patents that grant from these patent families are generally expected to expire between 2022 and 2025, subject to possible patent term extensions.

We have exclusively licensed three families of patents and patent applications directed to novel AAV capsids from the University of Massachusetts. These families of patents and applications, pending and/or granted in the United States and other territories, and comprises 32 granted patents and 18 applications. Patents have been granted in the United States, Europe and Japan. Nationalization for some members has taken place in Switzerland, Germany, Denmark, Spain, France, Great Britain, Ireland, Italy, Netherlands, and Sweden. Patents that grant from these patent families are generally expected to expire between 2030 and 2035, subject to possible patent term extensions.

We have non-exclusively licensed a patent family directed to production methods for AAV in insect cells from the NIH, U.S. Department of Health and Human Services. This family of patents is granted in the United States, Canada, Australia and Europe and further nationalized in Germany, France and Great Britain and comprises 8 granted patents. Patents that grant from this patent family are generally expected to expire in 2022, subject to possible patent term extensions.

We have non-exclusively licensed two families of patents and patent applications directed to novel AAV capsids from the Board of Trustees of the Leland Stanford Junior University. These families of patents and applications, pending and/or granted in the United States, comprise 7 granted patents and one application. Patents that grant from these patent families are generally expected to expire between 2027 and 2032, subject to possible patent term extensions.

We have non-exclusively licensed two families of patents and patent applications directed to AAV capsids from REGENX. These families of patents and patent applications are pending and/or granted in the United States and other territories and comprise 79 granted patents and 16 applications. Patents have been granted in Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, Korea, Mexico, New Zealand, Philippines, Singapore, and the United States. Patents that grant from these patent families are generally expected to expire between 2022 and 2026, subject to possible patent term extensions. Notice of termination of this license was sent to REGENX in February 2019.

We have non-exclusively licensed two families of patents and patent applications from Ablexis, LLC. These families of patents and patent applications are pending and/or granted in the United States and other territories and comprise 24 granted patents and 21 applications. Patents have been granted in Australia, Canada, Europe, Korea, New Zealand and the United States. Nationalization for some members has taken place in Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Netherlands, Poland, Spain, Switzerland, and United Kingdom. Patents that grant from these patent families are generally expected to expire between 2029 and 2030, subject to possible patent term extensions.

We have non-exclusively licensed two families of patents and patent applications directed to AAV capsids from the California Institute of Technology. These families of patents and patent applications are pending in the United States and internationally and comprise three granted patents and 21 applications. Patents have been granted in the United States. Patents that grant from these patent families are generally expected to start to expire in 2034, subject to possible patent term extensions.

#### **Trademark Protection**

We own U.S. Reg. Nos. 4,545,283 for the service mark VOYAGER THERAPEUTICS and 4,621,083 for the service mark VOYAGER THERAPEUTICS Logo for "pharmaceutical research and development in the field of gene therapy." These marks were granted registration on the Principal Register of the United States Patent and Trademark Office, or USPTO, on June 3, 2014 and October 14, 2014, respectively.

We also own pending trademark applications in the USPTO for the marks V-TAG and the V-TAG Logo, for "medical system comprised of a surgical device for guiding, locating or placing a diagnostic device or therapeutic device, namely, stents, probes, needles, leads, grafts, pumps, syringes, catheters, and implants during a medical procedure and related software sold as a unit, for use in the field of neurology; MRI-compatible medical system comprised of an MRI-compatible surgical device for guiding, locating or placing a diagnostic device or therapeutic device, namely, stents, probes, needles, leads, grafts, pumps, syringes, catheters, and implants during a MRI-guided procedure and related software sold as a unit, for use in the field of neurology," as well as European Community trademark registrations for VOYAGER TRAJECTORY ARRAY GUIDE (No. 017430042, registered May 8, 2018) and V-TAG (No. 017430182, registered May 8, 2018) for these same goods.

We plan to register trademarks in connection with our biological products.

#### **Trade Secret Protection**

Finally, we may rely, in some circumstances, on trade secrets to protect our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

# **Government Regulation and Product Approval**

In the United States, biological products, including gene therapy products, are licensed by FDA for marketing under the Public Health Service Act, or PHS Act, and regulated under the Federal Food, Drug, and Cosmetic Act, or FDCA. Both the FDCA and the PHS Act and their corresponding regulations govern, among other things, the testing, manufacturing, safety, purity, potency, efficacy, labeling, packaging, storage, record keeping, distribution, import, export, reporting, advertising and other promotional practices involving biological products. FDA clearance must be obtained before clinical testing of biological products, and each clinical study protocol for a gene therapy product is reviewed by the FDA and, in some instances, the NIH, through its RAC. FDA licensure also must be obtained before marketing of biological products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

Within the FDA, the Center for Biologics Evaluation and Research, or CBER, regulates gene therapy products. Within CBER, the Office of Tissues and Advanced Therapies (OTAT) is responsible for gene therapy review and evaluation. CBER works closely with the NIH and its RAC, which makes recommendations to the NIH on gene therapy issues and engages in a public discussion of scientific, safety, ethical and societal issues related to proposed and ongoing gene therapy protocols. The FDA and the NIH have published guidance documents with respect to the development and submission of gene therapy protocols. The FDA also has published guidance documents related to, among other things, gene therapy products in general, their preclinical assessment, observing subjects involved in gene therapy studies for delayed adverse events, viral shedding, environmental assessments, potency testing, and chemistry, manufacturing and control information in gene therapy INDs. FDA guidance documents provide the agency's current thinking about a particular subject but are not legally binding.

# U.S. Biological Products Development Process

The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- · completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- · preparation of clinical trial material in accordance with good manufacturing practices, or GMPs;
- · submission to the FDA of an application for an IND, which must become effective before human clinical trials may begin;
- · approval by an institutional review board, or IRB, reviewing each clinical site before each clinical trial may be initiated;
- · approval by an institutional biosafety committee, or IBC, assessing the safety of the clinical research and identifying any potential risk to public health or the environment;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practice, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety, purity, potency, and efficacy, of the proposed biological product for its intended use;
- · submission to the FDA of a BLA, for marketing approval that includes substantive evidence of safety, purity, potency, and efficacy from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection prior to BLA approval of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;

- · potential FDA audit of the nonclinical and clinical study sites that generated the data in support of the BLA;
- potential FDA Advisory Committee meeting to elicit expert input on critical issues and including a vote by external Committee members;
- FDA review and approval, or licensure, of the BLA, and payment of associated user fees; and
- · compliance with any post approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct post approval studies.

Before testing any biological product candidate, including a gene therapy product, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical tests, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

Previously, when a gene therapy study was conducted at, or sponsored by, institutions receiving NIH funding for recombinant DNA research, prior to the submission of an IND to the FDA, a protocol and related documentation was to be submitted to and the study was registered with the NIH Office of Biotechnology Activities, or OBA, pursuant to the NIH Guidelines for Research Involving Recombinant DNA Molecules, or NIH Guidelines. Compliance with the NIH Guidelines was mandatory for investigators at institutions receiving NIH funds for research involving recombinant DNA, however many companies and other institutions not otherwise subject to the NIH Guidelines had voluntarily followed them. Under an FDA and NIH proposal in 2018, the role of the Recombinant DNA Advisory Committee, or RAC, in reviewing gene therapy protocols would be entirely eliminated and sponsors would no longer be required to submit reports to NIH on such protocols. Going forward, NIH says the RAC will continue to function as an advisory board to NIH on emerging fields such as gene editing, synthetic biology and neurotechnology.

The clinical study sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing typically continues after the IND is submitted. An IND is an exemption from the FDCA that allows an unapproved product to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational product to humans. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA requests certain changes to a protocol before the study can begin, or the FDA places the clinical study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. With gene therapy protocols, if the FDA allows the IND to proceed, but the RAC decides that full public review of the protocol is warranted, the FDA will request at the completion of its IND review that sponsors delay initiation of the protocol until after completion of the RAC review process. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, studies may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such studies.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or subjects under the supervision of qualified investigators, generally physicians not employed by or under the study sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical study will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical study must be reviewed and approved by an independent IRB, at or servicing each institution at which the clinical study will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals

participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical study subject or his or her legal representative and must monitor the clinical study until completed. Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. Clinical trials involving recombinant or synthetic (or both) nucleic acid molecules performed at or sponsored by an institution that receives any NIH funding for such research also must be reviewed by an IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product is initially introduced into healthy human subjects and tested for safety. In the
  case of some products for severe or life-threatening diseases, especially when the product may be too inherently
  toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
   Guidelines on clinical trials with gene therapy products issued by OTAT state that the FDA has determined that
  the benefit-risk ratio of these products does not warrant their evaluation in healthy human subjects.
- *Phase 2*. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. The FDA recommends that sponsors observe subjects for potential gene therapy-related delayed adverse events for a 15-year period, including a minimum of five years of annual examinations followed by ten years of annual queries, either in person or by questionnaire, of trial subjects.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, the NIH and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2, and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Human gene therapy products are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the study period, the number of patients the FDA will require to be enrolled in the studies in order to establish the safety, efficacy, purity and potency of human gene therapy products, or that the data generated in these studies will be acceptable to the FDA to support marketing approval. The NIH and the FDA have a publicly accessible database, the Genetic Modification Clinical Research Information System which includes information on gene transfer studies and serves as an electronic

tool to facilitate the reporting and analysis of adverse events on these studies. The FDA has issued various guidance documents regarding gene therapies, including draft guidance documents released in July 2018 relating to gene therapies for human retinal disorders and gene therapies for rare diseases, and on January 15, 2019, the FDA issued a statement that it would issue additional guidance to facilitate the development of gene therapy products.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on its ClinicalTrials.gov website.

# Expanded Access to an Investigational Drug for Treatment Use

Expanded access, sometimes called "compassionate use," is the use of investigational new drug products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. The rules and regulations related to expanded access are intended to improve access to investigational drugs for patients who may benefit from investigational therapies. FDA regulations allow access to investigational drugs under an IND by the company or the treating physician for treatment purposes on a case-bycase basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the drug under a treatment protocol or Treatment IND Application.

When considering an IND application for expanded access to an investigational product with the purpose of treating a patient or a group of patients, the sponsor and treating physicians or investigators will determine suitability when all of the following criteria apply: patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational drug for the requested treatment will not interfere initiation, conduct, or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

On December 13, 2016, the 21st Century Cures Act established (and the 2017 Food and Drug Administration Reauthorization Act later amended) a requirement that sponsors of one or more investigational drugs for the treatment of a serious disease(s) or condition(s) make publicly available their policy for evaluating and responding to requests for expanded access for individual patients. Although these requirements were rolled out over time, they have now come into full effect. This provision requires drug and biologic companies to make publicly available their policies for expanded access for individual patient access to products intended for serious diseases.

Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 study; or 15 days after the drug or biologic receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access

program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

## U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA, must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee. Under federal law, the submission of most applications is subject to an application user fee, which for federal fiscal year 2019 is \$2,588,478 for an application requiring clinical data. The sponsor of an approved application is also subject to an annual program fee, which for fiscal year 2019 is \$309,915. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for product candidates designated as orphan drugs, unless the product candidate also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. The application also needs to be published and submitted in an electronic format that can be processed through the FDA's electronic systems. If the electronic submission is not compatible with FDA's systems, the BLA can be refused to file. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical trial sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that usually describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized. As a condition for approval, the FDA may also require additional non-clinical testing as a Phase 4 commitment.

One of the performance goals agreed to by the FDA under the PDUFA is to review standard BLAs in 10 months from filing and priority BLAs in six months from filing, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

# Post-Approval Requirements

Maintaining substantial compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP. We will rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Following approval, the manufacturing facilities are subject to biennial inspections by the FDA's biologics team and such inspections may result in an issuance of FDA Form 483 deficiency observations or a warning letter, which can lead to plant shutdown and other more serious penalties and fines. Prior to the institution of any manufacturing changes, a determination needs to be made whether FDA approval is required in advance. If not done in accordance with FDA expectations, the FDA may restrict supply and may take further action. Annual product reports are required to be submitted annually. Other post-approval requirements applicable to biological products, include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary o

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval or license revocation, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

# Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant Orphan Drug Designation, or ODD, to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. ODD must be requested before submitting a BLA. After the FDA grants ODD, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. ODD does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has ODD receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same biological product for the same indication for seven years, except in limited circumstances, such as not being able to supply the product for patients or showing clinical superiority to the product with orphan exclusivity. This is the case despite an earlier court opinion holding that the Orphan Drug Act unambiguously required the FDA to recognize orphan exclusivity regardless of a showing of clinical superiority.

Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity.

Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, priority review, accelerated approval, and breakthrough therapy designation, that are intended to expedite or simplify the process for the development and FDA review of biological products that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new biological products to patients earlier than under standard FDA review procedures. To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a biological product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track BLA before the application is complete, a process known as rolling review.

The FDA may give a priority review designation to biological products that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Most products that are eligible for fast track designation may also be considered appropriate to receive a priority review.

In addition, biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the biological product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a biological product receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the biological product may be subject to accelerated withdrawal procedures.

Moreover, under the Food and Drug Administration Safety and Innovation Act enacted in 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a biological product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the biological product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Biological products designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, priority review, accelerated approval and breakthrough therapy designation, do not change the standards for approval and may not ultimately expedite the development or approval process.

Expedited programs for regenerative medicine therapies for serious conditions

As part of the 21st Century Cures Act, Congress amended the FDCA to create an expedited development and approval program for regenerative medicine advanced therapies, which include cell therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products. As of November 2017, the FDA has interpreted this definition as follows: gene therapies, including genetically modified cells, that lead to a durable modification of cells or tissues may meet the definition of a regenerative medicine advanced

therapy. The FDA has now determined that 'in vitro' gene therapies will qualify as a regenerative medicine advanced therapy based on this definition. VY-AADC is an 'in vitro' gene therapy for Parkinson's disease and received this designation on June 18, 2018. Regenerative medicine advanced therapies do not include those human cells, tissues, and cellular and tissue-based products regulated solely under section 361 of the Public Health Service Act and 21 CFR Part 1271. The new program is intended to facilitate efficient development and expedite review of regenerative medicine advanced therapies, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition.

A drug sponsor may request that the FDA designate a drug as a regenerative medicine advanced therapy concurrently with or at any time after submission of an IND. The FDA has 60 calendar days to determine whether the drug meets the criteria, including whether there is preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs for a serious or life-threatening disease or condition. A new drug application or BLA for a regenerative medicine advanced therapy may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with the FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative medicine advanced therapy that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval.

#### U.S. Patent Term Restoration

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application, less any time the applicant failed to act with due diligence. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

# Market and Data Exclusivity

The 2010 Patient Protection and Affordable Care Act, or the ACA, which was signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 or BPCIA. The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. As of January 1, 2019, the FDA has approved 17 biosimilar products for use in the United States. No interchangeable biosimilars have been approved. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Additional guidance is expected to be finalized by FDA in the near term.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the FDA must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that

the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

# Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or patent protection, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an application sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. Thus, pediatric exclusivity adds six months to existing exclusivity periods applicable to biological products under the BPCIA—namely, the four-year period during which the FDA will not consider an application for a biosimilar product, and the 12-year period during which the FDA will not approve a biosimilar application.

# Other Healthcare Laws

Although we currently do not have any products on the market, we may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations, many of which may become more applicable to us if our product candidates are approved and we begin commercialization. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

In addition, the ACA is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. With regard to biopharmaceutical products, in addition to the Biologics Price Competition and Innovation Act of 2009 included in the ACA, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, that while not a law, is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA.

The current administration has also taken executive actions to undermine or delay implementation of the ACA. Since January 2017, President Trump has signed two Executive Orders which delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA.

One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the Trump administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, the Center for Medicare & Medicaid Services has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than \$12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

With enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective January 1, 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices.

Further, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. For example, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on May 11, 2018, the Trump administration issued a plan to lower drug prices. Under this blueprint for action, the Trump administration indicated that the Department of Health and Human Services will: take steps to end the gaming of regulatory and patent processes by drug makers to unfairly protect monopolies; advance biosimilars and generics to boost price competition; evaluate the inclusion of prices in drug makers' ads to enhance price competition; speed access to and lower the cost of new drugs by clarifying policies for sharing information between insurers and drug makers; avoid excessive pricing by relying more on value-based pricing by expanding outcome-based payments in Medicare and Medicaid; work to give Part D plan sponsors more negotiation power with drug makers; examine which Medicare Part B drugs could be negotiated for a lower price by Part D plans, and improving the design of the Part B Competitive Acquisition Program; update Medicare's drug-pricing dashboard to increase transparency; prohibit Part D contracts that include "gag rules" that prevent pharmacists from informing patients when they could pay less out-of-pocket by not using insurance; and require that Part D plan members be provided with an annual statement of plan payments, out-of-pocket spending, and drug price increases.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription product and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our

product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

#### Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

# U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

Review and Clearance of Companion Diagnostics in the United States

If safe and effective use of a therapeutic depends on an *in vitro* diagnostic, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves the therapeutic product. In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and *in vitro* companion diagnostics. According to the guidance, for novel drugs, a companion diagnostic device and its corresponding therapeutic should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product's labeling. In July 2016, the FDA issued a draft guidance intended to assist sponsors of the drug therapeutic and *in vitro* companion diagnostic device on issues related to co-development of the products.

If FDA determines that a companion diagnostic device or delivery device (combination product) is essential to the safe and effective use of a novel therapeutic product or indication, FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic or delivery device is not approved or cleared for that indication. Approval or clearance of the companion diagnostic or delivery device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. The review of *in vitro* companion diagnostics in conjunction with the review of our therapeutic treatments for cancer will, therefore, likely involve coordination of review by the FDA's Center for Drug Evaluation and Research and the FDA's CDRH Office.

Under the FDCA, *in vitro* diagnostics, including companion diagnostics, are regulated as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval.

The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must

prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to fees for medical device product review. For federal fiscal year 2019, the standard fee for review of a PMA was \$322,147 and the small business fee was \$80,537.

A 510(k) must demonstrate that the proposed device is substantially equivalent to another legally marketed device, or predicate device, that did not require premarket approval. In evaluating a 510(k), the FDA will determine whether the device has the same intended use as the predicate device, and (a) has the same technological characteristics as the predicate device, or (b) has different technological characteristics, and (i) the data supporting substantial equivalence contains information, including appropriate clinical or scientific data, if deemed necessary by the FDA, that demonstrates that the device is as safe and as effective as a legally marketed device, and (ii) does not raise different questions of safety and effectiveness than the predicate device. Most 510(k) do not require clinical data for clearance, but the FDA may request such data. The FDA seeks to review and act on a 510(k) within 90 days of submission, but it may take longer if the agency finds that it requires more information to review the 510(k). If the FDA concludes that a new device is not substantially equivalent to a predicate device, the new device will be classified in Class III and the manufacturer will be required to submit a PMA to market the product. On July 23, 2018, the CDRH of the FDA cleared the 510(k) for our V-TAG<sup>TM</sup> device that is compatible for use with MRIs.

Government Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials, e.g., a clinical trial application for each clinical trial for each EU country in which the trial is conducted; a clinical trial notification is required in Japan.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Coverage, Pricing and Reimbursement for Biopharmaceutical Products

Sales of our products, when and if approved for marketing, will depend, in part, on the extent to which our products will be covered by third-party payors, such as federal, state, and foreign government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for medical products, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor not to cover our product candidates could reduce physician usage of our products once approved and have a material adverse effect on our sales, results of operations and financial condition.

# **Our Corporate Information**

We were incorporated under the laws of Delaware in June 2013. Our principal executive offices are located at 75 Sidney Street, Cambridge, MA 02139. Other operations, including laboratory space, are located at 64 Sidney Street,

Cambridge, MA 02139. We lease our office and laboratory space, which consist of approximately 74,000 square feet located in two locations in Cambridge, Massachusetts. Our lease expires in 2026.

## **Employees**

As of December 31, 2018, we employed 123 full-time employees in the United States, including 92 in research and development and 31 in general and administrative, and one part-time employee. Thirty-nine of our employees have either an MD, PhD, or PharmD. We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective-bargaining arrangements. We consider our employee relations to be positive.

#### **Legal Proceedings**

As of the date of this Annual Report on Form 10-K, we were not party to any material legal matters or claims. In the future, we may become party to legal matters and claims arising in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on our financial position, results of operations or cash flows.

#### **Available Information**

Our Internet address is http://www.voyagertherapeutics.com. We make available, free of charge, on or through our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities and Exchange Act as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. The information on our website is not part of this Annual Report for the year ended December 31, 2018.

#### ITEM 1A. RISK FACTORS

The following risk factors and other information in this Annual Report on Form 10-K, including our financial statements and related notes thereto, should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see page 3 of this Annual Report on Form 10-K for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

## Risks Related to Our Financial Position and Need for Capital

We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage gene therapy company with a limited operating history and have not yet generated revenues from the sales of our product candidates. Investment in biotechnology companies is highly speculative because it entails substantial upfront capital expenditures and significant risk that the product candidate will fail to obtain regulatory approval or become commercially viable. We have not yet demonstrated the ability to complete any clinical trials of our product candidates, obtain marketing approvals, manufacture a commercial-scale product or conduct sales and marketing activities necessary for successful commercialization. We continue to incur significant expenses related to research and development, and other operations in order to commercialize our product candidates. As a result, we are not and have never been profitable and have incurred losses since our inception. Our net losses were \$88.3 million, \$70.7 million, and \$40.2 million for the years ended December 31, 2018, 2017, and 2016 respectively. As of December 31, 2018, we had an accumulated deficit of \$269.1 million.

We historically have financed our operations primarily through private placements of our redeemable convertible preferred stock, public offerings of our common stock; and strategic collaborations, including those with Sanofi Genzyme, AbbVie, and Neurocrine, which we collectively refer to our Strategic Collaborations. On November 16, 2015 we closed our initial public offering whereby we sold 5,750,000 shares of common stock at a public offering price of \$14.00 per share, including 750,000 shares of common stock issued upon the full exercise by the underwriters of their option to purchase additional shares, resulting in net proceeds to us of \$72.9 million after deducting underwriting discounts, commissions and offering expenses payable by us. On November 7, 2017, we sold 5,175,000 shares of common stock to the public at an offering price of \$12.00 per share, including 675,000 shares of common stock issued upon the full exercise by the underwriters of their option to purchase additional shares, resulting in net proceeds to us of \$58.0 million after deducting underwriting discounts, commissions, and offering expenses payable by us. On January 28, 2019, in connection with our collaboration with Neurocrine, we agreed to sell 4,179,728 shares of common stock to Neurocrine at a price of \$11.9625 per share, for an aggregate purchase price of approximately \$50.0 million. The sale of shares to Neurocrine is subject to customary closing conditions, including certain antitrust approvals, that have not been satisfied as of the date of this Annual Report on Form 10-K. As a result, we have not yet issued such shares to Neurocrine, but, if the applicable closing conditions are met, we expect to do so promptly.

To date, we have devoted substantially all of our financial resources to building our gene therapy platform, selecting product programs, conducting research and development, including preclinical development of our product candidates, building our intellectual property portfolio, building our team, and establishing Strategic Collaborations. We expect that it could be several years, if ever, before we have a commercialized product candidate. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if, and as, we:

- · continue investing in our gene therapy platform to optimize vector engineering, manufacturing and dosing and delivery techniques;
- continue to advance our clinical candidate, VY-AADC, as a treatment for Parkinson's disease through the ongoing Phase 1b clinical trial and into our RESTORE-1 Phase 2 clinical trial;
- · initiate additional preclinical studies and clinical trials for, and continue research and development of, our other programs;
- conduct joint research and development under our Strategic Collaborations for the research, development, and commercialization of certain of our pipeline programs;
- continue our process research and development activities, as well as establish our research-grade and commercial manufacturing capabilities;
- · identify additional neurological diseases for treatment with our AAV gene therapies and develop additional programs or product candidates;
- · work to identify and optimize novel AAV capsids;
- · develop, obtain and maintain regulatory clearances for devices to deliver our AAV gene therapies;
- · seek marketing and regulatory approvals for VY-AADC or other product candidates or devices that arise from our programs that successfully complete clinical development;
- · maintain, expand, protect and enforce our intellectual property portfolio;
- · identify, acquire or in-license other product candidates and technologies;

- develop a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- expand our operational, financial and management systems and personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- increase our product liability and clinical trial insurance coverage as we expand our clinical trials and commercialization efforts; and
- · continue to operate as a public company.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses will increase if:

- · we are required by the U.S. Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA, or other regulatory agencies to perform trials or studies in addition to those currently expected;
- · there are any delays in receipt of regulatory clearance to begin our planned clinical programs or to use companion devices required in such clinical programs; or
- there are any delays in enrollment of patients in or completing our clinical trials or the development of our product candidates.

To become and remain profitable, we must develop and eventually commercialize, alone or with our collaborators, product candidates with significant market potential, which will require us to be successful in a range of challenging activities. These activities can include completing preclinical studies and clinical trials of our product candidates; obtaining marketing approval for these product candidates; developing and obtaining marketing approval of any required companion devices; manufacturing at clinical and commercial scale; marketing and selling those products that are approved; satisfying any post-marketing requirements and achieving an adequate level of market acceptance of and obtaining and maintaining adequate coverage and reimbursement from third-party payors for such products; and protecting our rights to our intellectual property portfolio. We may never succeed in any or all of these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause our stockholders to lose all or part of their investment.

We may not be able to generate sufficient revenue from the commercialization of our product candidates and may never be profitable.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with our collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our current and future product candidates. Our lead product candidate VY-AADC is being evaluated in a Phase 1b clinical trial, and we are randomizing patients in our RESTORE-1 Phase 2 clinical trial. We do not anticipate generating revenues from product sales for the next several years, and we may never succeed in doing so. Our ability to generate future revenues from product sales depends heavily on our and our collaborators' success in:

· completing preclinical and clinical development of our product candidates and any required companion devices and identifying new product candidates;

- seeking and obtaining regulatory and marketing approvals for product candidates for which we complete clinical trials:
- launching and commercializing product candidates for which we obtain regulatory and marketing approval by establishing a sales force, marketing and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- obtaining and maintaining adequate coverage and reimbursement by government and third-party payors for our product candidates if and when approved;
- · maintaining and enhancing a sustainable, scalable, reproducible and transferable manufacturing process for our vectors and product candidates;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide
  adequate products and services, in both amount and quality, to support clinical development and the market
  demand for our product candidates, if and when approved;
- · obtaining an adequate level of market acceptance of our product candidates as a viable treatment option;
- · addressing any competing technological and market developments;
- · implementing additional internal systems and infrastructure, as needed;
- · negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- obtaining, maintaining, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- · avoiding and defending against third-party claims of interference or infringement; and
- · attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, EMA, or other regulatory authorities to perform preclinical studies and clinical trials in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development efforts or other operations.

We expect our expenses to increase in connection with our ongoing and planned activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant expenses related to product sales, medical affairs, marketing, manufacturing and distribution. Since the completion of our IPO on November 16, 2015, we have also incurred costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital or enter into business development transactions when needed or on

acceptable terms, we could be forced to delay, reduce or eliminate certain of our research and development programs or any future commercialization efforts.

Our operations have consumed significant amounts of cash since inception. As of December 31, 2018, our cash, cash equivalents, and marketable debt securities were \$155.8 million. Based upon our current operating plan, we expect that our existing cash, cash equivalents, and marketable debt securities, as well as amounts expected from the upfront payment and expected reimbursement of development costs from the Neurocrine Collaboration Agreement and the upfront payment from the AbbVie Alpha-Synuclein Collaboration Agreement entered into in 2019, will enable us to fund our operating expenses and capital expenditure requirements into mid-2022.

Our future capital requirements will depend on many factors, including:

- the scope, progress, results, and costs of product discovery, preclinical studies and clinical trials for our product candidates and any required companion devices;
- · the scope, progress, results, costs, prioritization, and number of our research and development programs;
- the progress and status of our Strategic Collaborations including any research and development costs for which
  we are responsible, the potential exercise by our collaboration partners of options to develop or license certain
  products and product candidates, and our potential receipt of future milestone payments and royalties from our
  collaboration partners;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, preclinical development and clinical trial costs, or the achievement of milestones or occurrence of other developments that trigger payments, under any other collaboration agreement to which we might become a party;
- the costs, timing and outcome of regulatory review of our product candidates;
- · our ability to establish and maintain collaboration, distribution, or other marketing arrangements for our product candidates on favorable terms, if at all;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies or acquire or invest in other businesses, such as our investment in MRI Interventions, Inc., or MRIC;
- the costs related to evaluating possible alternative devices that may be useful in the delivery of our product candidates, including our ongoing development of V-TAG;
- · the costs of securing manufacturing arrangements for pre-commercial and commercial production;
- the level of product sales from any product candidates for which we obtain marketing approval in the future;
   and
- the costs of establishing or contracting for sales, manufacturing, marketing, distribution, and other commercialization capabilities if we obtain regulatory approvals to market our product candidates.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive, and uncertain process that takes years to complete. We may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our product revenues, if any, and any commercial milestones or royalty payments

under our collaboration agreements, will be derived from sales of products that may not be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing and business development to achieve our business objectives. Adequate additional financing or business development transactions may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

# Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate product revenues sufficient to achieve profitability, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and licensing arrangements. We do not have any committed external source of funds other than the amounts we are entitled to receive from our collaboration partners for potential option exercises, the achievement of specified regulatory and commercial milestones, and royalty payments under our collaboration agreements. To the extent that we raise additional capital through the sale of equity or equity-linked securities, including convertible debt, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights as holders of our common stock. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, obtaining additional capital, acquiring or divesting businesses, making capital expenditures or declaring dividends. Our issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our common stock to decline. Further, our existing stockholders may not agree with the terms of such financings.

If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves. Such collaborations, alliances, or licensing arrangements could therefore cause the market price of common stock to decline.

# Our limited operating history may make it difficult for our stockholders to evaluate the success of our business to date and to assess our future viability.

We are an early-stage company. Our operations to date have been limited to building our team, business planning, raising capital, establishing our intellectual property portfolio, determining which neurological diseases to pursue, advancing our product candidates including delivery and manufacturing and conducting preclinical studies and clinical trials. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. To achieve our current goals, we will need to transition in the future from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, our stockholders should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

# Risks Related to the Development and Regulatory Approval of Our Product Candidates

Our AAV gene therapy product candidates are based on a relatively novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all. Only one AAV gene therapy product has been approved in the United States. In Europe, only two AAV gene therapy products have been approved.

We have concentrated our research and development efforts to date on our gene therapy platform, identifying our initial targeted disease indications, and our initial product candidates. Our future success depends on our successful development of viable AAV gene therapy product candidates. Currently, only one of our product candidates, VY-AADC, is in clinical development, and the remainder of our product candidates are in preclinical development. We cannot accurately predict when or if any of our product candidates will prove effective or safe in humans or whether these product candidates will receive marketing approval. There can be no assurance that we will not experience problems or delays in developing our product candidates and that such problems or delays will not cause unanticipated costs, or that any such development problems can be solved. We also may experience unanticipated problems or delays in expanding our manufacturing capacity.

The clinical trial requirements of the FDA, the EMA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the product candidate. The regulatory approval process for novel product candidates such as gene therapies can be more expensive and take longer than for other, better known or more extensively studied product candidates. Until August 2017, the FDA had never approved a gene therapy product. Since that time, it has approved Luxturna, an AAV gene therapy product by Spark Therapeutics, Inc., or Spark, for patients with an inherited form of vision loss. The FDA has also approved two other non-AAV gene therapy products, Kymriah by Novartis International AG, for pediatric and young adult patients with a form of acute lymphoblastic leukemia and Yescarta by Kite Pharma, Inc., for adult patients with certain forms of non-Hodgkin lymphoma. In Europe, two AAV gene therapy products, Glybera by uniQure N.V., or uniQure, and Luxturna by Spark Therapeutics, Inc., or Spark, have been granted marketing authorization; however, uniQure decided not to pursue renewal of such authorization in 2017 and has since withdrawn Glybera from the European market. The European Commission also approved two other non-AAV gene therapy products, Kymriah by Novartis International AG, and Yescarta by Kite Pharma, Inc.

It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in either the United States or the European Union or how long it will take to commercialize our product candidates. The few regulatory approvals to date may not be indicative of what the FDA, European Commission, or other regulatory authorities may require for approval or whether different or additional preclinical studies or clinical trials may be required to support regulatory approval in a particular jurisdiction. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product candidate to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects may be harmed.

Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. Such requirements may lengthen the regulatory requirements review process, require us to perform additional studies, and increase our development costs or may force us to delay, limit, or terminate certain of our programs.

The Center for Biologics Evaluation and Research, or CBER, of the FDA regulates biological products for human use. The Office of Tissues and Advanced Therapies, or OTAT, formerly known as the Office of Cellular, Tissue and Gene Therapies, within CBER reviews gene therapy and related products and has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER in its review.

NIH-funded institutions need to have their institutional biosafety committee, or IBC, as well as their institutional review board, or IRB, review proposed clinical trials to assess the safety of the trial. The Phase 1b clinical trial of VY-AADC and the separate Phase 1 trial exploring the delivery of VY-AADC using a posterior trajectory are being conducted at the University of California San Francisco, or UCSF, and University of Pittsburgh Medical Center, or

UPMC. and two other sites and therefore are subject to oversight by these authorities. Such trials will need to be re-reviewed by the respective institutional IRBs if the protocol for the trial is further amended. For any new clinical trial protocols, including those of our RESTORE-1 Phase 2 clinical trial, the same processes and issues apply.

Adverse developments in clinical trials of gene therapy products conducted by us or others may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. Similarly, EMA and local health authorities of individual countries within the European Union may issue new guidelines concerning the clinical development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. The EMA and agencies at both the federal and state level in the United States have expressed an interest in further regulating new biotechnologies, including gene therapy. In addition, gene therapy products are considered genetically-modified organism, or GMO, products and are regulated as such in each country. Designation of the type of GMO product and subsequent handling and disposal requirements can vary across countries and is variable throughout the EU. Addressing each specific country requirement and obtaining approval to commence a clinical trial in these countries could result in delays in starting, conducting, or completing a clinical trial. Similar issues could be faced in other regions of the world including the Asia-Pacific region.

These regulatory review committees and advisory groups and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory and advisory groups, and comply with applicable guidelines. We have requested feedback from the FDA on among other matters, the regulatory pathway for VY-AADC and design of our proposed pivotal program, including a randomized, placebo-controlled RESTORE-1 Phase 2 clinical trial and, if required, a randomized, placebo-controlled RESTORE-2 Phase 3 clinical trial. We had multiple interactions with the FDA throughout 2018 and received certain written feedback requiring additional clarification. In December 2018, we held a Type B meeting with the FDA to discuss the overall development and pivotal program for VY-AADC. Based on the meeting discussion and subsequent written feedback from the FDA, we plan to submit a revised trial protocol that will include an increase in the target number of patients in the RESTORE-1 Phase 2 trial, resulting in 75 to 100 total patients in the trial, and to conduct, in staggered-parallel, the RESTORE-2 Phase 3 trial of similar size and design to RESTORE-1. These updates incorporate guidance from the FDA from the Type B meeting to conduct two adequate and well-controlled clinical trials for a large patient population such as Parkinson's disease. We plan to continue to seek and incorporate FDA guidance in our ongoing development plans. If we fail to consult or solicit guidance from regulators, we may be required to delay or discontinue development of certain of our product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of increased or lengthier regulatory approval process and further restrictions on development of our product candidates can be costly and could negatively impact our or our collaborators' ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

# Results from preclinical studies and early-stage clinical trials may not be indicative of efficacy in late-stage clinical trials.

All of our product candidates are in early stages of development. Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later stage clinical trials, interim results of a clinical trial do not necessarily predict final results and results from one completed clinical trial may not be replicated in a subsequent clinical trial with a similar study design. Some of our clinical trials, including our Phase 1 clinical trials and our Phase 1b clinical trial for VY-AADC, were conducted with small patient populations and were not blinded or placebo-controlled, making it difficult to predict whether the favorable results that we observed in such trials will be repeated in larger and more advanced clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage clinical trials. If a larger population of patients does not experience positive results, if these results are not reproducible, or if our products show diminishing activity over time, our products may not receive approval from the EMA or the FDA. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may encounter regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of product development. Failure to confirm favorable results from earlier trials by demonstrating the safety and effectiveness of our products in late-stage clinical trials with larger patient populations could harm our business and we may never succeed in commercialization or generating product revenue.

The doses and coverage of the putamen being employed in the ongoing VY-AADC Phase 1b clinical trial and the RESTORE-1 Phase 2 clinical trial are higher than those used in prior trials and may need to be further optimized or we may not generate sufficient clinical data in a placebo-controlled trial to achieve market authorization. Further, any favorable results which we obtain from our Phase 1b clinical trial might not be replicated in subsequent trials.

The clinical trial results of some of our collaborators have been negatively affected by factors that had not been fully anticipated prior to the examination of the trial results. For example, the magnitude of some of the clinical responses seen in the Phase 1 clinical trial of AAV2-AADC conducted by UCSF were similar to placebo effects observed in previous surgical therapies for Parkinson's disease. As a result, we are unable to rely on the results of this Phase 1 trial for an indication of the efficacy of treatment with VY-AADC. We believe that there is a need to optimize the dose and volume of infusion of VY-AADC to substantially increase the coverage of the putamen, the region of the brain targeted by VY-AADC, to achieve a clinical benefit. However, we can provide no assurances that we will be able to optimize these parameters and thereby achieve sufficient coverage of the putamen to achieve a clinical benefit.

The ongoing Phase 1b clinical trial of VY-AADC incorporated several design features in an attempt to increase the area of the putamen, particularly the posterior putamen, which receives VY-AADC treatment. We employed larger infusion volumes and higher doses of VY-AADC, and we used the ClearPoint\* System to provide real-time, intra-operative, magnetic resonance imaging, or MRI, assistance to the physician surgically administering VY-AADC to the patient.

In a separate Phase 1 clinical trial, we are also exploring posterior, or back of the head, delivery of drug into the putamen, compared to a transfrontal, or top of the head, delivery approach used in Cohorts 1 through 3 of the ongoing Phase 1b clinical trial described above. A posterior approach better aligns the infusion of VY-AADC with the anatomical structure of the putamen to potentially reduce the total procedure time and increase the total coverage of the putamen. Administration of VY-AADC with this posterior approach has been well-tolerated with no reported serious adverse events, or SAEs, with most patients discharged from the hospital the day after surgery.

Due to the nature of the techniques used in the Phase 1b clinical trial and the numerous variables that can be changed, it is possible that the data generated from this trial may not provide evidence of clinical benefit. For example, physicians may use cannulas, which are small tubes, of differing lengths in the infusion procedure, or may use differing infusion speeds or infusion angles. These differences could affect the dose of VY-AADC that ultimately reaches the putamen, leading to highly variable results. Similarly, we have limited experience to date with the posterior delivery approach which is the preferred surgical route of administration for the RESTORE-1 Phase 2 clinical trial, and it may not generate outcomes that are clinically superior to those of the transfrontal approach.

For the RESTORE-1 Phase 2 clinical trial, we have selected a dose of up to  $2.5 \times 10^{12}$  vector genomes, which is defined as a maximum total bilateral dose. This dose is between the up to maximum total vector genome doses administered in Cohorts 2 and 3 from the Phase 1b trial when considering the higher volume administered with the posterior trajectory and vector produced using the baculovirus system. We have not previously evaluated this dose in a clinical trial. The dose concentration and volume we have selected for the RESTORE-1 Phase 2 clinical trial may not achieve the desired safety and efficacy in the RESTORE-1 Phase 2 randomized, controlled clinical trial.

We expect that the RESTORE-1 Phase 2 trial will enroll 75-100 patients. Movement disorder specialists will identify and screen potential patients prior to referring to a surgical site for VY-AADC administration and provide clinical and safety follow-up after VY-AADC administration.

The RESTORE-1 Phase 2 trial is a randomized, double-blind, placebo-surgery controlled trial with a planned enrollment of 75 to 100 patients who have been diagnosed with Parkinson's disease for at least four years, are not responding adequately to oral medications, and have at least three hours of OFF time during the day as measured by a validated self-reported patient diary. Patients will be randomized 1:1 to either VY-AADC or placebo surgery.

The primary efficacy endpoint of the RESTORE-1 Phase 2 trial is the mean improvement from baseline to 12 months on time without troublesome dyskinesia, or good ON time, as measured by a validated self-reported patient diary at 12 months. Secondary endpoints include diary OFF time, other motor function and quality of life measures from the United Parkinson's Disease Rating Scales (UPDRS-II,-III scores), the Parkinson's Disease Questionnaire (PDQ-39), and patient's global function as measured by the proportion of participants with improvement on the Clinical Global Impression (CGI) score. The trial will also measure non-motor symptoms from the Non-Motor Symptom Scale (NMSS), as well as safety.

Biomarker data include measurements of the coverage of the putamen, the specific region of the brain targeted with VY-AADC, and measurements of AADC enzyme expression and activity in the putamen measured by positron emission tomography (PET) using fluorodopa F-18. Changes in patients' daily doses of oral levodopa and related medications will also be recorded.

We are using a different manufacturing process for our AAV gene therapy vector in our global RESTORE-1 Phase 2 clinical trial and our planned RESTORE-2 Phase 3 clinical trial. We have begun to manufacture VY-AADC using our baculovirus/Sf9 system as opposed to manufacturing in HEK 293 cells, which were used in our Phase 1 clinical trials. We have conducted studies to demonstrate comparability between the current version and the new version. It is possible, however, that the results of our RESTORE-1 Phase 2 clinical trial and our planned RESTORE-2 Phase 3 clinical trial in Parkinson's disease may differ from the results of our Phase 1b or our Phase 1 posterior clinical trials based on VY-AADC manufactured using our baculovirus/Sf9 system.

We intend to conduct, and may in the future conduct, clinical trials for product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

To date, we have only conducted clinical trials in the United States. However, we may in the future choose to conduct, one or more of our clinical trials or include sites in current or future clinical trials outside the United States. We generally plan to conduct our later stage and pivotal clinical trials of our product candidates globally. We currently plan to include sites located in Poland in our RESTORE-1 Phase 2 clinical trial.

Although the FDA may accept data from sites or clinical trials outside the United States, acceptance of these data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials or trial sites are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials or trial sites also complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any trial or trial site outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and would delay or permanently halt our development of the applicable product candidates.

Other risks inherent in conducting international clinical trials or using international trial sites include:

- foreign regulatory requirements that could restrict or limit our ability to conduct our clinical trials;
- · administrative burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment;
- failure of enrolled patients to adhere to clinical protocols or inadequate collection and assessment of clinical data as a result of differences in healthcare services or cultural customs;
- foreign exchange fluctuations;
- · diminished or loss of protection of intellectual property in the relevant jurisdiction; and
- · political and economic risks relevant to foreign countries.

We may encounter substantial delays or difficulties in commencement, enrollment or completion of our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, which could prevent us from commercializing our current and future product candidates on a timely basis, if at all.

Before obtaining marketing approval from regulatory authorities for the sale of our current and future product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates. Clinical trials are expensive, time-consuming and their outcomes are uncertain.

We have very limited experience with clinical trials. The RESTORE-1 Phase 2 clinical trial of VY-AADC is being conducted at several locations including UCSF and UPMC. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A clinical trial failure can occur at any stage of testing. Similarly, there may be delays or difficulties in our initiation of future clinical trials. Due to the additional regulatory uncertainties associated with gene therapy products, we did not initiate our RESTORE-1 Phase 2 clinical trial for our clinical candidate, VY-AADC, as a treatment for Parkinson's disease until we met with OTAT to discuss our proposed trial design and overall development plan. While we have received OTAT's feedback, and incorporated it as appropriate in our plans, the clinical trial as designed may not achieve the prospectively defined primary clinical endpoints or provide a favorable benefit to risk ratio to support a BLA filing or approval.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics, to complete our clinical trials in a timely manner or at all pursuant to the requirements of the FDA, EMA, or other regulatory authorities. Patient enrollment and trial completion are affected by many factors including:

- · perceived risks and benefits of AAV gene therapy approaches for the treatment of neurological diseases;
- · perceived risks of the delivery procedure, such as intracranial infusion for VY-AADC;
- formulation changes to our product candidates may require us to conduct additional clinical studies to bridge our modified product candidates to earlier versions;
- · size of the patient population and process for identifying patients;
- · design of the trial protocol;
- · eligibility and exclusion criteria;

- · patients with preexisting antibodies to the gene therapy vector that preclude their participation in the trial;
- perceived risks and benefits of the product candidate under study;
- availability of competing therapies and clinical trials;
- · severity of the disease under investigation;
- availability of genetic testing for potential patients;
- · proximity and availability of clinical trial sites for prospective patients;
- lack of adequate compensation of patients;
- · ability to obtain and maintain patient consent;
- · risk that enrolled patients will drop out before completion of the trial;
- our ability to locate appropriately trained physicians to conduct such clinical trials, which may be particularly difficult for the VY-AADC RESTORE-1 Phase 2 and RESTORE-2 Phase 3 clinical trials. We have historically used, and expect to use, the ClearPoint System, which is only available at a small number of academic medical centers in the United States;
- · our ability to commercially launch V-TAG, our real-time, intra-operative, MRI-compatible device, and to train physicians to conduct clinical trials using the device;
- · willingness of patients to participate in a placebo-controlled trial;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

Further, we plan to seek marketing approvals in the United States, the European Union and other jurisdictions, which may require that we conduct clinical trials in foreign countries. Our ability to successfully initiate, enroll and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with clinical research organizations, or CROs, and physicians;
- · different standards for the conduct of clinical trials;
- absence in some countries of established groups with sufficient regulatory expertise for review of AAV gene therapy protocols;
- · our inability to locate qualified local partners or collaborators for such clinical trials; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would harm our business, financial condition, results of operations and prospects.

Other events that may prevent successful or timely completion of clinical development include:

- · delays in reaching a consensus with regulatory authorities on trial design;
- · delays in reaching agreement on acceptable terms with prospective CROs, and clinical trial sites;
- delays in opening clinical trial sites or obtaining required IRB or independent ethics committee approval at each clinical trial site;
- · imposition of a clinical hold by regulatory authorities as a result of a serious adverse event or after an inspection of our clinical trial operations or trial sites; or our decision or the requirement of regulators or institutional review boards to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- failure by us, any CROs we engage, or any other third parties to adhere to clinical trial protocols or regulatory requirements;
- failure by us, any CROs we engage, or any other third parties to perform in accordance with the FDA's good clinical practices, or GCPs, or applicable regulatory guidelines in the European Union;
- · failure by physicians to adhere to delivery protocols leading to variable results;
- · delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical sites, including delays by third parties with whom we have contracted to perform certain of those functions;
- · insufficient or inadequate supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates, including potential delays in our RESTORE-1 Phase 2 clinical trial in Parkinson's disease associated with the commercial availability of V-TAG;
- · delays in having patients complete participation in a trial or return for post-treatment follow-up;
- · clinical trial sites or patients dropping out of a trial at a rate higher than we anticipate;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data:
- · receipt of negative or inconclusive clinical trial results;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- · occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors;
- · changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; or

• the cost of clinical trials of our product candidates may be greater than we anticipate.

Any inability to successfully complete preclinical studies and clinical trials could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- · be delayed in obtaining marketing approval for our product candidates, if at all;
- · obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a Risk Evaluation and Mitigation Strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- · experience damage to our reputation.

Our product candidates or the process for administering our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences following any potential marketing approval.

In past clinical trials that were conducted by others with non-AAV gene therapy vectors, several significant side effects were caused by gene therapy treatments, including reported cases of leukemia and death. Other potential side effects could include an immunologic reaction and insertional oncogenesis, which is the process whereby the insertion of a functional gene near a gene that is important in cell growth or division results in uncontrolled cell division, which could potentially enhance the risk of malignant transformation. If our vectors demonstrate a similar adverse effect, or other adverse effects, we may be required to halt or delay further clinical development of our product candidates or withdraw the product from the market post-approval. For example, in a recently published review of patients with hepatocellular carcinomas, it was shown that a small subset contained an integrated genome sequence of wild-type AAV2 and it was suggested that AAV2 may be associated with insertional oncogenesis.

In addition to side effects caused by the product candidate, the administration process or related procedures also can cause side effects. VY-AADC and VY-HTT01 will be administered directly to the targeted areas and cells in the brain, requiring the patient to undergo brain surgery. In a previous Phase 1 clinical trial conducted by UCSF, three patients experienced hemorrhages caused by the surgical procedure for administering VY-AADC. In the RESTORE-1 Phase 2 clinical trial of VY-AADC, we are using the ClearPoint System, which has only been used in limited gene

therapy neurosurgeries to date to provide accurate placement of the cannula in the putamen, to allow for real-time, intra-operative MRI to assist the physician in visualizing the delivery of VY-AADC to the putamen and to avoid specific blood vessels during the duration of the surgical procedure, with the goal of reducing the risk of hemorrhages. One patient in the ongoing Phase 1b trial at UCSF experienced two SAEs, a pulmonary embolism, or blood clot in the lungs, and related heart arrhythmia, or irregular heartbeat, which were determined to be related to the surgical procedure and prolonged immobility, not VY-AADC. In our Phase 2 and future trials, we may use V-TAG, a proprietary real-time, intra-operative, MRI-compatible device that we are currently developing. For VY-SOD102 in the treatment for ALS, the product candidate is planned to be injected directly into the spinal cord. Limited clinical data are available for this route of administration. If other side effects were to occur in connection with the surgical procedure, or problems were encountered with the use of V-TAG, our clinical trials could be suspended or terminated.

If in the future we are unable to demonstrate that such side effects were caused by the administration process or related procedures or are unable to modify the trial protocol adequately to address such side effects, the FDA, the European Commission, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. For products that "knock down" or reduce the amount of a gene or its encoded protein, their effects on other parts of the body, or "off target" effects, could result in unforeseen toxicity. Even if we are able to demonstrate that any future SAEs are not product-related, and regulatory authorities do not order us to cease further development of our product candidates, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.

Additionally, if any of our product candidates receives marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits outweigh its risks. Such REMS may include, among other things, a medication guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners or the limitation of the use of the product to specifically trained neurosurgeons and/or certain centers. Furthermore, adverse events which were initially considered unrelated to the study treatment of the clinical trial may later be found to be caused by the study treatment. If we or others later identify undesirable side effects caused by our product candidate, several potentially significant negative consequences could result, including:

- · regulatory authorities may suspend or withdraw approvals of such product candidate;
- · regulatory authorities may require additional warnings on the label;
- · we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- · we could be sued and held liable for harm caused to patients; and
- · our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and could significantly harm our business, prospects, financial condition and results of operations.

We may be unable to obtain orphan drug designation or exclusivity for any of our product candidates for which we seek such designation. If our competitors are able to obtain orphan drug exclusivity for products that constitute the same drug and treat the same indications as our product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time. For products for which we may obtain orphan drug designation or exclusivity, we may be unable to prevent the approval or marketing authorization of other similar products based upon regulator decisions regarding product "sameness".

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, or the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug or biological product if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biological product will be recovered from sales in the United States. We have received feedback from the FDA that VY-AADC for the treatment of Parkinson's disease does not qualify for orphan disease designation because the potential for its use in earlier stages of Parkinson's disease exceeds the 200,000 patient population criteria in the United States. In the European Union, EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, orphan designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biologic product. We have received feedback from the Committee for Orphan Medicinal Products that orphan designation likely would not be granted for VY-AADC in Parkinson's disease since the Committee does not grant such status for products targeting more severe stages of a disease.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the European Commission from approving another marketing application for a product that constitutes the same drug treating the same indication for that marketing exclusivity period, except in limited circumstances. If another sponsor receives such approval before we do (regardless of our orphan drug designation), we may be precluded from receiving marketing approval for our product for the applicable exclusivity period. The applicable period is seven years in the United States and 10 years in the European Union. The exclusivity period in the United States can be extended by nine months if the BLA sponsor submits pediatric data that adequately respond to a written request from the FDA for such data. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

We believe that all of our current programs may qualify for orphan drug designation except for VY-AADC for Parkinson's disease. Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs or biological products can be approved for the same condition. In the United States, even after an orphan drug is approved, the FDA may subsequently approve another drug or biological product for the same condition if the FDA concludes that the latter drug or biological product is not the same drug or biological product or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the European Union, marketing authorization may be granted to a similar medicinal product for the same orphan indication if:

- the second applicant can establish in its application that its medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior;
- · the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or

· the holder of the marketing authorization for the original orphan medicinal product cannot supply sufficient quantities of orphan medicinal product.

Even if we seek orphan drug designation from the FDA, the European Commission or other regulatory agencies for a product candidate, there can be no assurances that the regulatory agency or agencies will grant such designation. Additionally, the designation of any of our product candidates as an orphan drug does not guarantee that any regulatory agency will ultimately approve that product candidate or prevent other products from receiving marketing authorization due to decisions of the applicable regulatory agency regarding "sameness" of the products.

On August 3, 2017, the Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's pre-existing regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

A potential breakthrough therapy designation by the FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We have sought and may in the future seek a breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug or biological product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biological product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs or biological products that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the drugs or biological products no longer meet the conditions for qualification.

A potential regenerative medicine advanced therapy designation by the FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We have sought and may in the future seek a regenerative medicine advanced therapy, or RMAT, designation for some of our product candidates. Under the 21st Century Cures Act, or the Cures Act, to be eligible to receive RMAT designation from the FDA, a product candidate must be (i) considered a "regenerative medicine therapy" as defined in the Cures Act; (ii) intended to treat, modify, reverse, or cure one or more serious or life-threatening diseases or conditions; and (iii) indicated, in preliminary clinical evidence, to have the potential to address unmet medical needs for such diseases or conditions. Gene therapies, including genetically modified cells, that lead to a durable modification of cells or tissues may meet the definition in the Cures Act of a regenerative medicine therapy.

The RMAT program is intended to facilitate efficient development and expedite review of such therapies. A new drug application or a BLA for a product candidate that has received an RMAT designation may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A product candidate that has received an RMAT designation that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval.

In June 2018, the FDA granted RMAT designation for our VY-AADC gene therapy treatment for Parkinson's disease in patients with motor fluctuations that are refractory to medical management. The designation was based on data from our Phase 1b clinical trial.

RMAT designation is within the discretion of the FDA. Accordingly, even if we believe one of our other product candidates meets the criteria for RMAT designation, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of RMAT designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, the FDA may later decide that product candidate that received RMAT designation no longer meets the conditions for designation.

Fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process and does not assure FDA approval of our product candidate.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical need for this condition, the drug sponsor may apply for FDA fast track designation. VY-AADC has been granted fast track designation by the FDA. We may seek such a designation for our other product candidates. A fast track designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. Thus, fast track products may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

Priority review designation by the FDA may not lead to a faster regulatory review or approval process and, in any event, does not assure FDA approval of our product candidate.

If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the FDA's goal to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or thereafter.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we or any current or future collaborators are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or they may not be able to commercialize our products, and our ability to generate revenue may be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, export and import, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and comparable regulatory authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations to assist us in this process.

Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive; may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. In the United States, for example, the submission fee to obtain U.S. marketing approval is more than \$2.0 million, and may be higher in the future. Changes in marketing approval policies during the development period, in or the enactment of additional statutes or regulations, or in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we, or any future collaborators, ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Accordingly, if we or any future collaborators experience delays in obtaining approval or if we or they fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

# Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory oversight.

Even if we obtain any regulatory approval for our product candidates, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storing, advertising, promoting, sampling, record-keeping and submitting safety and other post-market information. Any regulatory approvals that we receive for our product candidates also may be subject to a REMS, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the quality, safety and efficacy of the product. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. FDA guidance advises that patients treated with some types of gene therapy undergo follow-up observations for potential adverse events for as long as 15 years. The holder of an approved BLA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product

labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP, requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or such regulatory authority disagrees with the promotion, marketing or labeling of that product, the regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory authority may:

- · issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- · suspend or withdraw regulatory approval;
- · suspend any ongoing clinical trials;
- · refuse to approve a pending BLA or comparable foreign marketing application, or any supplements thereto, submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the product;
- · seize or detain the product or otherwise require the withdrawal of the product from the market;
- refuse to permit the import or export of products; or
- · refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and adversely affect our business, financial condition, results of operations and prospects.

In addition, FDA policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would harm our business, financial condition, results of operations and prospects.

We face significant competition in an environment of rapid technological change and the possibility that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may harm our business and financial condition, and our ability to successfully market or commercialize our product candidates.

The biopharmaceutical industry is characterized by intense and dynamic competition to develop new technologies and proprietary therapies. Any product candidates that we successfully develop into products and commercialize may compete with existing therapies and new therapies that may become available in the future. While we believe that our gene therapy platform, product programs, product candidates and scientific expertise in the fields of gene therapy and neuroscience provide us with competitive advantages, we face potential competition from various sources, including larger and better-funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as from academic institutions, governmental agencies and public and private research institutions.

We are aware of several companies focused on developing AAV gene therapies in various indications, including Abeona Therapeutics, Inc., Adverum Biotechnologies, Inc., Aevitas Therapeutics, Inc., Agilis Biotherapeutics, LLC (acquired by PTC Therapeutics, Inc. in 2018), Applied Genetic Technologies Corporation, Asklepios BioPharmaceutical, Inc., Audentes Therapeutics, Inc., AveXis, Inc. (acquired by Novartis in 2018), Axovant Sciences Ltd., GenSight Biologics SA, LogicBio Therapeutics, Inc., Lysogene SA, MeiraGTx Ltd., NightstaRx Ltd, Prevail Therapeutics, Inc., REGENXBio Inc., Sarepta Therapeutics, Inc., Solid Biosciences, Inc., uniQure, Pfizer, and Spark Therapeutics, Inc., as well as several companies addressing other methods for modifying genes and regulating gene expression. Any advances in gene therapy technology made by a competitor may be used to develop therapies that could compete against any of our product candidates.

We expect that VY-AADC will compete with a variety of therapies currently marketed and in development for Parkinson's disease, including DBS marketed by Medtronic plc, Abbott Laboratories (acquired from St. Jude Medical in 2017), and other medical device companies, DUOPA/Duodopa marketed by AbbVie Inc., as well as other novel, non-oral forms of levodopa in development, including Mitsubishi Tanabe Pharma's ND0612 (acquired from NeuroDerm in 2017), Acorda Therapeutics' inhaled levodopa, INBRIJA (CVT-301), and Sunovion Pharmaceuticals' sublingual apomorphine, APL-130277. Gene therapy competition for Parkinson's disease previously included AMT-090 or AAV-GDNF, but this was deprioritized by uniQure in 2016. Axovant is developing a second generation LentiVector gene therapy, AXO-Lenti-PD (previously OXB-102, licensed from Oxford Biomedica in 2018). MeiraGTx is developing AAV-GAD, acquired from Vector Neurosciences, Inc. in 2018.

We expect that our preclinical programs will compete with a variety of therapies in development, including:

- VY-SOD102 for a monogenic form of ALS will potentially compete with IONIS-SOD1R<sub>x</sub> being developed by Ionis Pharmaceuticals, Inc., or Ionis, in collaboration with Biogen Inc., or Biogen, and a gene therapy being developed by AveXis (acquired by Novartis in 2018);
- VY-FXN01 for Friedreich's ataxia will potentially compete with AAV gene therapies being developed by Pfizer and by Agilis Biotherapeutics, LLC (acquired by PTC Therapeutics, Inc. in 2018), and BMN 290 being developed by BioMarin Pharmaceutical Inc.;
- VY-HTT01 for Huntington's disease will potentially compete with IONIS-HTTR<sub>x</sub> being developed by Ionis in collaboration with F. Hoffmann-La Roche Ltd., or Roche, WVE-120101 and WVE-120102 being developed by WAVE Life Sciences in collaboration with Takeda Pharmaceuticals, a Zinc Finger Protein (ZFP) therapy being developed by Sangamo Therapeutics, Inc. in collaboration with Shire plc, and gene therapies being developed by uniQure and Spark;
- Our Tau program for tauopathies including Alzheimer's disease, PSP, and FTD will potentially compete with tau antibodies being developed by Roche Genentech Inc. in collaboration with AC Immune SA, Eli Lilly & Co., AbbVie Inc., Biogen, and several other companies, as well as an antisense oligonucleotide program being developed by Ionis in collaboration with Biogen; and

VY-NAV01 for severe, chronic pain will potentially compete with  $Na_v1.7$  inhibitors being developed by Biogen, Sunovion, Amgen, Inc., and Astellas Pharma Inc, and  $Na_v1.8$  inhibitors being developed by Vertex.

We are also aware of several companies and institutions who have developed or are developing real-time, intraoperative, MRI-compatible devices that would compete with V-TAG. Investigators in the Phase 1b, the separate Phase 1 posterior trajectory trial, and the RESTORE-1 Phase 2 clinical trial of VY-AADC, have used and are using the ClearPoint System from MRIC.

Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and other resources, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative agreements with large and established companies. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly or earlier than us or may obtain orphan drug or other marketing exclusivity, which could result in our competitors establishing a strong market position before we are able to enter the market or reducing the number of available subjects for enrollment in our clinical trials to support regulatory submissions and approvals of our product. Additionally, technologies developed or acquired by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors. These third parties also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, and registering patients for clinical trials.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize. If we are not able to compete effectively against potential competitors, our business will not grow and our financial condition and operations will be harmed.

Even if we obtain and maintain approval for our product candidates from the FDA, we may never obtain approval for our product candidates outside of the United States, which would limit our market opportunities and adversely affect our business.

Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of our product candidates outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities of foreign countries also must approve the manufacturing and marketing of the product candidates in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials or manufacturing control requirements. In many countries outside the United States, a product candidate must be separately approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. We intend to submit a marketing authorization application to EMA for approval of our product candidates in the European Union but obtaining such approval from the European Commission following the opinion of EMA is a lengthy and expensive process. Even if a product candidate is approved, the FDA or the European Commission may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and the European Union also have requirements for approval of product candidates with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals an

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Regulatory approval for any of our product candidates may be withdrawn. If we fail to comply with the regulatory requirements, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects will be harmed.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the referendum could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

The United Kingdom has a period of a maximum of two years from the date of its formal notification to negotiate the terms of its withdrawal from, and future relationship with, the European Union. If no formal withdrawal agreement is reached between the United Kingdom and the European Union, then it is expected the United Kingdom's membership of the European Union will automatically terminate two years after the submission of the notification of the United Kingdom's intention to withdraw from the European Union. Discussions between the United Kingdom and the European Union focused on finalizing withdrawal issues and transition agreements are ongoing. However, limited progress to date in these negotiations and ongoing uncertainty within the UK Government and Parliament sustains the possibility of the United Kingdom leaving the European Union on March 29, 2019 without a withdrawal agreement and associated transition period in place, which is likely to cause significant market and economic disruption.

# **Risks Related to Third Parties**

To date, all of our revenue has been derived from our collaborations with Sanofi Genzyme and AbbVie, and if any of these, our other Strategic Collaborations, or future collaboration agreements were to be terminated, our business financial condition, results of operations and prospects would be harmed.

In February 2015, we entered into the Sanofi Genzyme Collaboration Agreement to leverage our combined expertise and assets in gene therapy for neurological diseases. Under the Sanofi Genzyme Collaboration Agreement, we received an upfront commitment of approximately \$100.0 million. Pursuant to the agreement, we granted Sanofi Genzyme an exclusive option to license, develop and commercialize (i) ex-U.S. rights to our Parkinson's disease, Friedreich's ataxia and Huntington's disease programs and a future program, or the Split Territory Programs, with an incremental option to co-commercialize the product candidate from our Huntington's disease program in the United States and (ii) worldwide rights to our spinal muscular atrophy program. If Sanofi Genzyme exercises an option for a Split Territory Program, except for our Parkinson's disease program, it is required to make an option exercise payment to us. Furthermore, at the inception of the agreement, we were eligible to receive up to \$745.0 million in the aggregate upon the achievement of specified regulatory and commercial milestones, as well as tiered royalty payments based on a percentage of net sales of product candidates from the programs for which Sanofi Genzyme exercised its option, or the Optioned Programs. Our research and development activities in connection with the collaboration might not be successful. We cannot accurately predict when or if any of our product candidates will prove effective or safe in humans or whether these product candidates will receive marketing approval. There can be no assurance that we will not experience problems or delays in development problems can be solved. If Sanofi Genzyme were to elect not to exercise an option, we would have incurred significant development expenses but not receive the option exercise payment or be eligible to receive future milestone or royalty payments related to such program. For example, in October 2017, Sanofi Genzyme notified us that it had decided not to exercise its option for the ex-U.S. righ

If Sanofi Genzyme exercises one or more options, following such exercise, Sanofi Genzyme will have sole responsibility for the development and commercialization of the product candidates from such program in the applicable territory. Sanofi Genzyme will have the sole discretion to determine and direct its efforts and resources, including the ability to discontinue all efforts and resources it applies to the development and, if approval is obtained, commercialization and marketing of the product candidates covered by the Optioned Programs in the applicable territories. Sanofi Genzyme may not be effective in obtaining approvals for the product candidates developed from the Optioned Programs or in marketing, or arranging for necessary supply, manufacturing or distribution relationships for, any approved products. Furthermore, Sanofi Genzyme may change its strategic focus or pursue alternative technologies in a manner that results in reduced, delayed or no revenue to us. Sanofi Genzyme has a variety of marketed products and product candidates under collaboration with other companies, including some of our competitors, and its own corporate objectives may not be consistent with our best interests. If Sanofi Genzyme fails to develop, obtain regulatory approval for or ultimately commercialize any product candidate from the Optioned Programs in the applicable territories, or if Sanofi Genzyme terminates our collaboration, our business, financial condition, results of operations and prospects would be harmed.

In addition, any dispute or litigation proceedings we may have with Sanofi Genzyme in the future could delay development programs, create uncertainty as to ownership of or access to intellectual property rights, distract management from other business activities and generate substantial expense. Finally, we also may not be able to seek and obtain a viable, alternative collaborator to partner with for the development and commercialization of the Split Territory Programs or the Optioned Programs.

In February 2018, we entered into an exclusive collaboration and option agreement with AbbVie, which we refer to as the AbbVie Tau Collaboration Agreement, for the research, development, and commercialization of AAV gene therapy products for the treatment of diseases of the central nervous system and other neurodegenerative diseases related to defective or excess aggregation of tau protein in the human brain, including Alzheimer's disease. Under the terms of the AbbVie Tau Collaboration Agreement, we received an upfront payment of \$69.0 million and may receive option exercise payments, future development and regulatory milestone payments and royalties.

Under the AbbVie Tau Collaboration Agreement, we are obligated to use diligent efforts to conduct research and development activities, including IND-enabling and Phase 1 clinical trial activities, for which we are solely financially responsible. As described above, our research and development activities in connection with a collaboration might not be successful. The AbbVie Tau Collaboration Agreement shall automatically terminate if AbbVie decides not to exercise one or more of its options prior to the expiration of the specified periods of the collaboration. If AbbVie did not exercise one or more of its options, we would have incurred significant research and development expenses but would not receive any future option exercise, milestone payments, or royalty payments under the collaboration.

Such research and development activities shall be pursuant to plans agreed to by the parties and overseen by a joint governance committee, or JGC. Initially, we will have final decision-making authority within the JGC, subject to specified limitations. If AbbVie exercises its license option, however, AbbVie will assume final decision-making authority within the JGC. If AbbVie exercises its license option, it will also be solely responsible for all development and commercialization activities relating to compounds and products licensed pursuant to the agreement, and, at AbbVie's request, we could be required to effect a full transfer of the manufacturing process for such compound and products. Even if AbbVie does not exercise any of its options under the AbbVie Tau Collaboration Agreement, we have agreed to grant AbbVie perpetual, exclusive or non-exclusive (as the case may be), worldwide licenses to certain know-how and patent rights developed by us or jointly by us and AbbVie arising from the collaboration.

AbbVie might not be effective in administering the JGC, obtaining approvals for the product candidates arising from our collaboration, or commercializing or manufacturing the resulting products. Further, AbbVie's objectives in connection with the collaboration may not be consistent with our best interests. AbbVie could use its leadership of the JGC or intellectual property it has licensed under the AbbVie Tau Collaboration Agreement in a manner adverse to us, or it could halt, slow, or deprioritize its development and commercialization efforts under the collaboration. In any such instances, our business, financial condition, results of operations and prospects could be materially harmed.

In January 2019, we entered into the Neurocrine Collaboration Agreement for the research, development and commercialization of four programs including our Parkinson's disease program, or AADC Program, our Friedreich's ataxia program, or FA Program, and two programs to be determined by us and Neurocrine at a later date, or the

Discovery Programs. Under the terms of the agreement, we will receive an upfront payment of \$165.0 million, inclusive of \$50.0 million for 4,179,728 shares of our common stock and may receive future development and regulatory milestones and royalties. The Neurocrine Collaboration Agreement is subject to certain conditions, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and other customary closing conditions.

Under the Neurocrine Collaboration Agreement, upon the expiration or termination of applicable waiting periods and the receipt of any required approvals or clearances including antitrust clearance, we have agreed to collaborate on the conduct of four collaboration programs: the AADC Program for the treatment of Parkinson's disease, our FA Program for the treatment of Friedreich's ataxia including the development of the VY-FXN01 product candidate, and two programs Discovery Programs.

Under the terms of the Neurocrine Collaboration Agreement, subject to the rights retained by us thereunder, we have agreed to collaborate with Neurocrine on, and to grant, exclusive, royalty-bearing, non-transferable, sublicensable licenses to certain of our intellectual property rights for all human and veterinary diagnostic, prophylactic, and therapeutic uses for the research, development, and commercialization of gene therapy Collaboration Products, under (i) the AADC Program, on a worldwide basis; (ii) the FA Program, in the United States and, upon expiration of Sanofi Genzyme's option to the Friedreich's ataxia program pursuant to the Sanofi Genzyme Collaboration without exercise of such option, all countries in the world in which the Neurocrine Collaboration Agreement remained in effect with respect to the FA Program; and (iii) each Discovery Program, on a worldwide basis.

Pursuant to development plans to be agreed by the parties, which will be overseen by a joint steering committee, we have operational responsibility, subject to certain exceptions, for the conduct of each Neurocrine Program (prior to specified transition events for each program), and are required to use commercially reasonable efforts to develop the Collaboration Products. Neurocrine has agreed to be responsible for all costs incurred by us in conducting these activities for each Neurocrine Program in accordance with an agreed budget. If we breach our development responsibilities or in certain circumstances upon a change in control of us, Neurocrine has the right but not the obligation to assume the activities under such Neurocrine Program.

Upon the occurrence of specified events for each program, Neurocrine has agreed to assume responsibility for development, manufacturing and commercialization activities for such program and to pay us milestones and royalties on future net sales. For each Existing Program, we have the option to co-develop and co-commercialize such Program upon the occurrence of a specified event. Should we elect to exercise our co-development and co-commercialization option, we and Neurocrine have agreed to enter into a cost- and profit-sharing arrangement whereby we and Neurocrine agree to jointly develop and commercialize Collaboration Products for such program and share in its costs, profits and losses, and we have agreed to forfeit certain milestones and royalties on net sales in the United States during the effective period of the applicable co-development and co-commercialization agreement. As described above, our research and development activities in connection with a collaboration might not be successful. Neurocrine may terminate the collaboration agreement in its entirety or on a program-by-program or country-by-country basis by providing at least 180-day advance notice if such notice is provided prior to the first commercial sale of the Collaboration Product to which the termination applies or one-year advance notice if such notice is provided after the first commercial sale of the Collaboration Product to which the termination applies. If Neurocrine were to terminate the agreement, we would become responsible for all research and development expenses relating to the Neurocrine Programs, and would not receive any future milestone payments or royalty payments under the Neurocrine Collaboration Agreement may also be terminated if specified regulatory agencies seek to enjoin the transaction or if we are unable to obtain antitrust clearance within 180 days of the applicable antitrust filings, which would prevent us from receiving any payments from Neurocrine under the agreement.

Neurocrine might not be successful in obtaining approvals for the product candidates arising from our collaboration, or commercializing or manufacturing the resulting products. Further, Neurocrine's objectives in connection with the collaboration may not be consistent with our best interests. With respect to the rights granted to Neurocrine by us, Neurocrine could take actions that may be adverse to us, or it could halt, slow, or deprioritize its development and commercialization efforts under the collaboration. In any such instances, our business, financial condition, results of operations and prospects could be materially harmed.

In February 2019, we entered into the AbbVie Alpha-Synuclein Collaboration Agreement for the research, development, and commercialization of AAV gene therapy products directed against alpha-synuclein for indications including Parkinson's disease and other synucleinopathies. Under the terms of the AbbVie Alpha-Synuclein Collaboration Agreement, we received an upfront payment of \$65.0 million and may receive option exercise payments, future development and regulatory milestone payments and royalties.

Under the terms of the agreement, we and AbbVie have agreed to collaborate on the research and development of the specified vectorized antibody compounds, or the Research Compounds. We are obligated to conduct research activities directed to constructing one or more virus vectors that encode antibodies designated by AbbVie. We are obligated to use diligent efforts to conduct antibody engineering and other research activities to create Research Compounds and to develop product candidates containing or comprised of such Research Compounds, which we refer to as Product Candidates. We are solely responsible for the costs and expenses during the research period. During a specified portion of the Research Period, AbbVie may exercise one or more of its exclusive development options to select up to a total of four Research Compounds and their corresponding product candidates to proceed to the Development Period. As described above, our research and development activities in connection with a collaboration might not be successful. The AbbVie Alpha-Synuclein Collaboration Agreement shall automatically terminate if AbbVie decides not to exercise one or more of its options prior to the expiration of the specified periods of the collaboration. If AbbVie did not exercise one or more of its options, we would have incurred significant research and development expenses but would not receive any future option exercise, milestone payments, or royalty payments under the collaboration.

Such research and development activities shall be pursuant to plans agreed to by the parties and overseen by a JGC. Initially, we will have final decision-making authority within the JGC, subject to specified limitations. If AbbVie exercises its license option, however, AbbVie will assume final decision-making authority within the JGC. If AbbVie exercises its license option, it will also be solely responsible for all development and commercialization activities relating to compounds and products licensed pursuant to the agreement, and, at AbbVie's request, we could be required to effect a full transfer of the manufacturing process for such compound and products. Even if AbbVie does not exercise any of its options under the AbbVie Alpha-Synuclein Collaboration Agreement, we have agreed to grant AbbVie perpetual, exclusive or non-exclusive (as the case may be), worldwide licenses to certain know-how and patent rights developed by us or jointly by us and AbbVie arising from the collaboration.

AbbVie might not be effective in administering the JGC, obtaining approvals for the product candidates arising from our collaboration, or commercializing or manufacturing the resulting products. Further, AbbVie's objectives in connection with the collaboration may not be consistent with our best interests. AbbVie could use its leadership of the JGC or intellectual property it has licensed under the AbbVie Alpha-Synuclein Collaboration Agreement in a manner adverse to us, or it could halt, slow, or deprioritize its development and commercialization efforts under the collaboration. In any such instances, our business, financial condition, results of operations and prospects could be materially harmed.

We have only used the ClearPoint System to deliver our product candidates. While other devices for delivery may be used in the future, any issues with the ClearPoint System or the manufacturer of the ClearPoint System, may result in delays in the development and commercialization of certain of our product candidates, which could have an adverse impact on our business.

The surgical approach that we are using for VY-AADC is similar, in some respects, to the stereotactic approach used for DBS. One primary difference with our approach is the ability to assist the physician in visualizing the delivery of VY-AADC to the putamen using real-time, intra-operative, MRI to avoid specific blood vessels to potentially reduce the risk of hemorrhages during the surgical procedure and to maximize the coverage of the putamen.

Investigators in the Phase 1b clinical trial, the separate Phase 1 posterior trajectory trial, and the RESTORE-1 Phase 2 clinical trial for VY-AADC, have used and are using the real-time, intra-operative, MRI system called the ClearPoint System from MRIC. However, not all neurosurgical units within the United States utilize this system and may employ other neuro-navigational systems that are not compatible with real-time MRI imaging. We intend to use the ClearPoint System at certain sites in our RESTORE-1 Phase 2 clinical trial and may choose to use it in future clinical trials of VY-AADC and any other of our product candidates that are injected directly into the brain. Therefore, any

issues with the ClearPoint System, such as a finding that use of the ClearPoint System causes adverse events or a product recall, or issues with the manufacturer of the ClearPoint System, such as bankruptcy or a decision to stop production of the system due to lack of profitability, could delay the development or commercialization of certain of our product candidates, including VY-AADC, as there currently is no other manufacturer of the ClearPoint System. Outside the United States, the ClearPoint System is not widely available or utilized in neurosurgical units.

Management of MRIC, the manufacturer of the ClearPoint System, has expressed substantial doubt as to the ability of MRIC to continue as a going concern on several occasions. As of September 30, 2018, MRIC reported cash and cash equivalents of \$3.7 million and secured debt (senior and junior) totaling approximately \$3.3 million on its balance sheet. MRIC also reported a net loss of \$1.4 million and \$4.9 million for the three and nine months ended September 30, 2018.

We developed V-TAG as our own real-time, intra-operative, MRI-compatible device that can be used with other neuro-navigational systems to dose VY-AADC and for other surgical procedures. We believe that the experience we have gained from delivering VY-AADC in our clinical trials to date and our work to develop V-TAG may inform AAV gene therapy delivery for our Huntington's disease program and other projects. In July 2018, we received 510(k) regulatory clearance of V-TAG from the Center for Devices and Radiological Health of the FDA. There are additional steps needed in making this device available for use including the manufacture of the product and compliance with state and federal laws and regulations for medical devices.

We are currently exploring collaborations for V-TAG and expect to rely on third parties in the development and manufacture of the device. In May 2018, for example, we entered into a master services and supply agreement with MRIC which provides for MRIC to perform certain manufacturing, supply, development, and services as requested by us, including the supply of the ClearPoint System and cannula devices as well as to collaborate on V-TAG. Collaborations, including our collaboration with MRIC, are subject to risks similar to those described elsewhere in this "Risk Factors" section, and the corporate objectives of such current and potential future collaborators may not be consistent with our best interests. If we are unable to enter into additional collaborations or any collaborations are not successful, use of V-TAG in our clinical trials could be adversely affected, and our clinical trials, including our RESTORE-1 Phase 2 clinical trial, could be delayed.

We may seek to enter into collaborations in the future with other third parties. If we are unable to enter into such collaborations, or if these collaborations are not successful, our business could be adversely affected.

We may seek to enter into additional collaborations in the future, including sales, marketing, distribution, development, licensing, and/or broader collaboration agreements. Our likely collaborators include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, biotechnology companies, and medical device manufacturers. However, we may not be able to enter into additional collaborations on favorable terms or at all. Our ability to generate revenues from our collaborations will depend on our and our collaborators' abilities to successfully perform the functions assigned to each of us in these arrangements. In addition, our collaborators might have the ability to abandon research or development projects and terminate applicable agreements. Moreover, an unsuccessful outcome in any clinical trial for which our collaborator is responsible could be harmful to the public perception and prospects of our gene therapy platform.

Our relationship with any future collaborations may pose several risks, including the following:

- collaborators have significant discretion in determining the amount and timing of the efforts and resources that they will apply to these collaborations;
- · collaborators may not perform their obligations as expected;
- · the preclinical studies and clinical trials conducted as part of these collaborations may not be successful;

- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on preclinical study or clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay preclinical studies and clinical trials, provide insufficient funding for preclinical studies
  and clinical trials, stop a preclinical study or clinical trial or abandon a product candidate, repeat or conduct new
  preclinical studies or clinical trials or require a new formulation of a product candidate for preclinical studies or
  clinical trials;
- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates;
- collaborators could independently develop, or develop with third parties, products that compete directly or
  indirectly with our product candidates if the collaborators believe that competitive products are more likely to
  be successfully developed or can be commercialized under terms that are more economically attractive than
  ours:
- product candidates developed in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the
  preferred course of development of any product candidates, may cause delays or termination of the research,
  development or commercialization of such product candidates, may lead to additional responsibilities for us
  with respect to such product candidates or may result in litigation or arbitration, any of which would be
  time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary
  information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or
  proprietary information or expose us to potential litigation;
- · disputes may arise with respect to the ownership or inventorship of intellectual property developed pursuant to our collaborations;
- · collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- the terms of our collaboration agreement may restrict us from entering into certain relationships with other third parties, thereby limiting our options; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to the development or commercialization of product candidates in the most efficient manner, or at all. If our collaborations do not result in the successful development and commercialization of products, or if one of our collaborators terminates its agreement with us, we may not receive any future research

funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed, and we may need additional resources to develop our product candidates. Additionally, subject to its contractual obligations to us, if a collaborator of ours were to be involved in a business combination, it might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators, and the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this periodic report also apply to the activities of our collaborators.

We will face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement with any future collaborators will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of several factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our gene therapy platform. If we license rights to product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.

We have relied, and we expect to continue to rely on third parties to conduct, supervise and monitor our clinical trials, and if these third parties perform in an unsatisfactory manner, our business could be harmed.

We expect to rely on CROs and clinical trial sites to ensure our clinical trials are conducted properly and on time. We may also engage third parties such as clinical data management organizations, medical institutions and clinical investigators to conduct or assist in our clinical trials or other clinical development work. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our third-party service providers' activities. Nevertheless, we will be responsible for ensuring that each of our clinical studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards. Our reliance on these third-parties does not relieve us of our regulatory responsibilities. For example, our Phase 1b clinical trial of VY-AADC and our separate Phase 1 trial exploring the delivery of VY-AADC using a posterior trajectory were conducted at several locations, including UCSF and UPMC. We expect to conduct our RESTORE-1 Phase 2 clinical trial at over twenty clinical trial sites, including neurosurgical and neurology patient referral sites in the United States and Europe. If any locations terminate the clinical trial, we would be required to find another party to conduct any new trials. We may be unable to find a new party to conduct new trials of our product candidates or obtain clinical supply of our product candidates or AAV vectors for such trials.

We and our third-party service providers are required to comply with the FDA's GCPs for conducting, recording and reporting the results of IND-enabling studies and clinical studies to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are

protected. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites at which the FDA may determine that our clinical trials did not comply with GCPs. If we or our third-party service providers fail to comply with applicable GCPs, the clinical data generated in our future clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving any marketing applications. In addition, our future clinical trials will require a sufficient number of patients to evaluate the safety and effectiveness of our product candidates. Accordingly, if we or our third-party service providers fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process. Failure to comply can also result in fines, adverse publicity, and civil and criminal sanctions.

Our third-party service providers are not our employees, and we are therefore unable to directly monitor whether or not they devote sufficient time and resources to our clinical and nonclinical programs. These third-party service providers may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If our third-party service providers do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

# **Risks Related to Manufacturing**

Gene therapies and their companion diagnostics are novel, complex and difficult to manufacture. We could experience manufacturing problems that result in delays in the development or commercialization of our product candidates or otherwise harm our business.

The manufacture of gene therapy products is technically complex and necessitates substantial expertise and capital investment. Production difficulties caused by unforeseen events may delay the availability of material for our clinical studies. To meet the requirements of our current and planned future trials we have developed a proprietary manufacturing platform that provides a robust and scalable process for AAV production. We are using the baculovirus/Sf9 AAV production system, a technology for producing AAV gene therapy vectors at scale in insect-derived cells. The process has been successfully transferred to our contract manufacturing organizations where it is used in manufacturing clinical materials in accordance with the FDA's current good manufacturing practices, or cGMPs. We have also built an onsite, state-of-the-art process research and development facility to enable the manufacturing of high quality AAV gene therapy vectors at laboratory scale.

We presently contract with third parties for the manufacturing of our program materials. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. The use of contracted manufacturing and reliance on collaboration partners is relatively cost efficient and has eliminated the need for our direct investment in manufacturing facilities and additional staff early in development. Although we rely on contract manufacturers, we have personnel with manufacturing and quality experience to oversee our contract manufacturers.

To date, our third-party manufacturers have met our manufacturing requirements for our program materials. We expect third-party manufacturers to be capable of providing sufficient quantities of our program materials to meet anticipated clinical trial scale demands. To meet our projected needs for commercial manufacturing, third parties with whom we currently work might need to increase their scale of production or we will need to secure alternate suppliers. We believe that there are alternate sources of supply for our program materials that can satisfy our clinical and commercial requirements, although we cannot be certain that identifying and establishing relationships with such sources, if necessary, would not result in significant delay or material additional costs.

To date, our third-party manufacturers have met our quality standards for our program materials. The manufacturers of pharmaceutical products must comply with strictly enforced cGMP requirements, state and federal

regulations, as well as foreign requirements when applicable. Any failure of us or our contract manufacturing organizations to adhere to or document compliance to such regulatory requirements could lead to a delay or interruption in the availability of our program materials for clinical study. If we or our manufacturers were to fail to comply with the FDA, EMA, or other regulatory authority, it could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. Our potential future dependence upon others for the manufacture of our product candidates may also adversely affect our future profit margins and our ability to commercialize any product candidates that receive regulatory approval on a timely and competitive basis.

Biological products are inherently difficult to manufacture. Our program materials are manufactured using technically complex processes requiring specialized equipment and facilities, highly specific raw materials, cells, and reagents, and other production constraints. Our production process requires a number of highly specific raw materials, cells, and reagents with limited suppliers. Even though we aim to have backup supplies of raw materials, cells, and reagents whenever possible, we cannot be certain they will be sufficient if our primary sources are unavailable. A shortage of a critical raw material, cell line, or reagent, or a technical issue during manufacturing may lead to delays in clinical development or commercialization plans. Any changes in the manufacturing of components of the raw materials we use could result in unanticipated or unfavorable effects in our manufacturing processes, resulting in delays.

Companion diagnostic devices may be required to diagnose a genetic disease or to determine patient antibody levels to certain components in a product, and could also require a sophisticated, technically complex manufacturing processes. If we or our contract manufacturing organizations fail to manufacture such diagnostics or comply with relevant regulatory requirements or approvals, we might seek to transition such manufacturing processes to another contract manufacturing organization. We might not be able to transition such processes in a timely manner or at all, and our commercialization and development efforts could be delayed.

Delays in obtaining regulatory approval of our or our collaborators' manufacturing process and facility or disruptions in our manufacturing process may delay or disrupt our commercialization efforts. Until recently, no cGMP gene therapy manufacturing facility in the United States had received approval from the FDA for the manufacture of an approved gene therapy product.

Before we can begin to commercially manufacture our product candidates in our own facility, or the facility of a collaborator, we must obtain regulatory approval from the FDA for our manufacturing process and our collaborator's facility. A manufacturing authorization must also be obtained from the appropriate European Union regulatory authorities. Until recently, no cGMP gene therapy manufacturing facility in the United States had received approval from the FDA for the manufacture of an approved gene therapy product and, therefore, the timeframe required for us to obtain such approval is uncertain. In addition, we must pass a pre-approval inspection of our or our collaborator's manufacturing facility by the FDA and other relevant regulatory authorities before any of our product candidates can obtain marketing approval. In order to obtain approval, we will need to ensure that all of our processes, methods and equipment are compliant with cGMP, and perform extensive audits of vendors, contract laboratories and suppliers. If any of our vendors, contract laboratories or suppliers is found to be out of compliance with cGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with cGMP, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action and may not be permitted to sell any products that we may develop.

Failure to comply with ongoing regulatory requirements could cause us to suspend production or put in place costly or time-consuming remedial measures.

The regulatory authorities may, at any time, following approval of a product for sale, audit the manufacturing facilities for such product, or institute biennial inspections. If any such inspection or audit identifies a failure to comply with applicable regulations, or if a violation of product specifications or applicable regulations occurs independent of such an inspection or audit, the relevant regulatory authority may require remedial measures that may be costly or

time-consuming to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a manufacturing facility. Any such remedial measures imposed upon our third-party manufacturers or us could harm our business, financial condition, results of operations and prospects.

If our third-party manufacturers or we fail to comply with applicable cGMP regulations, FDA and foreign regulatory authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product candidate or suspension or revocation of a pre-existing approval. Such an occurrence may cause our business, financial condition, results of operations and prospects to be harmed.

Additionally, if supply from any third-party manufacturers is delayed or interrupted, there could be a significant disruption in the supply of our clinical or commercial material. We have agreements in place with our contract manufacturers pursuant to which we are collaborating on cGMP manufacturing processes and analytical methods for the manufacture of our AAV product candidates. Therefore, if we are unable to enter into an agreement with our contract manufacturers to manufacture clinical or commercial material for our product programs, or if our agreement with our contract manufacturers were terminated, we would have to find suitable alternative manufacturers. This could delay our or our collaborators' ability to conduct clinical trials or commercialize our current and future product candidates. The regulatory authorities also may require additional trials if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and could result in a delay in our desired clinical and commercial timelines.

Any contamination in the manufacturing process for our products or product candidates, shortages of raw materials, cells or reagents, or failure of any of our key suppliers to deliver necessary components could result in delays in our clinical development or marketing schedules.

Given the nature of biologics manufacturing, there is a risk of contamination. Any contamination could adversely affect our ability to produce product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage.

Some of the raw materials required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could adversely affect our development timelines and our business, financial condition, results of operations and prospects.

# Interruptions in the supply of product candidates or inventory loss may harm our operating results and financial condition.

Our product candidates are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as strict government standards for the manufacture and storage of our product candidates, subjects us to manufacturing risks. While product candidate batches released for use in clinical trials or for commercialization undergo sample testing, some defects may only be identified following product release. In addition, process deviations or unanticipated effects of approved process changes may result in these intermediate products not complying with stability requirements or specifications. Our product candidates must be stored and transported at temperatures within a certain range. If these environmental conditions deviate, our product candidates' remaining shelf-lives could be impaired or their efficacy and safety could be negatively impacted, making them no longer suitable for use.

The occurrence, or suspected occurrence, of manufacturing and distribution difficulties can lead to lost inventories and, in some cases, product recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and delays of new product launches. Any interruption in the supply of finished products or the loss thereof could hinder our ability to timely distribute our products and satisfy customer demand. Any unforeseen failure in the storage of the product or loss in supply could delay our clinical trials and, if our product candidates are approved, result in a loss of our market share and negatively affect our business, financial condition, results of operations and prospects.

# **Risks Related to Our Business Operations**

We may not be successful in our efforts to identify or discover additional product candidates and may fail to capitalize on programs or product candidates that may be a greater commercial opportunity, or for which there is a greater likelihood of success.

The success of our business depends upon our ability to identify, develop and commercialize product candidates generated through our gene therapy platform. Research programs to identify new product candidates require substantial technical, financial and human resources. Although VY-AADC is currently in clinical development and our other product candidates are in preclinical development, we may fail to identify other potential product candidates for clinical development for several reasons. For example, our research may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects, may be commercially impracticable to manufacture or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our spending on current and future research and development programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate, which could harm our business, financial condition, results of operations and prospects.

Our future success depends on our ability to retain key members of our management team, and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, technical, and scientific expertise of principal members of our management, scientific, and clinical teams including our former President and Chief Executive Officer, Steven M. Paul, M.D., who now serves as a senior advisor, director, and member of our Science and Technology Committee, and G. Andre Turenne, who joined us as President and Chief Executive Officer in July 2018. While we have entered into employment agreements or offer letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are "at will" employees. We currently do not have "key person" insurance on any of our employees. The loss of the services of one or more of our current employees might impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel is also critical to our success. There currently is a shortage of skilled individuals with substantial gene therapy experience, which is likely to continue. As a result, competition for skilled personnel, including in gene therapy research and vector manufacturing, is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms, if at all, given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for individuals with similar skill sets. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. In addition, failure to succeed in preclinical or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and could harm our business, financial condition, results of operations and prospects.

# If we are unable to manage expected growth in the scale and complexity of our operations, our performance may suffer.

If we are successful in executing our business strategy, we will need to expand our managerial, operational, financial and other systems and resources to manage our operations, continue our research and development activities and, in the longer term, build a commercial infrastructure to support commercialization of any of our product candidates that are approved for sale. We can provide no assurances that we will have sufficient resources in the future to manage all of our planned programs. Future growth would impose significant added responsibilities on members of management, may lead to significant added costs, and may divert our management and business development resources. It is likely that our management, finance, development personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and product candidates requires that we continue to develop more robust business processes and improve our systems and procedures in each of these areas and to attract and retain sufficient numbers of talented employees. We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our research, development and growth goals.

# Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the European Commission and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant impact on other sanctions.

# Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been and continue to be a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved products.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, which we refer to, collectively, as the ACA. Among the provisions of the ACA of potential importance to our business and our product candidates are the following:

 an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- · expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- · extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- · expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- · new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 unless additional congressional action is taken, and the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

With enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective January 1, 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Further, each chamber of the Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA in the future.

The Trump administration has also taken executive actions to undermine or delay implementation of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the Trump administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than \$12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

Further, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. For example, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on May 11, 2018, the Trump administration issued a plan to lower drug prices. Under this blueprint for action, the Trump administration indicated that the Department of Health and Human Services will: take steps to end the gaming of regulatory and patent processes by drug makers to unfairly protect monopolies; advance biosimilars and generics to boost price competition; evaluate the inclusion of prices in drug makers' ads to enhance price competition; speed access to and lower the cost of new drugs by clarifying policies for sharing information between insurers and drug makers; avoid excessive pricing by relying more on value-based pricing by expanding outcome-based payments in Medicare and Medicaid; work to give Part D plan sponsors more negotiation power with drug makers; examine which Medicare Part B drugs could be negotiated for a lower price by Part D plans, and improving the design of the Part B Contracts that include "gag rules" that prevent pharmacists from informing patients when they could pay less out-of-pocket by not usin

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Finally, legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as

subject us and any future collaborators to more stringent product labeling and post-marketing testing and other requirements.

Under the Cures Act and the Trump Administration's regulatory reform initiatives, the FDA's policies, regulations and guidance may be revised or revoked and that could prevent, limit or delay regulatory approval of our product candidates, which would impact our ability to generate revenue.

In December 2016, the Cures Act was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as the implementation of statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. An under-staffed FDA could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the Trump administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a "Regulatory Reform Officer" and establish a "Regulatory Reform Task Force" to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations, however it is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

We may be subject, directly or indirectly, to federal, state, and foreign healthcare laws and regulations, including fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state laws and regulations, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims act, and the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to data privacy laws by both the federal government and the states in which we conduct our business. Such laws that may constrain the business or financial arrangements and relationships through which we conduct our operations include, but are not limited to:

the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly
and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or
rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for either

the referral of an individual for, or the purchase, recommendation, leasing or furnishing of, an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. Further, the ACA amended the intent requirement of the federal Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it;

- the federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent, or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. The ACA provided and recent government cases against pharmaceutical and medical device manufacturers support the view that federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may implicate the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional
  federal criminal statutes that prohibit a person from knowingly and willfully executing or attempting to execute
  a scheme or from making false or fraudulent statements to defraud any healthcare benefit program, regardless
  of the payor (e.g., public or private);
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to HIPAA, published in January 2013, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers;
- federal transparency laws, including the federal Physician Payments Sunshine Act, which is part of the ACA, that requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to Center for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members, by the 90th day of each subsequent calendar year, and disclosure of such information is made by CMS on a publicly available website; and
- state and/or foreign law equivalents of each of the above federal laws, such as state anti-kickback and false claims laws that may apply to arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances, such as specific disease states.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational

harm, diminished profits and future earnings, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU General Data Protection Regulation, or the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR will be a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance. Compliance with the GDPR has been and will continue to be a rigorous and time-intensive process that has increased and will continue to increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we or our collaborators may be subject to fines and penalties, litigation, and reputational harm in connection with any European activities, which could adversely affect our business, prospects, financial condition and results of operations.

# Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidates that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and may face an even greater risk if we commercialize any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- · decreased demand for any product candidates that we may develop;
- · loss of revenue;
- · substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- · withdrawal of clinical trial participants;
- · the inability to commercialize any product candidates that we may develop; and

· injury to our reputation and significant negative media attention.

Although we maintain product liability insurance coverage in the amount of \$5.0 million per occurrence and \$5.0 million in the aggregate, and clinical testing liability insurance in the amount of \$10.0 million per occurrence and \$10.0 million in the aggregate, this insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

If we, our collaborators, or any third-party manufacturers engaged by us or our collaborators fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We, our collaborators, and any third-party manufacturers we engage are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the generation, handling, use, storage, treatment, manufacture, transportation and disposal of, and exposure to, hazardous materials and wastes, as well as laws and regulations relating to occupational health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biologic and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain general liability insurance and workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could harm our business, financial condition, results of operations and prospects.

Further, with respect to the operations of any current or future collaborators or third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products.

# Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the most recent global financial crisis, could result in a variety of risks to our business, including weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in the European Union, which is recovering from a severe economic crisis. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third-party payors or our collaborators. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, sabotage, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or the operations of those third parties with which we contract, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions, and could require a substantial expenditure of resources to remedy. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We could also be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in our information systems and networks, including personal information of our employees. Outside parties may attempt to penetrate our systems or those of the third parties with which we contract or to fraudulently induce our employees or employees of such third parties to disclose sensitive information to gain access to our data.

The number and complexity of these threats continue to increase over time. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become more sophisticated. Despite our efforts, the possibility of these events occurring cannot be eliminated entirely. Although we maintain cyber risk insurance for certain costs we may incur due to a cyber-related event, this insurance may not provide adequate coverage against potential liabilities. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position and the market perception of the effectiveness of our security measures could be harmed, our credibility could be damaged, and the further development and commercialization of our product candidates could be delayed.

# The Tax Cuts and Jobs Act of 2017 could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act of 2017, or TCJA, which significantly revised the Internal Revenue Code of 1986, as amended. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely), one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the TCJA. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

# We might not be able to utilize a significant portion of our net operating loss carryforwards.

As of December 31, 2018, we had both federal and state net operating loss carryforwards of \$162.9 million and \$163.8 million, respectively, which expire beginning in 2033. These net operating loss carryforwards could expire unused and be unavailable to offset our future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain how various states will respond to the newly enacted federal

tax law. If our ability to use our historical net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

# Risks Related to the Commercialization of Our Product Candidates

The affected populations for our product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates.

Our projections of the number of people who have the diseases we are seeking to treat, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are estimates based on our knowledge and understanding of these diseases. The total addressable market opportunity for our product candidates will ultimately depend upon a number of factors including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access and product pricing and reimbursement. Prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward-looking and speculative. The process we have used in developing an estimated prevalence range for the indications we are targeting has involved collating limited data from multiple sources. While we believe these sources are reliable, we have not independently verified the data. Accordingly, the prevalence estimates included in our periodic reports and other reports filed with or furnished to the SEC should be viewed with caution. Further, the data and statistical information used in such reports, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources.

The use of such data involves risks and uncertainties, and such data is subject to change based on various factors. Our estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of the diseases we seek to address. The number of patients with the diseases we are targeting in the United States, the European Union and elsewhere may turn out to be lower than expected or may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or access, all of which would harm our results of operations and our business.

If we are unable to establish sales, medical affairs and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any product revenue.

To successfully commercialize any products that may result from our clinical development programs, we will need to further develop these capabilities, either on our own or with others. The establishment and development of our own commercial team or the establishment of a contract sales force to market any products we may develop will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability.

Under our collaboration agreement with Sanofi Genzyme, Sanofi Genzyme has an exclusive option to license, develop and commercialize ex-U.S. rights to our Friedreich's ataxia program, a future program to be designated by Sanofi Genzyme and our Huntington's disease program. Additionally, we have granted Sanofi Genzyme an incremental option to co-commercialize our Huntington's disease program in the United States and to acquire worldwide rights to our spinal muscular atrophy program. If Sanofi Genzyme exercises any of these options, we would be eligible to receive specified option fees. In addition, we would be eligible to receive specified milestone payments and royalties for any product developed in such programs.

Under our collaboration and option agreement with AbbVie related to defective or excess aggregation of tau protein in the human brain, AbbVie has options to advance certain compounds into further development and to obtain an exclusive, worldwide license, with the right to sublicense, under certain of our intellectual property rights to develop and commercialize such compounds and corresponding products for all human diagnostic, prophylactic and therapeutic uses. If AbbVie exercises any of these options, we would be eligible to receive specified option fees. In addition, we would be eligible to receive specified development and regulatory milestone payments and tiered royalties on the global commercial net sales products developed under our tau collaboration.

Under our collaboration agreement with Neurocrine, Neurocrine will fund the clinical development through the readout of the RESTORE-1 Phase 2 clinical trial for VY-AADC. After the data readout of the RESTORE-1 Phase 2 trial, we have the option to either: (1) co-commercialize VY-AADC with Neurocrine in the U.S. under a 50/50 cost- and profit-sharing arrangement and receive milestones and royalties based on ex-U.S. sales, or (2) grant Neurocrine full global commercial rights in exchange for milestone payments and royalties based on global sales. Under the terms of the agreement for the FA Program, Neurocrine will fund the development through the Phase 1 clinical trial of VY-FXN01. After the data readout of the Phase 1 trial, we have the option to either: (1) co-commercialize VY-FXN01 with Neurocrine in the U.S. under a 60/40 cost- and profit-sharing arrangement, or (2) grant Neurocrine full worldwide commercial rights in exchange for milestone payments and royalties based on global sales, subject to Sanofi Genzyme's option to commercialize the FA Program in countries outside the United States. Under the terms of the agreement for the two Discovery Programs, Neurocrine will fund the development of those programs and we have the right to earn milestone payments and royalties based on global sales. Under the terms of the agreement for the two Discovery Programs, Neurocrine will fund the development of the programs and we have the right to earn milestone payments and royalties based on global sales.

Under our collaboration and option agreement with AbbVie directed against pathological species of alpha-synuclein for the potential treatment of Parkinson's disease and other synucleinopathies, AbbVie has options to advance certain compounds into further development and to obtain an exclusive, worldwide license, with the right to sublicense, under certain of our intellectual property rights to develop and commercialize such compounds and corresponding products for all human diagnostic, prophylactic and therapeutic uses. If AbbVie exercises any of these options, we would be eligible to receive specified option fees. In addition, we would be eligible to receive specified regulatory and commercial milestone payments and tiered royalties on the global commercial net sales products developed under our alpha-synuclein collaboration.

In the future, we may seek to enter into collaborations regarding other of our product candidates with other entities to utilize their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any current or future collaborators do not commit sufficient resources to commercialize our products, or we are unable to develop the necessary capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We compete with many companies that currently have extensive, experienced and well-funded medical affairs, marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. We might face unforeseen costs and expenses associated with creating an independent sales and marketing organization. Our sales personnel might also face difficulties obtaining access to physicians or being able to persuade adequate numbers of physicians to use or prescribe our products or selling our products if we lack complementary products, which could disadvantage us compared to companies with more extensive product lines. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our potential products. If any of our product candidates is approved but fails to achieve market acceptance among physicians, patients, or third-party payors, we will not be able to generate significant revenues from such product, which could harm our business, financial condition, results of operations and prospects.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.

We expect the cost of a single administration of gene therapy products, such as those we are developing, to be substantial, when and if they receive regulatory approval. We expect that coverage and reimbursement by government and private payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other

third-party payors. Coverage and reimbursement by a third-party payor may depend upon several factors, including the third-party payor's determination that use of a product is:

- · a covered benefit under its health plan;
- · safe, effective and medically necessary;
- · appropriate for the specific patient and the indication;
- convenient and easy-to-administer compared to alternative treatments;
- · cost-effective compared to alternative treatments; and
- · neither experimental nor investigational.

No uniform policy requirement for coverage and reimbursement for biopharmaceutical products exists among third-party payors. Therefore, coverage and reimbursement for such products can differ significantly from payor to payor. As a result, obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require us to provide to each different payor supporting scientific, clinical and cost-effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment including our research, development, manufacture, sales, and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement for newly approved drugs and biologics, and coverage may be m

There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. In the United States, third-party payors, including government payors such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare and Medicaid programs increasingly are used as models for how private payors and government payors develop their coverage and reimbursement policies. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products.

The CMS is responsible for determining whether a product should be approved for coverage and reimbursement under the Medicare program. It is difficult to predict what CMS will decide with respect to coverage and reimbursement for novel products such as ours, as there is no body of established practices and precedents for these types of products. Currently, no gene therapy product has been approved for coverage and reimbursement by the CMS. Moreover, reimbursement agencies in the European Union may be more conservative than CMS. For example, several cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European Union Member States. It is difficult to predict what third-party payors will decide with respect to the coverage and reimbursement for our product candidates, especially given that the cost of our product candidates is likely to be very high and pricing of such products is highly uncertain.

Outside the United States, international operations generally are subject to extensive government price controls and other market regulations, and increasing emphasis on cost-containment initiatives in the European Union, Canada and other countries may put pricing pressure on us. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable product revenues.

Moreover, increasing efforts by government and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Payors increasingly are considering new metrics as the basis for reimbursement rates, such as average sales price, or ASP, average manufacturer price, or AMP, and Actual Acquisition Cost. The existing data for reimbursement based on some of these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and CMS has begun making pharmacy National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug and device products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product

Therefore, it is difficult to project the impact of these evolving reimbursement metrics on the willingness of payors to cover candidate products that we or our partners are able to commercialize. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products such as ours.

The commercial success of any of our product candidates will depend upon its degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Ethical, social and legal concerns about gene therapy could result in additional regulations restricting or prohibiting our products. Even with the requisite approvals from the FDA in the United States, EMA in the European Union and other regulatory authorities internationally, the commercial success of our product candidates will depend, in part, on the acceptance of physicians, patients and health care payors of gene therapy products in general, and our product candidates in particular, as medically necessary, cost-effective and safe. Any product that we commercialize may not gain acceptance by physicians, patients, health care payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of gene therapy products and, in particular, our product candidates, if approved for commercial sale, will depend on several factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the potential and perceived advantages of product candidates over alternative treatments;

- the cost of treatment relative to alternative treatments;
- · the clinical indications for which the product candidate is approved by the FDA or the European Commission, or other regulatory authorities;
- · patient awareness of, and willingness to seek, genotyping;
- the willingness of physicians to prescribe new therapies;
- the willingness of physicians to undergo specialized training with respect to administration of our product candidates:
- · the willingness of the target patient population to try new therapies;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling or restrictions on the use of our products together with other medications;
- · relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- · publicity concerning our products or competing products and treatments; and
- · sufficient third-party payor coverage and reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched.

Our gene therapy approach utilizes vectors derived from viruses, which may be perceived as unsafe or may result in unforeseen adverse events. Negative public opinion and increased regulatory scrutiny of gene therapy may damage public perception of the safety of our product candidates and adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

Gene therapy remains a novel technology, with few gene therapy products approved to date in the United States and the European Union. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians who specialize in the treatment of genetic diseases targeted by our product candidates, prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. For example, earlier gene therapy trials led to several well-publicized adverse events, including cases of leukemia and death seen in other trials using non-AAV gene therapy vectors. Serious adverse events in our clinical trials, or other clinical trials involving gene therapy products or our competitors' products, even if not ultimately attributable to the relevant product candidates, and the resulting publicity, could result in increased government regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

If we obtain approval to commercialize our product candidates outside of the United States, in particular in the European Union, a variety of risks associated with international operations could harm our business.

We expect that we will be subject to additional risks in commercializing our product candidates outside the United States, including:

- different regulatory requirements for approval of drugs and biologics in foreign countries;
- · reduced or loss of protection under our intellectual property rights;
- · unexpected changes in tariffs, trade barriers and regulatory requirements;
- · economic weakness, including inflation, or political instability in particular foreign economies and markets;
- · compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- · workforce uncertainty in countries where labor unrest is more common than in the United States;
- · shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires, or from economic or political instability; and
- · greater difficulty with enforcing our contracts in jurisdictions outside of the United States.

We must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In many foreign countries, it is common for others to engage in business practices that are prohibited by U.S. laws and regulations applicable to us, including the FCPA. In addition, the FCPA presents particular challenges in the pharmaceutical industry because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Although we expect to implement policies and procedures designed to comply with these laws and policies, there can be no assurance that our employees, contractors and agents will comply with these laws and policies. If we are unable to successfully manage the challenges of international expansion and operations, our business and operating results could be harmed

# **Risks Related to Our Intellectual Property**

Our rights to develop and commercialize our product candidates are subject to, in part, the terms and conditions of licenses granted to us by others.

We are reliant upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our technology and products, including technology related to our manufacturing process and our product candidates. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. These licenses may also require us to grant back certain rights to licensors and to pay certain amounts relating to sublicensing patent and other rights under the agreement.

In some circumstances, particularly in-licenses with academic institutions, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain, enforce or defend the patents, covering technology that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If our licensors fail to maintain such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected. In certain circumstances, we have or may license technology from third parties on a non-exclusive basis. In such instances, other licensees may have the right to enforce our licensed patents in their respective fields, without our oversight or control. Those other licensees may choose to enforce our licensed patents in a way that harms our interest, for example, by advocating for claim interpretations or agreeing on invalidity positions that conflict with our positions or our interest. In addition to the foregoing, the risks associated with patent rights that we license from third parties will also apply to patent rights we own or may own in the future.

Further, in many of our license agreements we are responsible for bringing any actions against any third party for infringing on the patents we have licensed. Certain of our license agreements also require us to meet development thresholds to maintain the license, including establishing a set timeline for developing and commercializing products and minimum yearly diligence obligations in developing and commercializing the product. Certain of our license agreements contain "no challenge" clauses which preclude and prevent us from taking any action to limit or narrow the intellectual property of a licensor. In some cases these limitations extend to any intellectual property of our licensor and not just that which is licensed to us. Such constraints may limit our ability to develop or commercialize products or to expand such efforts beyond the scope of any license. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- · the sublicensing of patent and other rights under our collaborative development relationships;

- · our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship or ownership of inventions and know-how resulting from the creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

If we fail to comply with our obligations under these license agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to develop, manufacture, or market products covered by the license or may face other penalties under the agreements. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

Furthermore, the research resulting in certain of our licensed patent rights and technology was funded by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive, royalty-free license authorizing the U.S. government, or a third party on its behalf, to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The U.S. government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government, or a third party on its behalf, of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

If we are unable to obtain and maintain patent protection for our products and technology, or if the scope of the patent protection obtained is not of sufficient breadth, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our products and technology may be adversely affected.

Our success depends, in large part, on our and our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and manufacturing technology. We and our licensors have sought, and we intend to seek in the future, to protect our proprietary position by filing patent applications in the United States and abroad related to many of our technologies and product candidates that are important to our business.

The patent prosecution process is expensive, time-consuming and complex, and we may not have and may not in the future be able to file, prosecute, maintain, enforce, defend or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. For example, in some cases, the work of certain academic researchers in the gene therapy field has entered the public domain, which may compromise our ability to obtain patent protection for certain inventions related to or building upon such prior work. Consequently, we may not be able to obtain any such patents to prevent others from using our technology for, and developing and marketing competing products to treat, these indications. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. In some cases, we may be able to obtain patent protection, but such protections may expire before we commercialize the product protected by those rights, leaving us no meaningful protection for our products. In other cases, where our intellectual property is being managed by a third-party collaborator, licensee or partner, that third party may fail to act diligently in prosecuting, maintaining, defending or

enforcing our patents. Such conduct may result in the failure to maintain or obtain protections, loss of rights, loss of patent term or, in cases where a third party has acted negligently or inequitably, patents being found unenforceable.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon our ability to generate additional preclinical or clinical data that support the patentability of our proposed claims. We may not be able to generate sufficient additional data on a timely basis, or at all. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value, narrow the scope, or eliminate the enforceability of our and our licensors' patent protection.

We may not be aware of all third-party intellectual property rights potentially relating to our product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, only upon issuance or not at all. Therefore, we cannot be certain that we, or a licensor, were the first to make the inventions claimed in any owned or any licensed patents or pending patent applications, respectively, or which entity was the first to file for patent protection until such patent application publishes or issues as a patent. Databases for patents and publications, and methods for searching them, are inherently limited, so it is not practical to review and know the full scope of all issued and pending patent applications. As a result, the issuance, scope, validity, enforceability, and commercial value of our and our licensed patent rights are uncertain.

Even if the patent applications we license or may own in the future do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

In spite of a legal presumption of validity, the issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability which may be challenged in the courts and patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our intellectual property licenses with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology, resulting in termination of our access to such intellectual property, or increase our financial or other obligations to our licensors.

The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, result in loss of access, or increase what we believe to be our financial or other obligations under the relevant agreement, any of which could harm our business, financial condition, results of operations and prospects.

We may not be successful in obtaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to certain intellectual property, through licenses from third parties, to develop our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of

our business likely will depend, in part, on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical or technical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We sometimes collaborate with non-profit and academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to develop our program.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the United States Patent and Trademark Office, or USPTO, and various government patent agencies outside of the United States over the lifetime of our licensed patents and/or applications and any patent rights we may own in the future. We rely on our outside counsel or our licensing partners to pay these fees due to patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction, and may compromise the strength of other intellectual property in our portfolio. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

On February 1, 2019 the government of Venezuela, in response to certain US sanctions, began to require that foreign entities pay all official fees, including patent fees (either for pending matters or new petitions), in PETRO, a "cryptocurrency" created by the Nicolás Maduro administration in February 2018 as a way to collect U.S. dollars while avoiding American financial sanctions issued under an Executive Order of President Trump on March 19, 2018. The Executive Order banned transactions involving "any digital currency, digital coin, or digital token, that was issued by, for, or on behalf of the Government of Venezuela on or after January 9, 2018." The prohibition is applicable to any U.S. entity unless exempted by license. We do not hold such a license and therefore may not be able to secure patents in Venezuela.

## We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. Our intellectual property rights may vary from country to country and foreign protections could

be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products or methods of treatment, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, an April 2014 report from the Office of the United States Trade Representative identified a number of countries, including India and China, where challenges to the procurement and enforcement of patent rights have been reported. Several countries, including India and China, have been listed in the report every year since 1989. With Brexit, there is uncertainty associated with obtaining, defending, and enforcing intellectual property rights in the United Kingdom. International treaties and regulations promulgated as a result of this transition could impede or eliminate our ability to obtain or maintain meaningful intellectual property rights in the United Kingdom. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Issued patents covering our technology or product candidates could be found invalid or unenforceable if challenged in court. We may not be able to protect our trade secrets in court.

If one of our licensing partners or we initiate legal proceedings against a third party to enforce a patent covering our technology or one of our product candidates, the defendant could counterclaim that the patent covering such technology or product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that an individual connected with prosecution of the patent, including an inventor, an employee of the company, a collaborator or advisor, withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include pre-issuance submissions, *ex parte* re-examination, post-grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions. Some of these mechanisms may even be exploited anonymously by third parties. Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our technology or product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which the patent examiner and we or our licensing partners were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose part or, all of the patent protection on one or more of our product candidates or our supporting technology. Such a loss of patent protection could ha

In addition to the protection afforded by patents, we rely on trade secret protection, nondisclosure, and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. Some courts inside and outside the United States are less willing or unwilling to

protect trade secrets. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, collaborators, contractors, and other third parties. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

# Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may become party to, or threatened with, infringement litigation claims regarding our products and technology, including claims from competitors or from nonpracticing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Moreover, we may become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including *ex parte* re-examination, post grant review and *inter partes* review before the USPTO or foreign patent offices. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of the merit of the claim. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could adversely affect our ability to commercialize our product candidates or any other of our product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such asserted third-party U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Similar challenges exist in other jurisdictions. If we are found to infringe a third-party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third-party to continue developing, manufacturing and marketing our product candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our product candidates or force us to cease some of our business operations, which could harm our business. In addition, we may be forced to redesign our product candidates, seek new regulatory approvals, and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, reputation, financial condition, results of operations and prospects.

# Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Competitors may infringe our intellectual property rights or the intellectual property rights of our licensing partners, or we may be required to defend against claims of infringement. To counter infringement or unauthorized use claims or to defend against claims of infringement can be expensive and time consuming. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our

common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could adversely affect our ability to compete in the marketplace.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our directors, employees, consultants, and advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that these individuals do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees, consultants, advisors and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

# Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes several significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a "first-to-invent" system to a "first-inventor-to-file" system, allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first-inventor-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO has promulgated regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-inventor-to-file provisions, became effective on March 16, 2013. The Leahy-Smith Act has resulted in an increased investment in filing applications earlier, and consequently has increased the uncertainties and costs surrounding the prosecution of our patent applications, and may increase the enforcement or defense of our issued patents, all of which could harm our business, financial condition, results of operations and prospects.

The administrative tribunal created by the Leahy-Smith Act, known as the Patent Trial and Appeals Board, or PTAB, may have an impact on the operation of our business in the future. For example, the initial results of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent

claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could therefore increase the likelihood that our own licensed patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them. Moreover, if such challenges occur, we may not have the right to control the defense. In certain situations, we may be required to rely on our licensor to consider our suggestions and to defend such challenges, with the possibility that it may not do so in a way that best protects our interests.

We also may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in other contested proceedings such as opposition, derivation, reexamination, *inter partes* review, or post-grant review proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products.

The patent positions of companies engaged in the development and commercialization of biologics and pharmaceuticals are particularly uncertain as the courts address issues such as patenting genes or gene products. The most recent guidance provided under *Berkheimer v HP, Inc.* (April 19, 2018) and *Vanda Pharmaceuticals, Inc. v West-Ward Pharmaceuticals* (June 7, 2018) instruct USPTO examiners on the ramifications of the court rulings as applied to natural products and principles including all naturally occurring nucleic acids. Patents for certain of our product candidates contain claims related to specific DNA sequences that are naturally occurring and, therefore, could be the subject of future challenges made by third parties. In addition, the recent USPTO guidance could make it impossible for us to pursue similar patent claims in patent applications we may prosecute in the future.

We cannot assure you that our efforts to seek patent protection for our technology and products will not be negatively impacted by the court decisions referenced above, rulings in other cases or changes in guidance or procedures issued by the USPTO. We cannot fully predict what impact decisions from the Supreme Court's decisions in *Mayo Collaborative Services v. Prometheus Laboratories* and *Molecular Pathology v. Myriad Genetics, Inc.* or other applicable court decisions may have on the ability of life science companies to obtain or enforce patents relating to their products and technologies in the future. These decisions, the guidance issued by the USPTO and rulings in other cases or changes in USPTO guidance or procedures could have an adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Moreover, although the Supreme Court has held that isolated segments of naturally occurring DNA are not patent-eligible subject matter, certain third parties could allege that activities that we may undertake infringe other gene-related patent claims, and we may deem it necessary to defend ourselves against these claims by asserting non-infringement and/or invalidity positions, or paying to obtain a license to these claims. In any of the foregoing or in other situations involving third-party intellectual property rights, if we are unsuccessful in defending against claims of patent infringement, we could be forced to pay damages or be subjected to an injunction that would prevent us from utilizing the patented subject matter. Such outcomes could harm our business, financial condition, results of operations or prospects.

Outside the United States, other courts have also begun to address the patenting of genetic material. In August 2015, the Australian High Court ruled that isolated genes cannot be patented in Australia. The decision did not address methods of using genetic material. Any ruling of a similar scope in other countries could affect the scope of our intellectual property rights. The ambiguities and changing law in all countries as to patenting genetic material may directly affect our ability to secure and/or maintain patent protection for our products.

If we do not obtain patent term extension and data exclusivity for our product candidates, our business may be harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of our product candidates, one or more of our U.S. patents, which may cover non-gene therapy compounds, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act. The

Hatch-Waxman Act permits a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended per FDA-approved product, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Further, certain of our licenses currently or in the future may not provide us with the right to control decisions the licensor or its other licensees on Orange Book listings or patent term extension decisions under the Hatch-Waxman Act. Thus, if one of our important licensee patents is eligible for a patent term extension under the Hatch-Waxman Act, and it covers a product of another licensee in addition to our own product candidate, we may not be able to obtain that extension if the other licensee seeks and obtains that extension first. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements.

The Biologics Price Competition and Innovation Act of 2009 provides 12 years of market exclusivity for a reference biological product. We may not be able to obtain such exclusivity for our products. Moreover, the applicable time-period or the scope of patent protection afforded during any such extension could be less than we request. If we are unable to obtain patent term extension or the scope of term of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be materially reduced.

If our trademarks and trade name are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We own service mark registrations in the USPTO for the marks "VOYAGER THERAPEUTICS" and "VOYAGER THERAPEUTICS Logo" and European Community trademark registrations for the marks "V-TAG" and "VOYAGER TRAJECTORY ARRAY GUIDE." We also own pending trademark applications in the USPTO for the marks "V-TAG" and the V-TAG Logo. Our trademarks or our trade name may be challenged, infringed, circumvented or declared generic or found to infringe prior third-party marks. We may not be able to protect our rights in our trademarks or in our trade name, which we need in order to build name recognition among potential partners or customers in our markets of interest. It is possible that competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of prior registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade name. Over the long term, if we are unable to establish name recognition based on our trademarks and trade name, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce and protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights and other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

## Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and such rights may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make gene therapy products that are similar to our product candidates but that are not
  covered by the claims of the patents that we own, license or may access in the future;
- · we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- · we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- · issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- · we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- · we may choose not to file a patent for certain inventions, trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on certain third parties to manufacture all or part of our product candidates and to perform quality testing, and because we collaborate with various organizations and academic institutions for the advancement of our gene therapy platform and pipeline, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may harm our business, financial condition, results of operations and prospects.

Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets by third parties. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business, financial condition, results of operations and prospects.

## Risks Related to Ownership of Our Common Stock

Our executive officers, directors, principal stockholders and their affiliates exercise significant influence over our company.

The holdings of our executive officers, directors, principal stockholders and their affiliates, including investment funds affiliated with Third Rock Ventures, Bellevue Asset Management, Armistice Capital, UBS Switzerland, and BlackRock Institutional Trust Company, N.A., represent beneficial ownership, in the aggregate, of approximately 56% of our outstanding common stock as of December 31, 2018. As a result, these stockholders, if they

act together, will be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- · delaying, deferring or preventing a change of control of us;
- · impeding a merger, consolidation, takeover or other business combination involving us; or
- · discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

## An active trading market for our common stock may not be sustained.

Our shares of common stock began trading on the Nasdaq Global Select Market on November 11, 2015. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares.

# If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. If no or few analysts maintain coverage of us, the trading price of our stock would likely decrease. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

## Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Persons who were our stockholders prior to our initial public offering continue to hold a substantial number of shares of our common stock. If such persons sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline.

In addition, shares of common stock that are either subject to outstanding options or restricted stock units, or RSUs, or reserved for future issuance under our stock incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, and, in any event, we have filed a registration statement permitting shares of common stock issued on exercise of options or the settlement of RSUs to be freely sold in the public market. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. In addition, we have registered on a registration statement on Form S-3 that has been declared effective, the sale of up to \$250.0 million in aggregate of an indeterminate number of shares of common stock and preferred stock, an indeterminate principal amount of debt securities, and an indeterminate number of warrants. In November 2017, under such shelf registration statement, we issued and sold 5,175,000 shares of common stock to the public at an offering price of \$12.00 per share, including 675,000 shares of common stock issued upon the full exercise by the underwriter of their option to purchase additional shares, resulting in net proceeds of \$58.0 million after deducting underwriting discounts, commissions, and offering expenses payable by us. The registration statement also registers the offering, issuance, and sale of common stock having up to a maximum aggregate offering price of \$75.0 million that we may issue and sell in at-the-market offerings or negotiated transactions under a sales agreement we entered into with Cowen and Company, LLC on December 1, 2016 pursuant to a sales agreement prospectus that forms a part of the registration statement. As of February 26, 2019, \$75.0 million in shares of common stock remained eligible for sale under the sales agreement. In January 2019, we executed a stock purchase agreement to sell common stock to Neurocrine for an aggregate purchase price of approximately \$50.0 million. The sale of shares to Neurocrine is subject to customary closing conditions, including certain antitrust approvals, that have not been satisfied as of the date of this Annual Report on Form 10-K. As a result, we have not yet issued such shares to Neurocrine, but, if the applicable closing conditions are met, we expect to do so promptly.

Certain holders of our common stock have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

The price of our common stock is likely to be volatile and may fluctuate substantially. From January 1, 2018 through December 31, 2018, the sales price of our common stock ranged from a high of \$31.91 to a low of \$8.30 on the Nasdaq Global Select Market. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price at which they purchased it. The market price for our common stock may be influenced by many factors, including:

- · our success in commercializing any product candidates for which we obtain marketing approval;
- · regulatory action and results of clinical trials of our product candidates or those of our competitors;
- the success of competitive products or technologies;
- the results of clinical trials of our product candidates;
- the results of clinical trials of product candidates of our competitors;
- the commencement, termination, and success of our collaborations;
- · regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- · the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or technologies, the cost of commercializing such product candidates, and the cost of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- · variations in our financial results or those of companies that are perceived to be similar to us;
- the ability to secure third-party reimbursement for our product candidates;
- · changes in the structure of healthcare payment systems;
- · market conditions in the pharmaceutical and biotechnology sectors;
- · general economic, industry and market conditions; and
- · the other factors described in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K.

If our operating results fall below the expectations of investors or securities analysts for a given period, the price of our common stock could decline substantially. Furthermore, any fluctuations in our operating results from period

to period may, in turn, cause the price of our stock to fluctuate substantially. We believe that such comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation often has been instituted against that company. We also may face securities class-action litigation if we cannot obtain regulatory approvals for or if we otherwise fail to commercialize our product candidates. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources, which could seriously harm our business, financial condition, results of operations and prospects.

We have broad discretion in how we apply our available funds, and we may not use these funds effectively, which could affect our results of operations and cause our stock price to decline.

Our management will have broad discretion in the application of our existing cash, cash equivalents and marketable securities and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply our available funds effectively could result in financial losses that could cause the price of our common stock to decline and delay the development of our product candidates and preclinical programs. Pending their use, we may invest our available funds in a manner that does not produce income or that loses value.

We are an "emerging growth company" and a "smaller reporting company" and the reduced disclosure requirements applicable to such companies may make our common stock less attractive to investors.

For so long as we remain an "emerging growth company," or EGC, as defined in the JOBS Act, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include:

- · not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting
  Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing
  additional information about the audit and the financial statements;
- · reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these exemptions until we are no longer an EGC. We would cease to be an EGC upon the earlier of: (i) the last day of the fiscal year in which we have total annual gross revenue of \$1.07 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of our IPO, which is December 31, 2020; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or SEC, which means the first day of the year following the first year in which the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of June 30th.

We expect to continue to take advantage of some, but not all, of the available exemptions. Even after we no longer qualify as an emerging growth company, we might still qualify as a smaller reporting company, or SRC, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and may decline.

In addition, the JOBS Act provides that an EGC may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, and particularly after we are no longer an EGC or SRC, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and rules subsequently implemented by the SEC and The Nasdaq Stock Market have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time-consuming and costly. For example, these rules and regulations have made it more difficult and more expensive for us to obtain director and officer liability insurance, and we have been required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an EGC, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe, or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Provisions in our amended and restated certificate of incorporation and bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of members of the board is elected each year;
- · allow the authorized number of our directors to be changed only by resolution of our board of directors;

- · limit the manner in which stockholders can remove directors from the board:
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors:
- · require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- · limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to
  institute a stockholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a
  potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of
  directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our amended and restated certificate of incorporation or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation, provides that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. Any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to this provision of our amended and restated certificate of incorporation. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that he, she or it finds favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find this provision of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be our stockholders' sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

#### ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

## ITEM 2. PROPERTIES

Our corporate headquarters are located in Cambridge, Massachusetts. Our current leased facilities encompass approximately 74,000 square feet of office and laboratory space, located at 75 Sidney Street and 64 Sidney Street, Cambridge, Massachusetts.

## ITEM 3. LEGAL PROCEEDINGS

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, as of December 31, 2018, we were not party to any legal matters, claims, or arbitration proceedings that may have, or have had in the recent past, significant effects on our financial position or profitability. No governmental proceedings are pending or, to our knowledge, contemplated against us. We are not a party to any material proceedings in which any director, member of senior management or affiliate of ours is either a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

## ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

## **PART II**

# ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock has been traded on the Nasdaq Global Select Market under the symbol "VYGR" since November 11, 2015. Prior to this time, there was no public market for our common stock. On February 22, 2019, the last reported sale price for our common stock on the Nasdaq Global Select Market was \$13.12 per share.

## Stockholders

As of February 22, 2019, there were approximately 15 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

## **Dividends**

We have not paid any cash dividends on our common stock since inception and do not anticipate paying cash dividends in the foreseeable future.

## Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

## **Unregistered Sales of Equity Securities**

On July 16, 2018, we issued to our new President and Chief Executive Officer, G. Andre Turenne, a non-statutory stock option to purchase an aggregate of 650,000 shares of our common stock at an exercise price of \$18.03 per share. This option was granted as an inducement material to Mr. Turenne's entry into employment with us and was issued outside our existing equity compensation plans in accordance with Nasdaq Stock Market Listing Rule 5635(c)(4). We also intend to issue non-statutory stock options to purchase an aggregate of 338,750 shares of our common stock and an aggregate of 58,125 restricted stock units, or RSUs, to certain of our future executive officers who have executed employment agreements but not yet commenced employment with us. These equity awards were granted as inducements material to the respective officers' entry into their employment agreements with us and will be issued outside of our existing equity compensation plans in accordance with Nasdaq Stock Market Listing Rule 5635(c)(4) on such officers' first day of employment.

We intend to file a registration statement on a Form S-8 to register the shares of common stock underlying the stock options granted to Mr. Turenne and the stock options and RSUs granted to our future executive officers prior to the time at which the shares underlying such options become exercisable or such RSUs become settleable.

Additionally, on January 28, 2019, in connection with the Neurocrine Collaboration, we agreed to sell 4,179,728 shares of Common Stock to Neurocrine at a price of \$11.9625 per share, for an aggregate purchase price of approximately \$50.0 million. The sale of shares to Neurocrine is subject to customary closing conditions, including certain antitrust approvals, that have not been satisfied as of the date of this Annual Report on Form 10-K. As a result, we have not yet issued such shares to Neurocrine, but, if the applicable closing conditions are met, we expect to do so promptly thereafter. We expect the shares to be issued in reliance on the exemption from registration under Section 4(a)(2) of the Securities Act of 1933, as amended, for a transaction by an issuer not involving any public offering within the meaning of Section 4(a)(2) thereunder.

## Purchases of Equity Securities by the Issuer or Affiliated Purchasers

There were no repurchases of shares of common stock made during the year ended December 31, 2018.

## ITEM 6. SELECTED FINANCIAL DATA

The following financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations", the financial statements and related notes, and other financial information included in this Annual Report on Form 10-K.

We have derived the statements of operations data for the years ended December 31, 2018, 2017, and 2016, and the balance sheet data as of December 31, 2018 and 2017, from our audited financial statements included elsewhere in this Annual Report on Form 10-K. We have derived the statements of operations data for the years ended December 31, 2015 and 2014, and the balance sheet data as of December 31, 2016, 2015, and 2014, from our audited consolidated financial statements not included in this Annual Report on Form 10-K. Historical results are not necessarily indicative of the results to be expected in future periods.

|   |          |              |     | Year e         | ende  | d December 31, |      |              |    |            |
|---|----------|--------------|-----|----------------|-------|----------------|------|--------------|----|------------|
|   |          | 2018         |     | 2017           |       | 2016           |      | 2015         |    | 2014       |
|   |          | (amoi        | unt | s in thousands | s, ex | kcept share an | ıd p | er share dat | a) |            |
| Consolidated statements of                        |          |              |     |                |       |                |      |              |    |            |
| operations data:                                  |          | <b>5</b> 640 | Φ.  | 40.405         | Φ.    | 4.4.000        | ф    | 4 = 00.4     | ф  |            |
| Collaboration revenue                             | \$       | 7,619        | \$  | 10,135         | \$    | 14,220         | \$   | 17,334       | \$ | _          |
| Operating expenses:                               |          | G 4 G 0 =    |     | 60.000         |       | 10.0.10        |      |              |    | 0.000      |
| Research and development                          |          | 64,905       |     | 62,260         |       | 42,249         |      | 27,679       |    | 8,898      |
| General and administrative                        |          | 33,809       | _   | 19,738         | _     | 13,270         |      | 9,909        |    | 5,469      |
| Total operating expenses                          |          | 98,714       | _   | 81,998         |       | 55,519         | _    | 37,588       | _  | 14,367     |
| Loss from operations                              |          | (91,095)     |     | (71,863)       |       | (41,299)       |      | (20,254)     |    | (14,367)   |
| Interest income (expense), net                    |          | 3,310        |     | 1,227          |       | 976            |      | 332          |    | (1)        |
| Other (expense) income, net                       |          | (683)        | _   | (62)           |       | 182            |      | (9,750)      |    | (1,949)    |
| Loss before income taxes                          |          | (88,468)     |     | (70,698)       |       | (40,141)       |      | (29,672)     |    | (16,317)   |
| Income tax (benefit) provision                    |          | (180)        |     |                |       | 52             |      |              | _  |            |
| Net loss  | \$       | (88,288)     | \$  | (70,698)       | \$    | (40,193)       | \$   | (29,672)     | \$ | (16,317)   |
| Other comprehensive loss                          |          |              |     |                |       |                |      |              |    |            |
| Net unrealized gain (loss) on                     |          |              |     | (0.0.0)        |       |                |      | (0=4)        |    |            |
| available-for-sale-securities, net                |          | 34           | _   | (235)          | _     | 199            | _    | (251)        | _  |            |
| Comprehensive loss                                | \$       | (88,254)     | \$  | (70,933)       | \$    | (39,994)       | \$   | (29,923)     | \$ | (16,317)   |
| Reconciliation of net loss to net                 |          |              |     |                |       |                |      |              |    |            |
| loss attributable to common                       |          |              |     |                |       |                |      |              |    |            |
| stockholders:                                     |          | (00.000)     | ф   | (50.600)       | ф     | (40.400)       | ф    | (00.050)     | Φ. | (4.6.04.5) |
| Net loss  | \$       | (88,288)     | \$  | (70,698)       | \$    | (40,193)       | \$   | (29,672)     | \$ | (16,317)   |
| Accretion of preferred stock to                   |          |              |     |                |       |                |      | (7.272)      |    | (1.200)    |
| redemption value<br>Accrued dividends on series A |          | _            |     | _              |       | _              |      | (7,373)      |    | (1,366)    |
| preferred stock                                   |          |              |     |                |       |                |      | (1,245)      |    |            |
| Net loss attributable to common                   |          |              | _   |                |       | <u> </u>       | _    | (1,243)      | _  |            |
| stockholders                                      | \$       | (88,288)     | \$  | (70,698)       | \$    | (40,193)       | \$   | (38,290)     | \$ | (17,683)   |
| Net loss per share attributable to                | <u>~</u> | (00,200)     | Ψ   | (70,000)       | Ψ     | (10,155)       | Ψ    | (50,250)     | Ψ  | (17,000)   |
| common stockholders—basic and                     |          |              |     |                |       |                |      |              |    |            |
| diluted <sup>(1)</sup>                            | \$       | (2.75)       | \$  | (2.64)         | \$    | (1.59)         | \$   | (9.14)       | \$ | (27.83)    |
| Weighted average number of                        |          |              |     |                |       |                |      |              |    |            |
| common shares used in net loss per                |          |              |     |                |       |                |      |              |    |            |
| share attributable to common                      |          |              |     |                |       |                |      |              |    |            |
| stockholders—basic and diluted <sup>(1)</sup>     |          | 32,065,781   | _   | 26,803,711     |       | 25,302,414     |      | 4,191,210    |    | 635,448    |
|   |          |              |     |                |       |                |      |              |    |            |

|   |               | I             | As of 1 | December 31, |               |             |
|---|---------------|---------------|---------|--------------|---------------|-------------|
|   | 2018          | 2017          |         | 2016         | 2015          | 2014        |
|   |               |               | (in t   | housands)    |               |             |
| Consolidated balance sheet data:            |               |               | `       | ĺ            |               |             |
| Cash, cash equivalents, and marketable debt |               |               |         |              |               |             |
| securities                                  | \$<br>155,806 | \$<br>169,052 | \$      | 174,418      | \$<br>224,345 | \$<br>7,035 |
| Working capital <sup>(2)</sup>              | 130,808       | 155,893       |         | 164,984      | 171,963       | 5,884       |
| Total assets                                | 177,029       | 184,477       |         | 189,566      | 229,457       | 11,497      |
| Redeemable convertible preferred stock      | _             | _             |         | _            | _             | 21,979      |
| Common stock and additional paid-in capital | 315,630       | 295,051       |         | 225,989      | 219,147       | 1           |
| Total stockholders' equity (deficit)        | 46,446        | 134,051       |         | 135,922      | 169,074       | (20,830)    |

<sup>(1)</sup> See Statements of Operations Data and Note 2 to our financial statements for further details on the calculation of net loss per share, basic and diluted, attributable to common stockholders and the weighted-average number of shares used in the computation of the per share amounts.

# ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this report, including those set forth under Item 1A. "Risk Factors" and under "Forward-Looking Statements" in this Annual Report on Form 10-K.

We are a clinical-stage gene therapy company focused on developing life-changing treatments for patients suffering from severe neurological diseases. We focus on neurological diseases where we believe an adeno-associated virus, or AAV, gene therapy approach that either increases or decreases the production of a specific protein can slow or reduce the symptoms experienced by patients, and therefore have a clinically meaningful impact. We have built a gene therapy platform that we believe positions us to be a leading company at the intersection of AAV gene therapy and severe neurological disease. Our gene therapy platform enables us to engineer, optimize, manufacture and deliver our AAV-based gene therapies that have the potential to provide durable efficacy following a single administration.

Additionally, we are working to identify novel AAV capsids, which are the outer viral protein shells that enclose the genetic material of the virus payload. Our team of experts in the fields of AAV gene therapy and neuroscience first identifies and selects severe neurological diseases that are well-suited for treatment using AAV gene therapy. We then engineer and optimize AAV vectors for delivery of the virus payload to the targeted tissue or cells. Our manufacturing process employs an established system that we believe will enable production of high quality AAV vectors at commercial-scale. In addition to our capsid optimization efforts, we leverage novel delivery paradigms, established routes of administration, and advances in dosing techniques to optimize delivery of our AAV gene therapies to target tissues, regions and cell types that are critical to the disease of interest. We believe we can achieve this directly, with targeted infusions to discrete regions of the brain or spinal cord, or systemically, in conjunction with our novel capsids.

Our business strategy focuses on discovering, developing, manufacturing and commercializing our gene therapy programs. As part of this strategy, we have developed core competencies specific to AAV gene therapy development and manufacturing and are beginning to build our commercial infrastructure. This business strategy also includes business development activities that may include in-licensing activities or partnering certain programs in specific geographies with collaborators, as we have demonstrated through our collaborations, including those with Sanofi Genzyme

<sup>(2)</sup> We define working capital as current assets less current liabilities. See our financial statements for further details regarding our current assets and current liabilities.

Corporation, which we refer to as Sanofi Genzyme, AbbVie Biotechnology Ltd and its affiliates, which we collectively refer to as AbbVie, and Neurocrine Biosciences, Inc., which we refer to as Neurocrine. Since our inception, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio, determining which neurological diseases to pursue, advancing our product candidates including delivery and manufacturing, and conducting preclinical studies and clinical trials. We do not have any product candidates approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through private placements of redeemable convertible preferred stock, public offerings of our common stock, our collaboration with Sanofi Genzyme, or the Sanofi Genzyme Collaboration, which commenced in February 2015 and our collaboration with AbbVie focusing on tau-related disease, or the AbbVie Tau Collaboration, which commenced in February 2018. Additionally, we recently entered into collaborations with Neurocrine, or the Neurocrine Collaboration, which we expect to commence in the first half of 2019, and with AbbVie focusing on pathological species of alpha-synuclein, or the AbbVie Alpha-Synuclein Collaboration.

On November 7, 2017, we completed the sale of 5,175,000 shares of common stock to the public at an offering price of \$12.00 per share, including 675,000 shares of common stock issued upon the full exercise by the underwriters of their option to purchase additional shares, resulting in net proceeds of \$58.0 million after deducting underwriting discounts, commissions, and offering expenses payable by us.

Since inception, we have incurred significant operating losses. Our net losses were \$88.3 million, \$70.7 million, and \$40.2 million for the years ended December 31, 2018, 2017, and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of \$269.1 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we.

- continue investing in our gene therapy platform to optimize vector engineering, manufacturing and dosing and delivery techniques;
- · continue to advance our clinical candidate, VY-AADC, as a treatment for Parkinson's disease through the ongoing Phase 1b clinical trial and our RESTORE-1 Phase 2 clinical trial;
- · initiate additional preclinical studies and clinical trials for, and continue research and development of, our other programs;
- · conduct joint research and development under our strategic collaborations for the research, development, and commercialization of certain of our pipeline programs;
- continue our process research and development activities, as well as establish our research-grade and commercial manufacturing capabilities;
- · identify additional neurological diseases for treatment with our AAV gene therapies and develop additional programs or product candidates;
- · work to identify and optimize novel AAV capsids;
- · develop, obtain and maintain regulatory clearances for devices to deliver our AAV gene therapies;
- · seek marketing and regulatory approvals for VY-AADC or other product candidates or devices that arise from our programs that successfully complete clinical development;
- · maintain, expand, protect and enforce our intellectual property portfolio;
- · identify, acquire or in-license other product candidates and technologies;

- develop a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- · expand our operational, financial and management systems and personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- · increase our product liability and clinical trial insurance coverage as we expand our clinical trials and commercialization efforts; and
- · continue to operate as a public company.

## **Financial Operations Overview**

#### Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales for the foreseeable future. For the year ended December 31, 2018, we recognized \$0.7 million of collaboration revenue from the Sanofi Genzyme Collaboration and \$6.9 million of collaboration revenue from the AbbVie Tau Collaboration. For additional information about our revenue recognition policy related to the collaborations, see the section titled "—Critical Accounting Policies and Estimates—Revenue."

For the foreseeable future, we expect substantially all of our revenue will be generated from our collaboration agreements with Sanofi Genzyme, AbbVie, Neurocrine, and any other strategic relationships we may enter into. If our development efforts are successful, we may also generate revenue from product sales.

#### **Expenses**

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our program discovery efforts, and the development of our programs and gene therapy platform, which include:

- · employee-related expenses including salaries, benefits, and stock-based compensation expense;
- costs of funding research performed by third parties that conduct research and development, preclinical activities, manufacturing and production design on our behalf;
- · the cost of purchasing lab supplies and non-capital equipment used in designing, developing and manufacturing preclinical study materials;
- consultant fees;
- · facility costs including rent, depreciation and maintenance expenses; and
- · fees for maintaining licenses under our third-party licensing agreements.

Research and development costs are expensed as incurred. Costs for certain activities, such as manufacturing, preclinical studies, and clinical trials, are generally recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and collaborators.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our product candidates. This is due to the numerous risks and uncertainties associated with developing such product candidates, including the uncertainty of:

- · successful enrollment in and completion of clinical trials;
- · establishing an appropriate safety profile;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- · receipt of marketing approvals from applicable regulatory authorities;
- commercializing the product candidates, if and when approved, whether alone or in collaboration with others;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- · continued acceptable safety profiles of the products following approval; and
- · retention of key research and development personnel.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs, timing and viability associated with the development of that product candidate.

Research and development activities are central to our business model. We expect research and development costs to increase significantly for the foreseeable future as our development programs progress, including as we continue to support the ongoing Phase 1b clinical trial and the separate Phase 1 trial exploring a posterior delivery approach and continue to enroll the RESTORE-1 Phase 2 clinical trial of VY-AADC as a treatment for Parkinson's disease, and move our other product candidates into clinical trials. Additionally, we expect research and development costs associated with activities under our Strategic Collaborations to increase. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

## General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, business development, legal and human resource functions. Other significant costs include corporate facility costs not otherwise included in research and development expenses, legal fees related to patent and corporate matters and fees for accounting and consulting services.

We anticipate that our general and administrative expenses will increase in the future to support continued research and development activities, including the RESTORE-1 Phase 2 clinical trial of VY-AADC, the expanded efforts in connection with our Strategic Collaborations, and the ongoing research and development activities and initiation of clinical trials for our other product candidates. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants. We also anticipate increased expenses associated with being a public company, including costs for audit, legal, regulatory, and tax-related services, director and officer insurance premiums, business development activities, and investor relations costs.

Other Income (Expense)

Other income (expense) consists primarily of the gain (loss) on the equity securities investment in MRI Interventions.

## **Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our consolidated financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates, if any, will be reflected in the financial statements prospectively from the date of change in estimates.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies used in the preparation of our financial statements require the most significant judgments and estimates.

Revenue Recognition - ASC 606

As of December 31, 2018, our revenue was generated from the Sanofi Genzyme Collaboration and the AbbVie Tau Collaboration. We recognize revenue in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 606 *Revenue from Contracts with Customers*, or ASC 606. Effective January 1, 2018, we adopted the provisions of ASC 606 using the modified retrospective transition method. Under this method, we recorded the cumulative effect of initially applying the new standard to all contracts as of the date of adoption.

We enter into collaboration agreements which are within the scope of ASC 606, under which we license rights to certain of our product candidates and perform research and development services. The terms of these arrangements typically include payment of one or more of the following: non-refundable, upfront fees; reimbursement of research and development costs; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect consideration we are entitled to in exchange for the goods or services we transfer to the customer.

The promised goods or services in our arrangement typically consist of license rights to our intellectual property or research and development services. We provide options to additional items in the contracts, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. We evaluate the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer and are considered distinct when (i) the

customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, we consider factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on their own or whether the required expertise is readily available and whether the goods or services are integral or dependent to other goods or services in the contract.

We estimate the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration or variable consideration. At the inception of each arrangement that includes variable consideration, we evaluate the amount of potential payment and the likelihood that the payments will be received. We utilize either the most likely amount method or expected amount method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration which is included in the transaction price may be constrained, and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

Our contracts often include development and regulatory milestone payments which are assessed under the most likely amount method and constrained if it is probable that a significant revenue reversal would occur. Milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues in the period of adjustment. To date, we have not recognized any consideration related to the achievement of development, regulatory, or commercial milestone revenue resulting from any of our collaboration arrangements.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any consideration related to sales-based royalty revenue resulting from any of our collaboration arrangements.

We allocate the transaction price based on the estimated stand-alone selling price of each of the performance obligations. We must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We utilize key assumptions to determine the stand-alone selling price for service obligations, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. Additionally, in determining the standalone selling price for material rights, we utilize comparable transactions, industry standards for product development and clinical trial success probabilities and estimates of option exercise likelihood. Variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated are consistent with the amounts we would expect to receive for the satisfaction of each performance obligation.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations which consist of licenses and other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Upfront payments and fees are recorded as deferred revenue upon receipt or when due until we perform our obligations under these arrangements. Amounts are recorded as accounts receivable when our rights to consideration are unconditional.

## **Accrued Research and Development Expenses**

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We record our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

### Stock-based Compensation

We account for our stock-based compensation awards in accordance with ASC Topic 718, *Compensation—Stock Compensation*, or ASC 718. ASC 718 requires all stock-based payments to employees and directors, including grants of restricted stock and stock options, to be recognized as expense in the statements of operations based on their grant date fair values. Grants of restricted stock and stock options to other service providers, referred to as non-employees, are required to be recognized as expense in the statements of operations based on their vesting date fair values. We estimate the fair value of options granted using the Black-Scholes option pricing model. We use the fair value of our common stock to determine the fair value of restricted stock awards.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to a lack of company-specific historical and implied volatility data, we have based the estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded, blended with the most recent period of historic volatility of our common stock. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to us, including stage of product development and life science industry focus. We use the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, Share-Based Payment, to calculate the expected term for options granted to employees and directors as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For options granted to non-employees, we utilize the contractual term of the arrangement as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with

the expected term of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and do not have current plans to pay any dividends on common stock.

The fair value of each option issued to employees and directors was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

|                          | Yea    | r ended December 3 | l,     |
|--------------------------|--------|--------------------|--------|
|                          | 2018   | 2017               | 2016   |
| Risk-free interest rate  | 2.8 %  | 2.0 %              | 1.5 %  |
| Expected dividend yield  | — %    | — %                | — %    |
| Expected term (in years) | 6.0    | 6.0                | 6.0    |
| Expected volatility      | 74.4 % | 73.7 %             | 73.1 % |

The fair value of each option issued to non-employees was estimated at each vesting and reporting date using the Black-Scholes option pricing model. The reporting date fair value was determined using the following weighted-average assumptions:

|                          | As     | of December 31, |        |
|--------------------------|--------|-----------------|--------|
|                          | 2018   | 2017            | 2016   |
| Risk-free interest rate  | 2.6 %  | 2.4 %           | 2.1 %  |
| Expected dividend yield  | — %    | — %             | — %    |
| Expected term (in years) | 7.6    | 8.5             | 9.1    |
| Expected volatility      | 73.2 % | 76.2 %          | 83.3 % |

We expense the fair value of our stock-based compensation awards to employees and directors on a straight-line basis over the associated service period, which is generally the period in which the related services are received. Stock-based compensation awards to non-employees are adjusted through stock-based compensation expense at each reporting period end to reflect the current fair value of such awards and are expensed on a straight-line basis.

We record the expense for stock-based compensation awards subject to performance-based milestone vesting over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the expected satisfaction of the performance conditions as of the reporting date. Management concluded that the achievement of the performance milestone for one of the three performance-based awards had been met during 2016. Accordingly, stock-based compensation expense in the amount of \$0.3 million, \$1.4 million, and \$1.1 million was recorded in the years ended December 31, 2018, 2017, and 2016, respectively.

Stock-based compensation totaled approximately \$15.7 million, \$9.1 million, and \$6.3 million the years ended December 31, 2018, 2017, and 2016 respectively. As of December 31, 2018, we had \$0.1 million and \$26.1 million of unrecognized compensation expense related to restricted stock awards and stock option awards, respectively, which are expected to be recognized over weighted-average remaining vesting periods at the time the milestones have been met and approximately 2.78 years, respectively. We expect the impact of our stock-based compensation expense for restricted stock and stock options granted to employees, directors and other service providers to grow in future periods due to the potential increases in the value of our common stock and headcount.

## **Results of Operations**

## Comparison of the years ended December 31, 2018 and 2017:

The following table summarizes our results of operations for the years ended December 31, 2018 and 2017, respectively, together with the changes in those items in dollars:

|  |     | Year     | ended  |            |    |         |
|--|-----|----------|--------|------------|----|---------|
|  |     | Decem    | ber 31 | l,         |    |         |
|  |     | 2018     |        | 2017       |    | Change  |
|  |     |          | (in    | thousands) |    |         |
| Collaboration revenue                        | \$  | 7,619    | \$     | 10,135     | \$ | (2,516) |
| Operating expenses: Research and development |     |          |        |            |    |         |
| Research and development                     |     | 64,905   |        | 62,260     |    | 2,645   |
| General and administrative                   |     | 33,809   |        | 19,738     |    | 14,071  |
| Total operating expenses                     |     | 98,714   |        | 81,998     |    | 16,716  |
| Other income:                                |     |          |        |            |    |         |
| Interest income                              |     | 3,310    |        | 1,227      |    | 2,083   |
| Other expense                                |     | (683)    |        | (62)       |    | (621)   |
| Total other income                           |     | 2,627    |        | 1,165      |    | 1,462   |
| Loss before income taxes                     | · · | (88,468) |        | (70,698)   | -  |         |
| Income tax provision                         |     | (180)    |        | <u> </u>   |    | (180)   |
| Net loss                                     | \$  | (88,288) | \$     | (70,698)   | \$ | (180)   |

#### Collaboration Revenue

Collaboration revenue was \$7.6 million for the year ended December 31, 2018, and \$10.1 million for the year ended December 31, 2017. Collaboration revenue included amounts related to the Sanofi Genzyme Collaboration in addition to research services related to the AbbVie Tau Collaboration, which commenced in February 2018. The decrease in revenue is primarily related the recognition of amounts related to our Parkinson's program under the Sanofi Genzyme Collaboration, or the PD Option, in the year ended December 31, 2017, the adoption of ASC 606 as of January 1, 2018, which resulted in the use of a proportional performance method in 2018 as compared to the use of straight-line method in 2017, as well as changes in estimates of costs to reach proof of principle on our Huntington's disease and Friedreich's ataxia programs. These reductions were offset by revenue recognized on research services performed under the AbbVie Tau Collaboration.

We recognized \$5.5 million of revenue in the year ended December 31, 2017 related to the portion of the upfront consideration under the Sanofi Genzyme Collaboration which had been allocated to Sanofi Genzyme's rights related to the PD Option. In the year ended December 31, 2017, Sanofi Genzyme decided not to exercise the PD Option, and we recognized all amounts allocated to their option at that time. Additionally, effective January 1, 2018, we adopted the provisions of ASC 606 for revenue recognition.

## Research and Development Expense

Research and development expense increased by \$2.6 million from \$62.3 million for the year ended December 31, 2017 to \$64.9 million for the year ended December 31, 2018. The following table summarizes our research and development expenses, for the years ended December 31, 2018 and 2017:

|  |                                       | Year   | ended   |           |               |
|--|---------------------------------------|--------|---------|-----------|---------------|
|  |                                       | Decen  | iber 31 | l,        |               |
|  |                                       | 2018   |         | 2017      | Change        |
|  | · · · · · · · · · · · · · · · · · · · |        | (in t   | housands) | <u>.</u>      |
| External research and development expenses | \$                                    | 28,890 | `\$     | 33,816    | \$<br>(4,926) |
| Employee and contractor related expenses   |                                       | 26,075 |         | 20,919    | 5,156         |

| Facility, technology, and other expenses | 9,305        | 6,705        | 2,600       |
|--|--------------|--------------|-------------|
| License fees                             | 635          | 820          | (185)       |
| Total research and development expenses  | \$<br>64,905 | \$<br>62,260 | \$<br>2,645 |

The change in research and development expense for the year ended December 31, 2018 was primarily attributable to the following:

- approximately \$5.2 million for increased research and development employee compensation costs as we
  continue to increase research and development headcount to support our ongoing development of our clinical
  and pre-clinical programs and platform;
- · approximately \$2.6 million for increased facility and other costs including rent, depreciation, maintenance and other expenses due to the additional space leased;
- offset by approximately \$4.8 million for decreased costs of funding research performed by third parties that conduct research and development. This reduction includes a decrease in preclinical activities, offset by an increase in clinical and manufacturing activities; further decreased by a reduction of approximately \$0.1 million attributable to in-kind research and development services incurred by Sanofi Genzyme and provided to us under the Sanofi Genzyme Collaboration; and approximately \$0.2 million related to decreased licensing costs.

## General and Administrative Expense

General and administrative expense increased by \$14.1 million from \$19.7 million for the year ended December 31, 2017 to \$33.8 million for the year ended December 31, 2018. The change in general and administrative expense was primarily attributable to the following:

- approximately \$9.6 million for increased employee compensation costs as we increase our administrative headcount to support our growing business. The increase included the recognition of \$5.4 million of stockbased compensation related to the retirement agreement with our former Chief Executive Officer, Dr. Steven Paul:
- approximately \$2.7 million for increased legal costs for general, business development, and intellectual property support; and
- · approximately \$1.7 million for increased facility and other costs including rent, depreciation, maintenance and other expenses.

## Other Income, Net

Other income of approximately \$2.6 million and \$1.2 million was recognized in the years ended December 31, 2018 and 2017 related to interest income on marketable securities balances offset by losses on our warrants to purchase shares of common stock and our common stock investment in MRI Interventions, Inc., or MRIC. The increase in other income is largely a result of higher cash balances year over year.

## Income Tax

We recorded an income tax provision of \$0.2 million related to our alternative minimum tax, or AMT, liability resulting in an income tax payable of \$0.1 million for the year ended December 31, 2017. The payable was due to the recognition of deferred revenue related to the Sanofi Genzyme Collaboration for income tax purposes. There was no income tax payable for the year ended December 31, 2018.

## Comparison of year ended December 31, 2017 and 2016:

The following table summarizes our results of operations for the year ended December 31, 2017 and 2016, respectively, together with the changes in those items in dollars:

|           |          | enaea   |                    |   |  |
|-----------|----------|---|--------------------|---|--|
|           | Decem    | ber 31,   | ,                  |   |  |
|           | 2017     |   | 2016               |   | Change   |
| ·         |          | (in t   | housands)          |   |  |
| \$        | 10,135   | \$  | 14,220             | \$  | (4,085)  |
| ·         | <u>.</u> |   |                    |   |  |
|           | 62,260   |   | 42,249             |   | 20,011   |
|           | 19,738   |   | 13,270             |   | 6,468  |
| ' <u></u> | 81,998   |   | 55,519             |   | 26,479   |
|           |          |   |                    |   |  |
|           | 1,227    |   | 976                |   | 251  |
|           | (62)     |   | 182                |   | (244)  |
| ' <u></u> | 1,165    |   | 1,158              |   | 7  |
| '         | (70,698) |   | (40,141)           |   | (30,557)   |
|           | ` —      |   | 52                 |   | (52)   |
| \$        | (70,698) | \$  | (40,193)           | \$  | (52)   |
|           | \$       | \$ 10,135<br>62,260<br>19,738<br>81,998<br>1,227<br>(62)<br>1,165<br>(70,698) | \$ 10,135 \$ (in t | \$ 10,135 \$ 14,220<br>\$ 2,260 42,249<br>19,738 13,270<br>81,998 55,519<br>1,227 976<br>(62) 182<br>1,165 1,158<br>(70,698) (40,141)<br>52 | 2017         2016           (in thousands)         \$           \$ 10,135         \$ 14,220         \$           62,260         42,249           19,738         13,270           81,998         55,519           1,227         976           (62)         182           1,165         1,158           (70,698)         (40,141)           —         52 |

## Collaboration Revenue

Collaboration revenue was \$10.1 million for the year ended December 31, 2017, and \$14.2 million for the year ended December 31, 2016, all of which related to the Sanofi Genzyme Collaboration. In October 2017, Sanofi Genzyme decided not to exercise its option for the ex-U.S. rights to the PD Option. Therefore, in the year ended December 31, 2017, we recognized \$5.5 million of revenue related to the portion of the upfront consideration which had been allocated to the PD Option. In addition, revenue recognized during the year ended December 31, 2017 and 2016 includes amounts recognized related to consideration allocated to research and development services for various programs under the Sanofi Genzyme Collaboration. During 2017 we reassessed the estimated period of performance for each of the units of accounting and determined that the estimated period would be extended for two units of accounting. During 2016 we deprioritized the development of VY-SMN101. These adjustments were made on a prospective basis and resulted in decreases in revenue recognized by \$2.1 million and \$9.5 million, respectively, for the year ended December 31, 2017.

## Research and Development Expense

Research and development expense increased by \$20.0 million from \$42.2 million for the year ended December 31, 2016 to \$62.2 million for the year ended December 31, 2017. The following table summarizes our research and development expenses, for the year ended December 31, 2017 and 2016, respectively:

|  | Year         | ended   |           |              |
|--|--------------|---------|-----------|--------------|
|  | Decem        | ber 31  | ,         |              |
|  | 2017         |         | 2016      | Change       |
|  |              | (in the | housands) |              |
| External research and development expenses | \$<br>33,816 | \$      | 20,413    | \$<br>13,403 |
| Employee and contractor related expenses   | 20,919       |         | 15,530    | 5,389        |
| Facility, technology, and other expenses   | 6,705        |         | 4,553     | 2,152        |
| License fees                               | 820          |         | 1,753     | (933)        |
| Total research and development expenses    | \$<br>62,260 | \$      | 42,249    | \$<br>20,011 |

The change in research and development expense was primarily attributable to research and development, and included the following:

- approximately \$14.5 million for increased costs of funding research performed by third parties that conduct research and development, preclinical and clinical activities and manufacturing and production design on our behalf and increased purchases of lab supplies and non-capital equipment used in designing, developing and manufacturing preclinical study materials, and an additional expense of approximately \$1.1 million attributable to in-kind research and development services incurred by Sanofi Genzyme and provided to us under the Sanofi Genzyme Collaboration;
- · approximately \$5.4 million for increased research and development employee-related and consultant compensation costs;
- approximately \$2.2 million for increased facility and other costs including rent, depreciation, maintenance and other expenses due to the additional leased space dedicated to research and development efforts at 64 Sidney Street and 75 Sidney Street; and
- offset by approximately \$0.9 million for decreased intellectual property and license fees.

#### General and Administrative Expense

General and administrative expense increased by \$6.4 million from \$13.3 million for the year ended December 31, 2016 to \$19.7 million for the year ended December 31, 2017. The change in general and administrative expense was primarily attributable to the following:

- approximately \$3.5 million for increased employee compensation cost due to increases in headcount and stockbased compensation;
- approximately \$0.8 million for increased facility and other costs including rent, depreciation, maintenance and other expenses; and
- approximately \$2.1 million for increased legal and intellectual property expenses.

## Other Income, Net

Other income of approximately \$1.2 million was recognized in the years ended December 31, 2017 and 2016 related to interest income on marketable securities balances offset by losses on our warrants to purchase shares of common stock of MRIC.

#### Income Tax

We recorded an income tax provision of \$0.2 million related to our alternative minimum tax, or AMT, liability resulting in an income tax payable of \$0.1 million for the year ended December 31, 2016. The payable was due to the recognition of deferred revenue related to the Sanofi Genzyme Collaboration for income tax purposes. There was no income tax payable for the year ended December 31, 2017. Our overall income tax provision was offset by an income tax benefit recorded to continuing operations of \$0.1 million associated with the recognition of the corresponding income tax associated with unrealized gains included in other comprehensive income. The net tax effect resulted in an overall income tax provision recorded to continuing operations of \$0.1 million. We recorded no income tax provision (benefit) for the year ended December 31, 2017.

## **Liquidity and Capital Resources**

## Sources of Liquidity

We have funded our operations primarily through private placements of redeemable convertible preferred stock, public offerings of our common stock, the Sanofi Genzyme Collaboration which commenced in February 2015, and the AbbVie Tau Collaboration which commenced in February 2018. Additionally, in January 2019, we entered into a Collaboration and License Agreement with Neurocrine Biosciences, Inc., or the Neurocrine Collaboration, which we expect to commence in the first half of 2019, and in February 2019, we entered into a Collaboration Agreement with AbbVie Ireland Unlimited Company, or the AbbVie Alpha-Synuclein Collaboration. Under the Neurocrine Collaboration, we will receive an upfront payment of \$165.0 million, including a \$50.0 million investment through the purchase of 4,179,728 shares of our common stock in a private placement, and under the AbbVie Alpha-Synuclein Collaboration, we will receive an upfront payment of \$65.0 million.

On November 16, 2015, we closed our IPO whereby we sold 5,750,000 shares of common stock, at a public offering price of \$14.00 per share, including 750,000 shares of common stock issued upon the full exercise by the underwriters of their option to purchase additional shares, resulting in net proceeds to us of \$72.9 million after deducting underwriting discounts and commissions and offering expenses payable by us. On November 7, 2017, we sold 5,175,000 shares of common stock to the public at an offering price of \$12.00 per share, including 675,000 shares of common stock issued upon the full exercise by the underwriters of their option to purchase additional shares, resulting in net proceeds to us of \$58.0 million after deducting underwriting discounts, commissions, and offering expenses payable by us.

As of December 31, 2018, we had cash, cash equivalents, and marketable debt securities of \$155.8 million.

## Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2018, 2017, and 2016:

|  |                |       | ear ended<br>cember 31, |                |
|--|----------------|-------|-------------------------|----------------|
|  | 2018           |       | 2017                    | 2016           |
|  |                | (in t | thousands)              |                |
| Net cash (used in) provided by:                      |                | `     |                         |                |
| Operating activities                                 | \$<br>(15,887) | \$    | (61,350)                | \$<br>(42,482) |
| Investing activities                                 | 26,467         |       | (3,681)                 | 47,721         |
| Financing activities                                 | 4,749          |       | 59,920                  | 514            |
| Net increase (decrease) in cash and cash equivalents | \$<br>15,329   | \$    | (5,111)                 | \$<br>5,753    |

## Cash Flows from Operating Activities

Net cash used in operating activities was \$15.9 million during the year ended December 31, 2018 compared to \$61.4 million during the year ended December 31, 2017. The decrease in cash used for operating activities was primarily due to the receipt of \$69.0 million related to the AbbVie Tau Collaboration in 2018, offset by increases in operating expenses due to increased research and development activities, as well as higher general and administrative expenses as a result of a higher headcount, legal fees, and other costs year over year. The decrease in cash used in operating activities was also offset by an increase in prepaid expenses and other current assets as well as a decrease in accrued expenses.

Net cash used in operating activities was \$61.4 million during the year ended December 31, 2017 compared to \$42.5 million of cash used in operating activities during the year ended December 31, 2016. The increase in cash used for operating activities was primarily due to an increase in operating expenses. The increase in operating expenses is primarily due to increased research and development activities as we advance our clinical and preclinical programs, as well as higher general and administrative expenses to support the increased research and development operations.

## Cash Flows from Investing Activities

Net cash provided by investing activities was \$26.5 million during the year ended December 31, 2018. The cash provided by investing activities for the year ended December 31, 2018 was primarily due to proceeds from maturities of marketable securities of \$364.0 million offset by purchase of marketable securities of \$333.2 million and purchases of property and equipment of \$4.9 million.

Net cash used in investing activities was \$3.7 million during the year ended December 31, 2017. The cash used in investing activities for the year ended December 31, 2017 was due to purchases of property and equipment of \$4.0 million, offset by net proceeds from maturities and purchases of marketable securities of \$0.3 million.

Net cash provided by investing activities was \$47.7 million during the year ended December 31, 2016. The cash provided by investing activities for the year ended December 31, 2016 was due to proceeds from maturities of marketable securities of \$165.1 million, partially offset by purchases of marketable securities of \$112.4 million and purchases of property and equipment of \$5.0 million.

## Cash Flows from Financing Activities

Net cash provided by financing activities was \$4.7 million during the year ended December 31, 2018 related to proceeds from exercises of stock options, and purchases by our employees of our common stock under our Employee Stock Purchase Plan.

Net cash provided by financing activities was \$59.9 million during the year ended December 31, 2017 and was largely driven by the \$58.0 million of net proceeds from our sale of common stock in November 2017 and proceeds from exercises of stock options.

Net cash provided by financing activities was \$0.5 million during the year ended December 31, 2016 and consisted of proceeds from exercises of stock options.

## **Funding Requirements**

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant expenses related to program sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital or enter into business development transactions when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

Based upon our current operating plan, we expect that our existing cash, cash equivalents, and marketable debt securities, as well as amounts expected from the upfront payment and expected reimbursement of development costs from the Neurocrine Collaboration Agreement and the upfront payment from the AbbVie Alpha-Svnuclein Collaboration Agreement entered into in 2019, will enable us to fund our operating expenses and capital expenditure requirements into mid-2022. Our future capital requirements will depend on many factors, including:

- · the scope, progress, results, and costs of product discovery, preclinical studies and clinical trials for our product candidates and any required companion devices;
- the scope, progress, results, costs, prioritization, and number of our research and development programs;

- the progress and status of our strategic collaborations, including any research and development costs for which we are responsible, the potential exercise by our collaboration partners of options to develop or license certain products and product candidates, and our potential receipt of future milestone payments and royalties from our collaboration partners;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, preclinical development and clinical trial costs, or the achievement of milestones or occurrence of other developments that trigger payments, under any other collaboration agreement to which we might become a party;
- the costs, timing and outcome of regulatory review of our product candidates;
- · our ability to establish and maintain collaboration, distribution, or other marketing arrangements for our product candidates on favorable terms, if at all;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies or acquire or invest in other businesses, such as our investment in MRIC;
- the costs related to evaluating possible alternative devices that may be useful in the delivery of our product candidates, including our ongoing development of V-TAG;
- · the costs of securing manufacturing arrangements for pre-commercial and commercial production;
- the level of product sales from any product candidates for which we obtain marketing approval in the future;
- the costs of establishing or contracting for sales, manufacturing, marketing, distribution, and other commercialization capabilities if we obtain regulatory approvals to market our product candidates.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete. We may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our product revenues, if any, and any commercial milestones or royalty payments under our collaboration agreements, will be derived from sales of products that may not be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing and business development transactions to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate product revenues sufficient to achieve profitability, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or equity-linked securities, including convertible debt, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights as holders of our common stock. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, obtaining additional capital, acquiring or divesting businesses, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds

through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

## **Contractual Obligations**

The following table summarizes our significant contractual obligations as of payment due date by period at December 31, 2018:

|                              |       |        | Le | ess Than |        |         |             |         | IV. | Iore than |
|------------------------------|-------|--------|----|----------|--------|---------|-------------|---------|-----|-----------|
|                              |       | Total  |    | 1 Year   | 1 to   | 3 Years | 3 to        | 5 Years |     | 5 Years   |
|                              |       |        |    |          | (in th | ousands | 5)          |         |     |           |
| Operating lease commitments( | 1) \$ | 40,844 | \$ | 4,325    | `\$    | 9,594   | <b>\$</b> 1 | 0,142   | \$  | 16,783    |

In February 2018, we executed a second amendment for additional space located at 75 Sidney Street in Cambridge, Massachusetts, concurrent to the existing leases with terms going through December 2024. In June 2018, we executed a third amendment for additional space located at 75 Sidney Street, including an extension to the term through November 2026. Additionally, we executed an amendment to the lease at 64 Sidney Street to extend the term through November 2026.

We enter into agreements in the normal course of business with clinical research organizations, contract manufacturing organizations, and institutions to license intellectual property. We have not included these future payments in the table of contractual obligations above since the contracts are cancelable at any time by us, generally upon 30 to 90 days prior written notice.

Our agreements to license intellectual property include potential milestone payments that are dependent upon the development of products using the intellectual property licensed under the agreements and contingent upon the achievement of clinical trial or regulatory approval milestones. We may also be required to pay annual maintenance fees or minimum amounts payable ranging from low-four digits to low five-digits depending upon the terms of the applicable agreement.

In February 2015, we entered into an agreement in connection with the Sanofi Genzyme Collaboration, or the Sanofi Genzyme Collaboration Agreement, pursuant to which we granted Sanofi Genzyme an exclusive option to license, develop, and commercialize (i) ex-U.S. rights to several programs including our programs for Parkinson's disease and Friedreich's ataxia, (ii) ex-U.S. rights and U.S. co-commercialization rights to our program for Huntington's disease, and (iii) worldwide rights to our program for Spinal Muscular Atrophy. Sanofi Genzyme's option for each program is triggered following the completion of the first proof of principle human clinical study on a program-by-program basis.

Subject to specified exceptions, we are solely responsible for all costs incurred in connection with the development of each of the covered programs prior to Sanofi Genzyme's exercise of its option for such program. Upon Sanofi Genzyme's exercise of its option to license most of the programs pursuant to our collaboration, we will have sole responsibility for the development and commercialization of such product in the United States, and Sanofi Genzyme shall have sole responsibility for development and commercialization of such product in the rest of the world. In the case of our Huntington's disease program, if Sanofi Genzyme exercises its co-commercialization rights, it will also be responsible for commercialization activities related to the Huntington's disease product in the United States. In the case of our Spinal Muscular Atrophy product, if Sanofi Genzyme exercises its option, it will be responsible for all development costs occurring following the option exercise date and all worldwide commercialization activities.

In February 2018, we entered into an agreement in connection with the AbbVie Tau Collaboration, or the AbbVie Tau Collaboration Agreement, pursuant to which we granted AbbVie an exclusive option to license, develop,

and commercialize AAV and other virus-based gene therapy products for the treatment of neurodegenerative diseases related to defective or excess aggregation of tau protein in the human brain, including Alzheimer's disease. The collaboration is comprised of a research period, a development period, and an exclusive license option. During the research period, we are obligated to use diligent efforts to conduct antibody engineering and other research activities to create research compounds and to develop product candidates. We will be solely responsible for the costs and expenses during the research period. During a specified portion of the research period, AbbVie may exercise one or more of its exclusive development options to select up to a total of three research compounds and their corresponding product candidates to proceed to the development period.

During the development period, we are obligated to use diligent efforts to conduct development activities, including IND-enabling and Phase 1 clinical trial activities, for such selected research compounds and their corresponding product candidates. We will be solely responsible for the costs and expenses during the development period. During a specified portion of the development period, AbbVie may exercise its exclusive license option to further develop and commercialize all of the research compounds and corresponding product candidates. Upon the exercise of its license option, AbbVie would be solely responsible for all development and commercialization activities relating to the licensed compounds and corresponding licensed products, subject to certain exceptions. We also may elect to share in AbbVie's development costs relating to a licensed product on an indication-by-indication basis in exchange for a specified increase in royalties.

In January 2019, we entered into an agreement in connection with the Neurocrine Collaboration, or the Neurocrine Collaboration Agreement, for the development and commercialization of our VY-AADC program, our gene therapy program for the treatment of Friedreich's ataxia including VY-FXN01, and two programs to be determined by us and Neurocrine at a later date, which we refer to herein as the Discovery Programs. Under the terms of the Neurocrine Collaboration Agreement, Neurocrine has agreed to pay us an upfront payment of \$165.0 million, along with funding for ongoing development of each program in accordance with an agreed budget, and up to \$1.7 billion in potential development, regulatory, and commercial milestone payments. Under the terms of the Neurocrine Collaboration Agreement, Neurocrine will fund the clinical development of the Phase 2 clinical program for VY-AADC for Parkinson's disease. After our receipt of topline data of the RESTÔRE-1 Phase 2 trial, we have the option to either (1) co-commercialize VY-AADC in the United States under a 50/50 cost- and profit-sharing arrangement and receive milestones and royalties based on ex-U.S. sales, or (2) grant Neurocrine full global commercial rights in exchange for milestone payments and royalties based on global sales. Under the terms of the Neurocrine Collaboration Agreement, Neurocrine will fund the development for VY-FXN01 for Friedreich's ataxia through the Phase 1 clinical trial. After the data readout of the Phase 1 trial, we have the option to either (1) co-commercialize VY-FXN01 with Neurocrine in the U.S. under a 60/40 cost- and profit-sharing arrangement, or (2) grant Neurocrine full worldwide commercial rights in exchange for milestone payments and royalties based on global sales, subject to Sanofi Genzyme's option to commercialize the FA Program in countries outside the United States. Under the terms of the agreement for the two Discovery Programs, Neurocrine will fund the development of those programs and we have the right to earn milestone payments and royalties based on global sales. Sanofi Genzyme retains an option for ex-U.S. rights to VY-FXN01 following the data readout of the Phase 1 trial; however, if Sanofi Genzyme declines its option, the ex-U.S. rights to VY-FXN01 would revert to us and be included under the territories licensed to Neurocrine. Under the terms of the Neurocrine Collaboration Agreement, Neurocrine will fund the development of the two Development Programs, and we will have the right to earn milestone payments and royalties on global sales.

In February 2019, we entered into an exclusive collaboration and option agreement with AbbVie to develop and commercialize vectorized antibodies directed against pathological species of alpha-synuclein for the potential treatment of Parkinson's disease and other diseases characterized by the abnormal accumulation of misfolded alpha-synuclein protein, or synucleinopathies. Under the terms of this agreement, we will receive an upfront payment of \$65.0 million and may receive future option fees, development, regulatory, and commercial milestone payments, and royalties. Under the terms of the agreement, we and AbbVie have agreed to collaborate on the research and development of specified vectorized antibody compounds, or Research Compound, comprised of an AAV or other viral capsid and a virus vector genome that encodes one or more antibodies that target and bind to the alpha-synuclein protein. The collaboration is comprised of a research period and a development period. We are obligated to conduct research activities directed to constructing one or more virus vectors that encode antibodies designated by AbbVie. We are obligated to use diligent efforts to conduct antibody engineering and other research activities to create Research Compounds and to develop product candidates containing or comprised of such Research Compounds, Product Candidates. We are solely

responsible for the costs and expenses during the Research Period. During a specified portion of the Research Period, AbbVie may exercise one or more of its exclusive development options to select up to a total of four Research Compounds and their corresponding Product Candidates to proceed to the Development Period, after which AbbVie may exercise its option to license such Product Candidates following Phase 1 results, for which we may earn up to \$245.0 million in option exercise payments in aggregate. In addition to the upfront payment and the potential option exercise payments, we are eligible to receive up to \$772.5 million in development and regulatory milestones for each Licensed Compound. We are also eligible to receive tiered, escalating royalties, in the mid-single-digit percentage range on aggregate net sales of Licensed Products on a Licensed Compound by Licensed Compound basis, as well as up to \$500.0 million in commercial milestones based on aggregate annual net sales thresholds of Licensed Products. The royalties are subject to potential reductions for biosimilar market penetration, patent claim expiration, and other provisions, subject to specified limits. Subject to certain exceptions, each of AbbVie and the Company has agreed to be financially responsible for all payments owed to a third party with which it has contracted for any use of in-licensed intellectual property under the Collaboration Agreement.

## **Off-Balance Sheet Arrangements**

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable Securities and Exchange Commission rules.

## JOBS Act

In April 2012, the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an emerging growth company, or EGC, can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

Subject to certain conditions, as an EGC, we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an EGC until the earlier of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (ii) December 31, 2020; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. We have policies requiring us to invest in high-quality issuers, limit our exposure to any individual issuer, and ensure adequate liquidity. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments, including cash equivalents, are in the form of money market fund and marketable securities and are invested in U.S. Treasury and U.S. government agency obligations. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have had a material effect on the fair market value of our portfolio.

We are not currently exposed to market risk related to changes in foreign currency exchange rates; however, we may contract with vendors that are located in Asia and Europe in the future and may be subject to fluctuations in foreign currency rates at that time.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition, or results of operations during the year ended December 31, 2018.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15.

# ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## ITEM 9A. CONTROLS AND PROCEDURES

## Management's Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act to mean controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures include, without limitation, controls and other procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2018. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of December 31, 2018, our disclosure controls and procedures were effective at the reasonable assurance level.

We continue to review and document our disclosure controls and procedures and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

## Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive officer and principal financial officer, or persons performing similar functions, and effected by a company's board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of a company's assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that a company's receipts and expenditures are being made only in accordance with authorizations of the company's management and directors; and
- · provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision of and with the participation of our principal executive officer and principal financial and accounting officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework (2013 framework). Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2018.

## ITEM 9B. OTHER INFORMATION

As previously discussed, we are a party to a license agreement with REGENX for the development and commercialization of gene therapies to treat ALS, Friedreich's ataxia and Huntington's disease. Pursuant to our license agreement, REGENX granted us a non-exclusive worldwide license to certain technology and an option to obtain a non-exclusive worldwide license for intellectual property pertaining to a specified AAV vector. We exercised an option to certain technology of REGENX in November 2016. We do not currently utilize any rights licensed under the REGENX license agreement.

On February 21, 2019, we provided REGENX notice that we were exercising our right to terminate our license agreement with REGENX in its entirety, effective on May 22, 2019, at the expiration of the required notice period. Upon the effective date of termination, we are required to grant to REGENX a non-exclusive, perpetual, irrevocable, worldwide, royalty-free, transferable, sublicensable license to certain improvements made by us during the term of the license (including any intellectual property rights with respect thereto). This grant back will allow for REGENX's use of the improvements in the research, development or commercialization of products in any therapeutic indication. Additionally, all licenses granted to us under the license agreement will terminate upon the effective date of termination.

## PART III

## ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Incorporated by reference from the information in our Proxy Statement for our 2019 Annual Meeting of Stockholders, which we expect to file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

## ITEM 11. EXECUTIVE COMPENSATION

Incorporated by reference from the information in our Proxy Statement for our 2019 Annual Meeting of Stockholders, which we expect to file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

# ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Incorporated by reference from the information in our Proxy Statement for our 2019 Annual Meeting of Stockholders, which we expect to file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

# ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Incorporated by reference from the information in our Proxy Statement for our 2019 Annual Meeting of Stockholders, which we expect to file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

# ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Incorporated by reference from the information in our Proxy Statement for our 2019 Annual Meeting of Stockholders, which we expect to file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates

### PART IV

# ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

# (a)(1) Financial Statements.

| Report of independent registered public accounting firm      | F-1 |
|--|-----|
| Consolidated Balance Sheets                                  | F-2 |
| Consolidated Statements of Operations and Comprehensive Loss | F-3 |
| Consolidated Statements of Stockholders' Equity              | F-4 |
| Consolidated Statements of Cash Flows                        | F-5 |
| Notes to consolidated financial statements                   | F-6 |

# (a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the Consolidated Financial Statements or Notes thereto set forth under Item 8 above.

(a)(3) Exhibits.

See the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The exhibits listed in the Exhibit Index below are filed or incorporated by reference as part of this Annual Report on Form 10-K.

# ITEM 16. FORM 10-K SUMMARY

This Annual Report on Form 10-K does not include a summary.

### Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Voyager Therapeutics, Inc.

### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Voyager Therapeutics, Inc. (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

# Adoption of ASU No. 2014-09 Revenue from Contracts with Customers (Topic 606)

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for revenue in 2018 due to the adoption of Accounting Standard Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), and the related amendments.

### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

### /s/ Ernst & Young LLP

We have served as the Company's auditor since 2015. Boston, Massachusetts February 26, 2019

# Voyager Therapeutics, Inc. Consolidated Balance Sheets (amounts in thousands, except share and per share data)

|  | Decem         | ber 31 | ,         |
|--|---------------|--------|-----------|
|  | <br>2018      |        | 2017      |
| Assets   |               |        |           |
| Current assets:  |               |        |           |
| Cash and cash equivalents  | \$<br>46,859  | \$     | 31,530    |
| Marketable securities, current   | 108,947       |        | 137,522   |
| Prepaid expenses and other current assets  | <br>6,675     |        | 2,738     |
| Total current assets   | 162,481       |        | 171,790   |
| Property and equipment, net  | 12,771        |        | 10,283    |
| Deposits and other non-current assets  | 1,149         |        | 1,304     |
| Marketable securities, non-current   | <br>628       |        | 1,100     |
| Total assets   | \$<br>177,029 | \$     | 184,477   |
| Liabilities and stockholders' equity   | ,             |        |           |
| Current liabilities:   |               |        |           |
| Accounts payable   | \$<br>1,038   | \$     | 1,020     |
| Accrued expenses   | 9,788         |        | 11,497    |
| Deferred revenue, current portion  | 20,847        |        | 3,380     |
| Total current liabilities  | <br>31,673    |        | 15,897    |
| Deferred rent  | 5,710         |        | 5,337     |
| Deferred revenue, net of current portion   | 92,199        |        | 28,180    |
| Other non-current liabilities  | 1,001         |        | 1,012     |
| Total liabilities  | 130,583       |        | 50,426    |
| Commitments and contingencies (see note 7)   | ,             | _      |           |
| Stockholders' equity:  |               |        |           |
| Preferred stock, \$0.001 par value: 5,000,000 shares authorized; no shares issued and outstanding at |               |        |           |
| December 31, 2018 and 2017   | _             |        | _         |
| Common stock, \$0.001 par value: 120,000,000 shares authorized; 32,364,895 and 31,572,044 shares     |               |        |           |
| issued and outstanding at December 31, 2018 and 2017, respectively                                   | 32            |        | 32        |
| Additional paid-in capital   | 315,598       |        | 295,019   |
| Accumulated other comprehensive loss   | (133)         |        | (287)     |
| Accumulated deficit  | <br>(269,051) |        | (160,713) |
| Total stockholders' equity   | 46,446        |        | 134,051   |
| Total liabilities and stockholders' equity   | \$<br>177,029 | \$     | 184,477   |

The accompanying notes are an integral part of these consolidated financial statements.

# Voyager Therapeutics, Inc. Consolidated Statements of Operations and Comprehensive Loss (amounts in thousands, except share and per share data)

|  | Year ended   |            |    |            |    |            |  |
|--|--------------|------------|----|------------|----|------------|--|
|  | December 31, |            |    |            |    |            |  |
|  |              | 2018       |    | 2017       |    | 2016       |  |
| Collaboration revenue  | \$           | 7,619      | \$ | 10,135     | \$ | 14,220     |  |
| Operating expenses:  |              |            |    |            |    |            |  |
| Research and development   |              | 64,905     |    | 62,260     |    | 42,249     |  |
| General and administrative                                       |              | 33,809     |    | 19,738     |    | 13,270     |  |
| Total operating expenses   |              | 98,714     |    | 81,998     |    | 55,519     |  |
| Operating loss   |              | (91,095)   |    | (71,863)   |    | (41,299)   |  |
| Other income (expense), net:                                     |              |            |    |            |    |            |  |
| Interest income, net   |              | 3,310      |    | 1,227      |    | 976        |  |
| Other (expense) income, net                                      |              | (683)      |    | (62)       |    | 182        |  |
| Total other income (expense), net                                |              | 2,627      |    | 1,165      |    | 1,158      |  |
| Loss before income taxes   |              | (88,468)   |    | (70,698)   |    | (40,141)   |  |
| Income tax provision   |              | (180)      |    |            |    | 52         |  |
| Net loss   | \$           | (88,288)   | \$ | (70,698)   | \$ | (40,193)   |  |
| Other comprehensive loss   |              |            |    |            |    |            |  |
| Net unrealized gain (loss) on available-for-sale-securities, net |              |            |    |            |    |            |  |
| of tax expense of \$128 for the year ended December 31, 2016     |              | 34         |    | (235)      |    | 199        |  |
| Total other comprehensive income (loss)                          | · · · · · ·  | 34         |    | (235)      |    | 199        |  |
| Comprehensive loss   | \$           | (88,254)   | \$ | (70,933)   | \$ | (39,994)   |  |
| Net loss per share, basic and diluted                            | \$           | (2.75)     | \$ | (2.64)     | \$ | (1.59)     |  |
| Weighted-average common shares outstanding, basic and diluted    |              | 32,065,781 |    | 26,803,711 |    | 25,302,414 |  |

The accompanying notes are an integral part of these consolidated financial statements.

# Voyager Therapeutics, Inc. Consolidated Statements of Stockholders' Equity (amounts in thousands, except share data)

|   |            |         | Additional | Accumulated<br>Other |              |               |
|---|------------|---------|------------|----------------------|--------------|---------------|
|   | Commoi     | ı Stock | Paid-In    | Comprehensive        | Accumulated  | Stockholders' |
|   | Shares     | Amount  | Capital    | Loss                 | Deficit      | Equity        |
| Balance at December 31, 2015  | 24,930,979 | \$ 25   | \$ 219,122 | \$ (251)             | \$ (49,822)  | \$ 169,074    |
| Vesting of restricted stock   | 601,501    | 1       | 17         |                      |              | 18            |
| Exercises of vested stock options   | 65,432     | _       |            | _                    | _            | 514           |
| Stock-based compensation expense  | _          | _       | 6,310      | _                    | _            | 6,310         |
| Unrealized gain on available-for-sale securities, net of tax                              | _          | _       | _          | 199                  | _            | 199           |
| Net loss  |            |         |            |                      | (40,193)     | (40,193)      |
| Balance at December 31, 2016  | 25,597,912 | \$ 26   | \$ 225,963 | \$ (52)              | \$ (90,015)  | \$ 135,922    |
| Vesting of restricted stock   | 573,803    | 1       | 12         |                      |              | 13            |
| Exercises of vested stock options   | 158,677    | _       |            | _                    | _            | 1,363         |
| Issuance of common stock under ESPP   | 66,652     | _       | 563        | _                    | _            | 563           |
| Issuance of common stock from public offering (net of underwriters discounts and issuance |            |         |            |                      |              |               |
| costs of \$4,100)   | 5,175,000  | 5       |            | _                    | _            | 57,994        |
| Stock-based compensation expense  | _          | _       | 9,129      | _                    | _            | 9,129         |
| Unrealized loss on available-for-sale securities, net of tax                              | _          | _       | _          | (235)                | _            | (235)         |
| Net loss  | _          | _       | _          | · -                  | (70,698)     | (70,698)      |
| Balance at December 31, 2017  | 31,572,044 | \$ 32   | \$ 295,019 | \$ (287)             | \$ (160,713) | \$ 134,051    |
| Vesting of restricted stock   | 319,891    |         | 9          |                      |              | 9             |
| Exercises of vested stock options   | 384,186    | _       |            | _                    | _            | 3,891         |
| Issuance of common stock under ESPP   | 88,774     | _       | 969        | _                    | _            | 969           |
| Stock-based compensation expense  | _          | _       | 15,710     | _                    | _            | 15,710        |
| Unrealized gain on available-for-sale securities, net of tax                              | _          | _       | _          | 34                   | _            | 34            |
| Cumulative-effect adjustment to beginning accumulated deficit and statement of operations |            |         |            |                      |              |               |
| resulting from ASU No. 2016-01  | _          | _       | _          | 120                  | (120)        | _             |
| Modified retrospective adjustment to beginning accumulated deficit and deferred revenue   |            |         |            |                      |              |               |
| resulting from ASU No. 2014-09  | _          | _       | _          | _                    | (19,930)     | (19,930)      |
| Net loss  |            |         |            |                      | (88,288)     | (88,288)      |
| Balance at December 31, 2018  | 32,364,895 | \$ 32   | \$ 315,598 | \$ (133)             | \$ (269,051) | \$ 46,446     |

 $\label{thm:companying} \textit{ notes are an integral part of these consolidated financial statements}$ 

# Voyager Therapeutics, Inc. Consolidated Statements of Cash Flows (amounts in thousands)

|   | Year ended<br>December 31, |    |           |    |           |
|---|----------------------------|----|-----------|----|-----------|
|   | 2018                       |    | 2017      |    | 2016      |
| Cash flow from operating activities   |                            |    |           |    |           |
| Net loss  | \$<br>(88,288)             | \$ | (70,698)  | \$ | (40,193)  |
| Adjustments to reconcile net loss to net cash used in operating activities: |                            |    |           |    |           |
| Stock-based compensation expense  | 15,710                     |    | 9,238     |    | 6,310     |
| Depreciation  | 2,117                      |    | 1,595     |    | 612       |
| Amortization of premiums and discounts on marketable securities             | (2,163)                    |    | (24)      |    | 696       |
| In-kind research and development expenses                                   | 176                        |    | 113       |    | 1,182     |
| Other non-cash items  | 859                        |    | 46        |    | 709       |
| Changes in operating assets and liabilities:                                |                            |    |           |    |           |
| Prepaid expenses and other current assets                                   | (3,937)                    |    | 1,630     |    | (847)     |
| Other non-current assets  | (180)                      |    | _         |    | 7         |
| Deferred revenue  | 61,380                     |    | (10,135)  |    | (14,582)  |
| Accounts payable  | (282)                      |    | 470       |    | (62)      |
| Accrued expenses  | (1,600)                    |    | 4,900     |    | 2,636     |
| Other non-current liabilities   | _                          |    | 1,000     |    | _         |
| Lease incentive benefit   | <br>321                    |    | 515       |    | 1,050     |
| Net cash used in operating activities                                       | (15,887)                   |    | (61,350)  |    | (42,482)  |
| Cash flow from investing activities   | <br>                       |    |           |    |           |
| Purchases of property and equipment   | (4,305)                    |    | (3,985)   |    | (5,029)   |
| Purchases of marketable securities  | (333,228)                  |    | (147,296) |    | (112,350) |
| Proceeds from maturities or sales of marketable securities                  | 364,000                    |    | 147,600   |    | 165,100   |
| Net cash provided by (used in) investing activities                         | 26,467                     |    | (3,681)   |    | 47,721    |
| Cash flow from financing activities   |                            |    |           | ,  |           |
| Proceeds from the issuance of stock net of discount and issuance costs      | _                          |    | 57,994    |    |           |
| Proceeds from the exercise of stock options                                 | 3,889                      |    | 1,363     |    | 514       |
| Proceeds from the purchase of common stock under ESPP                       | 860                        |    | 563       |    | _         |
| Net cash provided by financing activities                                   | <br>4,749                  |    | 59,920    |    | 514       |
| Net increase (decrease) in cash and cash equivalents                        | 15,329                     |    | (5,111)   |    | 5,753     |
| Cash, cash equivalents, and restricted cash beginning of period             | 32,265                     |    | 37,376    |    | 31,623    |
| Cash, cash equivalents, and restricted cash end of period                   | \$<br>47,594               | \$ | 32,265    | \$ | 37,376    |
| Supplemental disclosure of cash and non-cash activities                     |                            |    |           |    |           |
| Impact of adopting new accounting standards                                 | \$<br>20,050               | \$ | _         | \$ | _         |
| Capital expenditures incurred but not yet paid                              | \$<br>300                  | \$ | _         | \$ | 242       |

The accompanying notes are an integral part of these consolidated financial statements.

### VOYAGER THERAPEUTICS INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### 1. Nature of business

Voyager Therapeutics, Inc. (the "Company") is a clinical-stage gene therapy company focused on developing life-changing treatments for patients suffering from severe neurological diseases. The Company is focused on neurological diseases where it believes an adeno-associated virus ("AAV") gene therapy approach that either increases or decreases the production of a specific protein can slow or reduce the symptoms experienced by patients, and therefore have a clinically meaningful impact. The Company has built a gene therapy platform that it believes positions itself to be a leading company at the intersection of AAV gene therapy and severe neurological disease. The Company's gene therapy platform enables it to engineer, optimize, manufacture and deliver its AAV-based gene therapies that have the potential to provide durable efficacy following a single administration.

Additionally, the Company is working to identify novel AAV capsids, which are the outer viral protein shells that enclose the genetic material of the virus payload. The Company's team of experts in the fields of AAV gene therapy and neuroscience first identifies and selects severe neurological diseases that are well-suited for treatment using AAV gene therapy. The Company then engineers and optimizes AAV vectors for delivery of the virus payload to the targeted tissue or cells. The Company's manufacturing process employs an established system that it believes will enable production of high quality AAV vectors at commercial-scale. In addition to the Company's capsid optimization efforts, it leverages novel delivery paradigms, established routes of administration, and advances in dosing techniques to optimize delivery of its AAV gene therapies to target tissues, regions and cell types that are critical to the disease of interest. The Company believes it can achieve this directly, with targeted infusions to discrete regions of the brain or spinal cord, or systemically, in conjunction with its novel capsids.

The Company's business strategy focuses on discovering, developing, manufacturing and commercializing its gene therapy programs. As part of this strategy, the Company has developed core competencies specific to AAV gene therapy development and manufacturing and is beginning to build its commercial infrastructure. This business strategy also includes business development activities that may include in-licensing activities or partnering certain programs in certain geographies with collaborators, as the Company has demonstrated through its collaboration with Sanofi Genzyme (the "Sanofi Genzyme Collaboration"), its collaboration with AbbVie Biotechnology Ltd (the "AbbVie Tau Collaboration"), its collaboration with Neurocrine Biosciences. Inc. (the "Neurocrine Collaboration"), and its collaboration with AbbVie Ireland Unlimited Company (the "AbbVie Alpha-Synuclein Collaboration"). The Company is devoting substantially all of its efforts to product research and development, market development, and raising capital. The Company is subject to risks common to companies in the biotechnology and gene therapy industry, including but not limited to, the need to obtain sufficient capital to continue to fund its operations, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval for its product candidates, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations, and ability to transition from pilot-scale manufacturing to large-scale production of products.

The Company has incurred annual net operating losses in every year since inception. As of December 31, 2018, the Company had an accumulated deficit of \$269.1 million. The Company has not generated any product revenue and has financed its operations primarily through public offerings and private placements of its equity securities and funding from its collaborations with Sanofi Genzyme and AbbVie. Additionally, in January 2019, the Company entered into the Neurocrine Collaboration which is expected to commence in the first half of 2019. Under the Neurocrine Collaboration, the Company will receive an upfront payment of \$165.0 million, including a \$50.0 million investment in 4,179,728 shares of common stock. The effectiveness of this agreement is subject to certain conditions, including the expirations or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and other customary closing conditions. In February 2019, the Company announced the AbbVie Alpha-Synuclein Collaboration to develop and commercialize vectorized antibodies directed at pathological species of alpha-synuclein for the potential treatment of Parkinson's disease and other diseases (synucleinopathies) characterized by the abnormal accumulation of misfolded alpha-synuclein protein. Under the terms of the AbbVie Alpha-Synuclein Collaboration, the Company will receive an upfront payment of \$65.0 million. Based upon the current operating plan, the Company expects that its existing cash, cash equivalents, and marketable debt securities, as well as amounts expected

from the unfront payment and expected reimbursement of development costs from the Neurocrine Collaboration Agreement and the unfront payment from the AbbVie Alpha-Synuclein Collaboration Agreement entered into in 2019, will enable the Company to fund its operating expenses and capital expenditure requirements into mid-2022. There can be no assurance that the Company will be able to obtain additional debt or equity financing or generate product revenue or revenue from collaborative partners on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations, and financial condition.

### 2. Summary of significant accounting policies

The following is a summary of significant accounting policies followed in the preparation of these financial statements.

# Basis of presentation

The accompanying consolidated financial statements include those of the Company and its subsidiary, Voyager Securities Corporation, after elimination of all intercompany accounts and transactions. The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP").

# **Public offerings**

On October 29, 2015, in preparation for the Company's IPO, the Company's Board of Directors and stockholders approved a 1-for-4.25 reverse split of the Company's common stock, which became effective on October 29, 2015. All share and per share amounts in the consolidated financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital.

On November 16, 2015, the Company completed the sale of 5,750,000 shares of its common stock in its initial public offering (the "IPO"), at a price to the public of \$14.00 per share, resulting in net proceeds to the Company of \$72.9 million after deducting underwriting discounts, commissions and offering expenses payable by the Company.

On November 7, 2017, the Company completed the sale of 5,175,000 shares of its common stock in a public offering at a price to the public of \$12.00 per share, resulting in net proceeds to the Company of \$58.0 million after deducting underwriting discounts, commissions, and offering expenses payable by the Company.

### **Use of Estimates**

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. On an ongoing basis, the Company's management evaluates its estimates, which include, but are not limited to, estimates related to revenue recognition, accrued expenses, stock-based compensation expense, and income taxes. The Company bases its estimates on historical experience and other market specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

# Fair Value of Financial Instruments

ASC Topic 820, *Fair Value Measurement* ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances.

ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for

considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes between the following:

- · Level 1—Quoted market prices in active markets for identical assets or liabilities.
- · Level 2—Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted market prices, interest rates, and yield curves.
- Level 3—Unobservable inputs developed using estimates of assumptions developed by the Company, which
  reflect those that a market participant would use.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying amounts reflected in the balance sheets for cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values, due to their short-term nature.

# Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include cash held in banks and amounts held in money market funds.

### **Marketable Securities**

The Company classifies marketable debt securities with a remaining maturity of greater than three months when purchased as available-for-sale. Marketable debt securities with a remaining maturity date greater than one year and marketable equity securities are classified as non-current where the Company has the intent and ability to hold these securities for at least the next 12 months. During 2016, the Company invested in a supplier and received common stock and warrants to purchase common stock in that entity. The common stock is considered an available-for-sale marketable equity security and is included in non-current marketable securities, and the warrants are included in non-current assets.

All available for sale debt securities are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders' equity until realized. Any premium or discount arising at purchase is amortized and/or accreted to interest income and/or expense. Realized gains and losses are determined using the specific identification method and are included in other income (expense). If any adjustment to fair value reflects a decline in value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is "other than temporary" and, if so, recognizes the loss through a charge to the Company's statement of operations and comprehensive loss. No other than temporary losses have been recognized.

Cash, cash equivalents, and marketable securities as of December 31, 2018 and 2017 consist of the following:

|  | A  | mortized<br>Cost | realized<br>Gains |        | ealized<br>osses | Fair<br>Value |
|--|----|------------------|-------------------|--------|------------------|---------------|
|  | -  |                  | (in tho           | usands | )                |               |
| As of December 31, 2018                                  |    |                  |                   |        |                  |               |
| Money market funds included in cash and cash equivalents | \$ | 46,173           | \$<br>_           | \$     | _                | \$<br>46,173  |
| Marketable securities:                                   |    |                  |                   |        |                  |               |
| U.S. Treasury notes                                      |    | 108,951          | 1                 |        | 5                | 108,947       |
| Equity securities  |    | 1,220            |                   |        | 592              | 628           |
| Total marketable securities                              | \$ | 110,171          | \$<br>1           | \$     | 597              | \$<br>109,575 |
| Total money market funds and marketable securities       | \$ | 156,344          | \$<br>1           | \$     | 597              | \$<br>155,748 |
| As of December 31, 2017                                  |    |                  |                   |        |                  |               |
| Money market funds included in cash and cash equivalents | \$ | 30,469           | \$<br>_           | \$     | _                | \$<br>30,469  |
| Marketable securities:                                   |    |                  |                   |        |                  |               |
| U.S. Treasury notes                                      |    | 137,560          | _                 |        | 38               | 137,522       |
| Equity securities  |    | 1,220            | _                 |        | 120              | 1,100         |
| Total marketable securities                              | \$ | 138,780          | \$<br>            | \$     | 158              | \$<br>138,622 |
| Total money market funds and marketable securities       | \$ | 169,249          | \$<br>            | \$     | 158              | \$<br>169,091 |

All of the Company's marketable debt securities at December 31, 2018 and 2017 have a contractual maturity of one year or less.

### Restricted Cash

At December 31, 2018 and 2017, the Company maintained restricted cash totaling approximately \$0.7 million held in the form of money market accounts as collateral for the Company's facility lease obligation. The balance is included within deposits in other non-current assets in the accompanying consolidated balance sheets. The following table provides a reconciliation of cash, cash equivalents, and restricted cash within the condensed consolidated balance sheet that sum to the total of the same such amounts shown in the statement of cash flows:

|  | As of December 31, |        |     |            |    |        |  |  |  |  |
|--|--------------------|--------|-----|------------|----|--------|--|--|--|--|
|  |                    | 2018   |     | 2017       |    | 2016   |  |  |  |  |
|  |                    |        | (in | thousands) |    |        |  |  |  |  |
| Cash and cash equivalents  | \$                 | 46,859 | \$  | 31,530     | \$ | 36,641 |  |  |  |  |
| Restricted cash included in deposits and other noncurrent assets |                    | 735    |     | 735        |    | 735    |  |  |  |  |
| Total cash, cash equivalents, and restricted cash                | \$                 | 47,594 | \$  | 32,265     | \$ | 37,376 |  |  |  |  |

# **Property and Equipment**

Property and equipment consists of laboratory equipment, furniture and office equipment, and leasehold improvements and is stated at cost, less accumulated depreciation. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred; while costs of major additions and betterments are capitalized. Depreciation is calculated over the estimated useful lives of the assets using the straight-line method.

### Impairment of Long-Lived Assets

The Company evaluates long-lived assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book values of the assets to the expected future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book values of the assets exceed their fair value. The Company has not recognized any impairment losses from inception through December 31, 2018.

# Revenue Recognition

As of December 31, 2018, all of the Company's revenue is generated from its collaboration agreements with Sanofi Genzyme Corporation, a Sanofi company ("Sanofi Genzyme"), and AbbVie Biotechnology Ltd. and its affiliates collectively, ("AbbVie").

The Company enters into collaboration agreements which are within the scope of ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), under which the Company licenses rights to certain of the Company's product candidates and performs research and development services. The terms of these arrangements typically include payment of one or more of the following: non-refundable, upfront fees; reimbursement of research and development costs; development, regulatory, and commercial milestone payments; and royalties on net sales of licensed products.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The promised goods or services in the Company's arrangements typically consist of license rights to the Company's intellectual property and research and development services. The Company provides options to additional items in the contracts, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. The Company evaluates the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer and are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on its own or whether the required expertise is readily available and whether the goods or services are integral or dependent to other goods or services in the contract.

The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration or variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of potential payments and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected amount method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration which is included in the transaction price may be constrained, and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

The Company's contracts often include development and regulatory milestone payments which are assessed under the most likely amount method and constrained if it is probable that a significant revenue reversal would occur. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues in the period of adjustment. To date, the Company has not recognized any consideration related to the achievement of development, regulatory, or commercial milestone revenue resulting from any of the Company's collaboration arrangements.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any consideration related to sales-based royalty revenue resulting from any of the Company's collaboration arrangements.

The Company allocates the transaction price based on the estimated stand-alone selling price of each of the performance obligations. The Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the stand-alone selling price for service obligations, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. Additionally, in determining the standalone selling price for material rights, the Company utilizes comparable transactions, clinical trial success probabilities, and estimates of option exercise likelihood. Variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated are consistent with the amounts the Company would expect to receive for the satisfaction of each performance obligation.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Upfront payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional

# Research and Development

Research and development costs are charged to expense as incurred in performing research and development activities. The costs include employee compensation costs, external research, consultant costs, sponsored research, in-kind services provided under the Sanofi Genzyme agreement, license fees, process development and facilities costs. Facilities costs primarily include the allocation of rent, utilities and depreciation.

# **Research Contract Costs and Accruals**

The Company has entered into various research and development contracts with research institutions and other companies. These agreements are generally cancelable. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

### **Patent Costs**

The Company expenses patent application and related legal costs as incurred and classifies such costs as general and administrative expenses in the accompanying statements of operations.

# **Stock-Based Compensation Expense**

The Company accounts for its stock-based compensation awards in accordance with ASC Topic 718 *Compensation* —*Stock Compensation* ("ASC 718"). ASC 718 requires all stock-based payments to employees and directors, including grants of restricted stock and stock options, to be recognized as expense in the statements of operations based on their grant date fair values. Grants of restricted stock and stock options to other service providers,

referred to as non-employees, are required to be recognized as expense in the statements of operations based on their vesting date fair values. The Company estimates the fair value of options granted using the Black-Scholes option pricing model. The Company uses the fair value of its common stock to determine the fair value of restricted stock awards.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to a lack of company-specific historical and implied volatility data, the Company bases the estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded, blended with the most recent period of historic volatility of its common stock. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to the Company, including stage of product development and life science industry focus. The Company uses the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, Share-Based Payment, to calculate the expected term for stock options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For stock options granted to non-employees, the Company utilizes the contractual term of the arrangement as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

The Company expenses the fair value of its stock-based compensation awards to employees on a straight-line basis over the associated service period, which is generally the period in which the related services are received. Stock-based compensation awards to non-employees are adjusted through stock-based compensation expense at each reporting period end to reflect the current fair value of such awards and are expensed on a straight-line basis.

The Company records the expense for stock-based compensation awards subject to performance conditions over the remaining service period when management determines that achievement of the performance condition is probable. Management evaluates when the achievement of a performance condition is probable based on the expected satisfaction of the performance conditions as of the reporting date.

### **Income Taxes**

Income taxes are recorded in accordance with ASC Topic 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial reporting and the tax reporting basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the weight of available evidence, it is more likely than not that the deferred tax assets will be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2018, the Company does not have any significant uncertain tax positions.

# Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income or loss. Other comprehensive income or loss consists of unrealized gains or losses on marketable securities.

### Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods.

For purposes of the diluted net loss per share, unvested restricted common stock and outstanding stock options are considered to be potentially dilutive securities, but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive and therefore, basic and diluted net loss per share were the same for all periods presented.

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because to do so would be anti-dilutive:

|                                  | As of December 31, |           |           |  |  |  |  |  |
|----------------------------------|--------------------|-----------|-----------|--|--|--|--|--|
|                                  | 2018               | 2016      |           |  |  |  |  |  |
| Unvested restricted common stock | 235,294            | 557,979   | 1,167,984 |  |  |  |  |  |
| Outstanding stock options        | 4,225,152          | 3,143,566 | 1,871,237 |  |  |  |  |  |
| Total                            | 4,460,446          | 3,701,545 | 3,039,221 |  |  |  |  |  |

# Concentrations of Credit Risk and Off-Balance Sheet Risk

The Company has no financial instruments with off-balance sheet risk such as foreign exchange contracts, option contracts or other foreign currency hedging arrangements. Financial instruments that potentially subject the Company to a concentration of credit risk are cash and cash equivalents. The Company's cash is held in accounts at a financial institution that may exceed federally insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds.

# Concentration of Suppliers

The Company is dependent on a third-party manufacturer to supply certain products for research and development activities in its programs. In particular, the Company relies on a sole manufacturer to supply it with specific vectors related to the Company's research and development programs.

### **Segment Information**

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision maker, the Company's Chief Executive Officer, views the Company's operations and manages its business as a single operating segment, which is the business of developing and commercializing gene therapies.

# **Recently Adopted Accounting Pronouncements**

In January 2016, the Financial Accounting Standards Board ("FASB") issued ASC Update No. 2016-01, *Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities* ("Update No. 2016-01"). The purpose of Update No. 2016-01 is to improve financial reporting for financial instruments by reducing the number of items recorded to other comprehensive income. The Company adopted Update No. 2016-01 in the first quarter of 2018, using the modified retrospective method. Unrealized gains and losses previously recorded to other comprehensive income (loss) were reclassified to accumulated deficit and all future fair value changes will be recorded to other income (loss). The adoption of the standard on January 1, 2018 did not have a material impact on the Company's consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows* ("ASU 2016-15"), which simplifies certain elements of cash flow classification and is intended to reduce diversity in practice in how certain transactions are classified in the statement of cash flows. The update is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. The Company adopted ASU 2016-15 on January 1, 2018, and such adoption did not have a material impact on the Company's consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Restricted Cash* ("ASU 2016-18"). The amendments in ASU 2016-18 require an entity to reconcile and explain the period-over-period change in total cash, cash equivalents and restricted cash within its statements of cash flows and was adopted utilizing a full retrospective approach. The Company

adopted the new standard on January 1, 2018. The Company has included the necessary reconciliation within Note 2 "Restricted Cash".

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which supersedes the revenue recognition requirements in ASC 605, *Revenue Recognition* ("ASC 605"), and most industry-specific guidance. The new standard requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The update also requires additional disclosure about the nature, amount, timing, and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. Thereafter, a series of clarifying ASUs, narrow scope improvements and practical expedients were issued. This collective guidance resulted in the new revenue standard, ASC 606.

The Company adopted the new standard effective January 1, 2018 using the modified retrospective approach. The Company had one open contract, relating to the Sanofi Genzyme Collaboration, on the adoption date and has assessed it under the new revenue standard. The adoption of ASC 606 resulted in the changes to (i) the allocation of arrangement consideration, including the determination of estimated selling price and the allocation of variable consideration to specific performance obligations and (ii) the application of proportional performance as a measure of progress on service-related deliverables.

The Company has accounted for the impact of adopting ASC 606 as a cumulative catch-up under the modified retrospective approach, which is represented as an increase of \$20.0 million to deferred revenue with an offset to accumulated deficit, effective January 1, 2018. The following financial statement line items have been shown to reflect comparative balances under ASC 606 and ASC 605 for the year ended December 31, 2018, for both of the Sanofi Genzyme Collaboration and AbbVie Tau Collaboration, collectively.

### **Condensed Consolidated Statements of Operations and Comprehensive Loss**

|                                       |                                       | Year ended December 31, 2018          |               |                  |  |  |  |  |  |  |
|---------------------------------------|---------------------------------------|---------------------------------------|---------------|------------------|--|--|--|--|--|--|
|                                       |                                       | Under ASC 606                         | Under ASC 605 | Effect of change |  |  |  |  |  |  |
|                                       | · · · · · · · · · · · · · · · · · · · | (in thousands, except per share data) |               |                  |  |  |  |  |  |  |
| Collaboration revenue                 | \$                                    | 7,619                                 | \$ 11,095     | (3,476)          |  |  |  |  |  |  |
| Loss before income taxes              |                                       | (88,468)                              | (84,992)      | (3,476)          |  |  |  |  |  |  |
| Net loss                              |                                       | (88,288)                              | (84,812)      | (3,476)          |  |  |  |  |  |  |
| Net loss per share, basic and diluted |                                       | (2.75)                                | (2.64)        | (0.11)           |  |  |  |  |  |  |

### **Condensed Consolidated Balance Sheets**

|                               |    | As of December 31, 2018 |               |                  |          |  |  |  |  |  |
|-------------------------------|----|-------------------------|---------------|------------------|----------|--|--|--|--|--|
|                               |    | Under ASC 606           | Under ASC 605 | Effect of change |          |  |  |  |  |  |
|                               | ·  |                         |               | (in thousands)   | _        |  |  |  |  |  |
| Deferred revenue, current     | \$ | 20,847                  | \$            | 19,111 \$        | 1,736    |  |  |  |  |  |
| Deferred revenue, non-current |    | 92,199                  |               | 70,529           | 21,670   |  |  |  |  |  |
| Accumulated deficit           |    | (269,051)               |               | (245,645)        | (23,406) |  |  |  |  |  |

# **Condensed Consolidated Statements of Cash Flows**

|   | Year ended December 31, 2018 |              |                |                  |  |
|---|------------------------------|--------------|----------------|------------------|--|
|   | Uı                           | nder ASC 606 | Under ASC 605  | Effect of change |  |
|   |                              |              | (in thousands) |                  |  |
| Net loss  | \$                           | (88,288)     | \$ (84,812) \$ | (3,476)          |  |
| Adjustments to reconcile net loss to net cash used in operating activities: |                              |              | ,              |                  |  |
| Deferred revenue  |                              | 61,380       | 57,904         | 3,476            |  |
|   |                              |              |                |                  |  |

### **Recent Accounting Pronouncements**

In February 2016, the FASB issued ASU No. 2016-02, a comprehensive new lease accounting standard, which provides revised guidance on accounting for lease arrangements by both lessors and lessees and requires lessees to recognize a lease liability and a right-of-use asset for most leases. In July 2018, the FASB issued ASU No. 2018-11, *Leases* (Topic 842), *Targeted Improvements*, which provides an additional transition method that allows entities to initially apply the new lease requirements at the adoption date, not the earliest period presented, and recognize a cumulative effect adjustment to the opening balance of retained earnings in the period of adoption. The Company expects to elect this transition method at the adoption date of January 1, 2019. The Company also expects to elect a package of practical expedients, under which an entity need not reassess whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases, or initial direct costs for any existing leases. The Company is currently in the process of evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and related disclosures.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118, to address the application of GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Cuts and Jobs Act (the "Tax Reform Act"). The Company has recognized the provisional tax impacts related to the revaluation of the deferred tax assets and liabilities and included these amounts in its consolidated financial statements for the year ended December 31, 2017. The ultimate impact may differ from these provisional amounts due to, among other things, additional analysis, changes in interpretations and assumptions the Company has made, additional regulatory guidance that may be issued, and actions the Company may take as a result of the Tax Reform Act. The accounting was completed when the Company's 2017 U.S. corporate income tax return was filed in 2018, and no material differences arose as compared to provisional amounts initially reflected in the consolidated financial statements for the year ended December 31, 2017.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation: Improvements to Nonemployee Share-Based Payment Accounting* ("ASC 718"). The new standard largely aligns the accounting for share-based payment awards issued to employees and nonemployees by expanding the scope of ASC 718 to apply to nonemployee share-based transactions, as long as the transaction is not effectively a form of financing. The new guidance will be effective for the Company on January 1, 2019. The Company is currently evaluating the potential impact that this guidance may have on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement* (Topic 820): *Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"). The new standard added, modified or removed disclosure requirements under Topic 820 for clarity and consistency. ASU 2018-13 is effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company is currently evaluating the potential impact that this guidance may have on its consolidated financial statements.

### 3. Fair value measurements

Assets and liabilities measured at fair value on a recurring basis as of December 31, 2018 and 2017 are as follows:

|   |               | •  | oted Prices<br>in Active   | S     | Significant<br>Other | S  | ignificant          |
|---|---------------|----|----------------------------|-------|----------------------|----|---------------------|
|   |               |    | larkets for                | C     | Other                |    | observable          |
| Assets  | Total         |    | ntical Assets<br>(Level 1) |       | Inputs<br>(Level 2)  | (  | Inputs<br>(Level 3) |
|   |               |    | (in the                    | ousar | ıds)                 |    |                     |
| December 31, 2018   |               |    |                            |       |                      |    |                     |
| Money market funds included in cash and cash equivalents Marketable securities: | \$<br>46,173  | \$ | 46,173                     | \$    |                      | \$ | _                   |
| U.S. Treasury notes   | 108,947       |    | 108,947                    |       | _                    |    |                     |
| Equity securities   | 628           |    | 628                        |       | _                    |    | _                   |
| Total marketable securities   | \$<br>109,575 | \$ | 109,575                    | \$    |                      | \$ |                     |
| Warrants to purchase equity securities  | 234           |    |                            |       | 234                  |    |                     |
| Total   | \$<br>155,982 | \$ | 155,748                    | \$    | 234                  | \$ |                     |
| December 31, 2017   |               |    |                            |       |                      |    |                     |
| Money market funds included in cash and cash equivalents                        | \$<br>30,469  | \$ | 30,469                     | \$    | _                    | \$ | _                   |
| Marketable securities:  |               |    |                            |       |                      |    |                     |
| U.S. Treasury notes   | 137,522       |    | 137,522                    |       |                      |    |                     |
| Equity securities   | 1,100         |    | 1,100                      |       |                      |    | <u> </u>            |
| Total marketable securities   | \$<br>138,622 | \$ | 138,622                    | \$    |                      | \$ |                     |
| Warrants to purchase equity securities  | 569           |    |                            |       | 569                  |    | _                   |
| Total   | \$<br>169,660 | \$ | 169,091                    | \$    | 569                  | \$ |                     |

The Company measures the fair value of money market funds, U.S. Treasuries and equity securities based on quoted prices in active markets for identical securities. The Level 2 equity securities include warrants used to purchase equity securities that are valued using the Black-Scholes model. The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the awards, (c) the risk-free interest rate, and (d) expected dividends. The assumptions utilized to value the warrants to purchase equity securities as of December 31, 2018, 2017, and 2016 are as follows:

|                          |         | As of December 31, |        |
|--------------------------|---------|--------------------|--------|
|                          | 2018    | 2017               | 2016   |
| Risk-free interest rate  | 2.5 %   | 2.0 %              | 1.8 %  |
| Expected dividend yield  | — %     | — %                | — %    |
| Expected term (in years) | 2.7     | 3.7                | 4.7    |
| Expected volatility      | 112.7 % | 103.5 %            | 97.5 % |

The expected volatility is based on the historic volatility for the equity securities underlying the warrants and is calculated based on a period of time commensurate with the expected term assumption. The expected term is based on the remaining contractual life of the warrants on each measurement date. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the warrants. The expected dividend yield is assumed to be zero as the entity that issued the warrants has never paid and has not indicated any intention to pay dividends.

# 4. Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following:

|  | As of December 31, |    |       |  |  |
|--|--------------------|----|-------|--|--|
|  | 2018 2017          |    |       |  |  |
|  | (in tho            | s) |       |  |  |
| Prepaid research and development contracts | \$<br>4,497        | \$ | 1,330 |  |  |
| Other current assets                       | 1,360              |    | 766   |  |  |
| Prepaid insurance                          | 617                |    | 520   |  |  |
| Accrued interest receivable                | 201                |    | 122   |  |  |
| Total                                      | \$<br>6,675        | \$ | 2,738 |  |  |

# 5. Property and equipment, net

Property and equipment, net consists of the following:

|                                | As of December 31, |    |         |  |
|--------------------------------|--------------------|----|---------|--|
|                                | 2018 2017          |    |         |  |
|                                | (in thousands)     |    |         |  |
| Leasehold improvements         | \$<br>7,035        | \$ | 6,421   |  |
| Laboratory equipment           | 8,843              |    | 5,262   |  |
| Furniture and office equipment | 1,675              |    | 1,565   |  |
| Other                          | 306                |    | 25      |  |
| Construction in progress       | 19                 |    | _       |  |
| Total property and equipment   | <br>17,878         |    | 13,273  |  |
| Less: accumulated depreciation | <br>(5,107)        |    | (2,990) |  |
| Property and equipment, net    | \$<br>12,771       | \$ | 10,283  |  |

The Company recorded \$2.1 million, \$1.6 million, and \$0.6 million in depreciation expense during the years ended December 31, 2018, 2017, and 2016, respectively.

# 6. Accrued expenses

Accrued expenses consist of the following:

|                                | As of December 31, |    |        |  |  |
|--------------------------------|--------------------|----|--------|--|--|
|                                | <br>2018 2017      |    |        |  |  |
|                                | <br>(in thousands) |    |        |  |  |
| Employee compensation costs    | \$<br>3,780        | \$ | 3,383  |  |  |
| Research and development costs | 3,555              |    | 5,780  |  |  |
| Professional services          | 1,448              |    | 1,762  |  |  |
| Accrued goods and services     | 784                |    | 388    |  |  |
| Patent costs                   | 120                |    | 120    |  |  |
| Other                          | 101                |    | 64     |  |  |
| Total                          | \$<br>9,788        | \$ | 11,497 |  |  |

# 7. Commitments and contingencies

### **Operating Leases**

During April 2014, the Company entered into an agreement to lease the 75 Sidney Street facility under a non-cancelable operating lease that would have expired December 15, 2019. The lease includes two renewal options, each for five-year terms and at fair market value upon exercise. The lease contains escalating rent clauses which require higher rent payments in future years. The Company expenses rent on a straight-line basis over the term of the lease, including any rent-free periods.

In December 2015, the Company executed an amendment to the 75 Sidney Street lease to extend its term, and executed an agreement to lease a facility at 64 Sidney Street until December 31, 2024. The facility at 64 Sidney Street includes laboratory and office space, and was ready for occupancy in early 2017.

In February 2018, the Company executed a second amendment to the 75 Sidney Street lease to lease additional space to support its continued growth. The additional facility includes laboratory and office space, and was ready for occupancy in mid-2018.

In June 2018, the Company executed a third amendment to the 75 Sidney Street lease to lease additional space to further support its continued growth. The additional facility includes laboratory and office space, and was ready for occupancy in late 2018. The third amendment extended the term of the 75 Sidney Street lease until November 30, 2026. Additionally, the Company executed a second amendment to the 64 Sidney Street lease to extend that lease until November 30, 2026.

The Company received leasehold improvement incentives from the landlord totaling \$1.3 million and \$3.5 million for 75 Sidney Street and 64 Sidney Street, respectively. The Company recorded these incentives as a component of deferred rent and is amortizing these incentives as a reduction of rent expense over the life of the lease. The leasehold improvements have been recorded as fixed assets. The Company is entitled to receive approximately \$0.3 million of leasehold improvements for the additional space at 75 Sidney Street.

Rent expense of approximately \$4.0 million, \$2.9 million, and \$2.0 million was incurred during the years ended December 31, 2018, 2017, and 2016, respectively.

Future annual minimum lease payments at December 31, 2018 are as follows:

|       | Total Minimum  |
|-------|----------------|
|       | Lease Payments |
|       | (in thousands) |
| 2019  | 4,325          |
| 2020  | 4,731          |
| 2021  | 4,863          |
| 2022  | 5,001          |
| 2023  | 5,141          |
| 2024+ | 16,783         |
|       | \$ 40,844      |

### **Significant Agreements**

### **Sanofi Genzyme Collaboration Agreement**

Summary of Agreement

In February 2015, the Company entered into an agreement with Sanofi Genzyme (the "Sanofi Genzyme Collaboration Agreement") which included a non-refundable upfront payment of \$65.0 million. In addition, contemporaneous with entering into the Sanofi Genzyme Collaboration Agreement, Sanofi Genzyme entered into a Series B Stock Purchase Agreement, under which Sanofi Genzyme purchased 10,000,000 shares of Series B Preferred Stock for \$30.0 million. The fair value of the Series B Preferred Stock at the time of issuance was approximately \$25.0 million. The \$5.0 million premium over the fair value is accounted for as additional consideration under the Sanofi Genzyme Collaboration Agreement.

Under the Sanofi Genzyme Collaboration Agreement, the Company granted Sanofi Genzyme an exclusive option to license, develop and commercialize (i) ex-U.S. rights to the following programs, which are referred to as Split Territory Programs; VY-AADC ("Parkinson's Program"), VY-FXN01 ("Friedreich's ataxia Program"), a future program to be designated by Sanofi Genzyme ("Future Program), and VY-HTT01 ("Huntington's Program"), with an incremental option to co-commercialize VY-HTT01 in the United States and (ii) worldwide rights to VY-SMN101 ("Spinal Muscular Atrophy Program"). Sanofi Genzyme's option for the Split Territory Programs and the Spinal Muscular

Atrophy Program is triggered following the completion of the first proof-of-principle human clinical study ("POP Study"), on a program by program basis.

Prior to any option exercise by Sanofi Genzyme, the Company will collaborate with Sanofi Genzyme in the development of products under each Split Territory Program and the Spinal Muscular Atrophy Program pursuant to a written development plan and under the guidance of an Alliance Joint Steering Committee ("AJSC"), comprised of an equal number of employees from the Company and Sanofi Genzyme.

The Company is required to use commercially reasonable efforts to develop products under each Split Territory Program and the Spinal Muscular Atrophy Program through the completion of the applicable POP Study. During the development of these joint programs, the activities are guided by a Development Advisory Committee ("DAC"). The DAC may elect to utilize certain Sanofi Genzyme technology relating to the Parkinson's Program, the Huntington's Program or generally with the manufacture of Split Territory Program products.

The Company is solely responsible for all costs incurred in connection with the development of the Split Territory Programs and the Spinal Muscular Atrophy Program products prior to the exercise of an option by Sanofi Genzyme with the exception of the following: (i) at the Company's request and upon mutual agreement, Sanofi Genzyme will provide "in-kind" services valued at up to \$5.0 million and (ii) Sanofi Genzyme shall be responsible for the costs and expenses of activities under the Huntington's Program development plan to the extent such activities are covered by financial support Sanofi Genzyme is entitled to receive from a patient advocacy group, collectively Sanofi Genzyme "in-kind" and other funding.

Other than the Parkinson's Program (for which a POP Study has already been completed), if the Company does not initiate a POP Study for a given Split Territory Program by December 31, 2026 (or for the Future Program by the tenth anniversary of the date the Future Program is nominated by Sanofi Genzyme), and Sanofi Genzyme has not terminated the Sanofi Genzyme Collaboration Agreement with respect to the collaboration program, then Sanofi Genzyme shall be entitled, as its sole and exclusive remedy, to a credit of \$10.0 million for each such program against other milestone or royalty payments payable by Sanofi Genzyme under the Sanofi Genzyme Collaboration Agreement. However, if the POP Study is not initiated due to a regulatory delay or a force majeure event, such time period shall be extended for so long as such delay continues.

With the exception of the Parkinson's Program, Sanofi Genzyme is required to pay an option exercise payment of \$20.0 million or \$30.0 million for each Split Territory Program, as well as the Spinal Muscular Atrophy Program.

Upon Sanofi Genzyme's exercise of its option to license a given product in a Split Territory Program ("Split Territory Licensed Product"), the Company will have sole responsibility for the development of such Split Territory Licensed Product in the United States and Sanofi Genzyme shall have sole responsibility for development of such Split Territory Licensed Product in the rest of the world. The Company and Sanofi Genzyme will have shared responsibility for execution of ongoing development of such Split Territory Licensed Product that is not specific to either territory, including costs associated therewith. The Company is responsible for all commercialization activities relating to Split Territory Licensed Products in the United States, including all of the associated costs. Sanofi Genzyme is responsible for all commercialization activities relating to the Split Territory Licensed Products in the rest of the world, including all of the associated costs. If Sanofi Genzyme exercised its co-commercialization rights, Sanofi Genzyme will be the lead party responsible for all commercialization activities related to the Huntington's Licensed Product in the United States.

Upon exercise of the option, Sanofi Genzyme shall have the sole right to develop the Spinal Muscular Atrophy Product worldwide. Sanofi Genzyme shall be responsible for all of the development costs that occur after the option exercise date for the Spinal Muscular Atrophy Program. Sanofi Genzyme is also responsible for commercialization activities relating to the Spinal Muscular Atrophy Product worldwide.

Sanofi Genzyme is required to pay the Company for specified regulatory and commercial milestones, if achieved, up to \$540.0 million across all programs. The Company is no longer entitled to receive a total of \$105.0 million related to regulatory and commercial milestone payments for VY-AADC as a result of Sanofi Genzyme's decision to not exercise its option for the Parkinson's Program (the "PD Opt-Out"). The regulatory approval milestones are payable upon either regulatory approval in the United States or regulatory and reimbursement approval in the European Union and range from \$40.0 million to \$50.0 million per milestone, with an aggregate total of \$220.0 million, after accounting for the PD Opt-Out. The commercial milestones are payable upon achievement of specified annual net

sales in each program and range from \$50.0 million to \$100.0 million per milestone, with an aggregate total of \$320.0 million, after accounting for the PD Opt-Out.

In addition, to the extent any Split Territory Licensed Products or the Spinal Muscular Atrophy Licensed Product are commercialized, the Company is entitled to tiered royalty payments ranging from the mid-single digits to mid-teens based on a percentage of net sales by Sanofi Genzyme. Sanofi Genzyme is entitled to receive tiered royalty payments related to sales of the Split Territory Licensed Product ranging from the low-single digits to mid-single digits based on a percentage of net sales by the Company depending on whether the Company uses Sanofi Genzyme technology in the Split Territory Licensed Product. If Sanofi Genzyme elects to co-commercialize VY-HTT01 in the United States, the Company and Sanofi Genzyme will share in any profits or losses from VY-HTT01 product sales.

The Sanofi Genzyme Collaboration Agreement will continue in effect until the later of (i) the expiration of the last to expire of the option rights and (ii) the expiration of all payment obligations unless sooner terminated by the Company or Sanofi Genzyme. The Company and Sanofi Genzyme have customary termination rights including the right to terminate for an uncured material breach of the agreement committed by the other party and Sanofi Genzyme has the right to terminate for convenience.

### Accounting Analysis

At inception, the Sanofi Genzyme Collaboration Agreement included the following performance obligations: (i) research and development services for each of the Split Territory Programs and the Spinal Muscular Atrophy Program, (ii) participation in the AJSC, (iii) participation in the DAC and (iv) a material right associated with an option to obtain a development and commercial license in the Parkinson's Program ("PD Material Right"). The Company determined that the option to obtain a development and commercial license in the Parkinson's Program was a material right under ASC 606 primarily because there were no additional option exercise payments payable by Sanofi Genzyme at the time of option exercise. Therefore, the PD Material Right was considered a performance obligation at the inception of the arrangement. The options in the other Split Territory Programs and the Spinal Muscular Atrophy Program do not provide a material right to the standalone selling price for the underlying goods. Therefore, the other Split Territory Programs and the Spinal Muscular Atrophy Program options are not performance obligations at inception.

The Company has identified \$74.6 million of total transaction price consisting of the \$65.0 million upfront fee, the \$5.0 million premium paid in excess of fair value of the Series B Preferred Stock and \$4.6 million of Sanofi Genzyme "in-kind" funding, which represents the transaction price at adoption. Additional consideration to be paid to the Company upon the exercise of the license options by Sanofi Genzyme or upon reaching certain milestones are excluded from the transaction price as they relate to option fees and milestones that can only be achieved subsequent to the option exercise or are outside of the initial contract term.

The Company has allocated the transaction price to the separate performance obligations based on their relative standalone selling price. For all performance obligations, the Company determined the standalone selling price at contract inception based on each obligation's estimated standalone selling price ("ESP"). The Company determined the ESP for the service related deliverable for the research and development activities based on internal estimates of the costs to perform the services, including expected internal expenses and expenses with third parties for services and supplies, marked up to include a reasonable profit margin and adjusted for the scope of the potential license. Significant inputs used to determine the total expense of the research and development activities include, the length of time required and the number and costs of various studies that will be performed to complete the applicable POP Study. The ESP for the AJSC and DAC have been estimated based on the costs incurred to participate in the committees, marked up to include a reasonable profit margin. The ESP for the PD Material Right was determined based on the estimated value of the license adjusted for the estimated probability that the option would be exercised by Sanofi Genzyme.

Based on the relative standalone selling price allocation, the allocation of the transaction price to the separate performance obligations was as follows:

| nit of Accounting                      |       | Amount    |
|--|-------|-----------|
|  | (in t | housands) |
| Research and Development Services for: | ,     | Í         |
| Huntington's Program                   | \$    | 14,228    |
| Parkinson's Program                    |       | 6,040     |
| Friedreich's ataxia Program            |       | 14,821    |
| Spinal Muscular Atrophy Program        |       | 29,116    |
| Future Program                         |       | 2,239     |
| Committee Obligations:                 |       |           |
| AJSC                                   |       | 133       |
| DAC                                    |       | 207       |
| PD Material Right                      |       | 7,855     |
| Total                                  | \$    | 74,639    |

The Company recognizes the amounts associated with research and development services and committee obligations on a proportional performance basis over the period of service using input-based measurements such as costs incurred to date, to estimate proportion performed, and remeasures its progress towards completion at the end of each reporting period. The amount allocated to the PD Material Right was initially deferred and recognized in full prior to the adoption of ASC 606.

In October 2017, Sanofi Genzyme decided not to exercise the PD Material Right. Therefore, in the year ended December 31, 2017, the Company recognized revenue of \$7.8 million of consideration which had been allocated to the PD Material Right. In addition, revenue recognized during the years ended December 31, 2017 and 2016 include amounts recognized related to consideration allocated to research and development services for various programs under the Sanofi Genzyme Collaboration Agreement. During 2017 the Company reassessed the estimated period of performance for each of the units of accounting and determined that the estimated period would be extended for two units of accounting. During 2016 the Company deprioritized the development of VY-SMN101 for the treatment of Spinal Muscular Atrophy. As a result, the Company ceased recognizing the revenue allocated to this program. These adjustments were made on a prospective basis and resulted in decreases in revenue recognized by \$2.1 million and \$9.5 million, respectively, for the year ended December 31, 2017.

During the years ended December 31, 2018, 2017, and 2016, the Company recognized \$0.7 million, \$10.1 million, and \$14.2 million, respectively, of revenue associated with its collaboration with Sanofi Genzyme related to research and development services performed during the period and for consideration allocated to the PD Material Right, which was recognized during 2017. As of December 31, 2018, there is \$50.9 million of deferred revenue related to the Sanofi Genzyme Collaboration Agreement, which is classified as either current or noncurrent in the accompanying balance sheet based on the period the services are expected to be delivered.

Costs incurred relating to the programs that Sanofi Genzyme has the option to license under the Sanofi Genzyme Collaboration Agreement consist of internal and external research and development costs, which primarily include: salaries and benefits, lab supplies and preclinical research studies. All costs are included in research and development expenses in the Company's statement of operations during the years ended December 31, 2018, 2017, and 2016.

# **AbbVie Tau Collaboration Agreement**

Summary of Agreement

In February 2018, the Company entered into an exclusive collaboration and option agreement (the "AbbVie Tau Collaboration Agreement") with AbbVie for the research, development and commercialization of AAV and other virus-based gene therapy products for the treatment of diseases of the central nervous system and other neurodegenerative diseases related to defective or excess aggregation of tau protein in the human brain, including Alzheimer's disease.

Under the AbbVie Tau Collaboration Agreement, the Company and AbbVie have agreed to collaborate on the research and development of specified vectorized antibody compounds comprised of an AAV or other viral capsid and a virus vector genome that encodes one or more antibodies that target and bind to a tau protein. The collaboration is comprised of a research period (the "Research Period"), a development period (the "Development Period"), and an exclusive license option (the "License Option"). The AbbVie Tau Collaboration Agreement included a non-refundable upfront payment of \$69.0 million for services during the Research Period.

During the Research Period, each party has agreed to identify up to five antibodies for inclusion in the collaboration. Subject to certain conditions and exceptions, the parties will select up to three antibodies (each, a "Research Antibody") as candidates for creation of research compounds (each, a "Research Compound"), with AbbVie having the right to select two of the three Research Antibodies. The Company is required to use diligent efforts to conduct antibody engineering and other research activities to create Research Compounds and to develop product candidates containing or comprised of such Research Compounds ("Product Candidates"). The Company is solely responsible for its costs and expenses during the Research Period. During a specified portion of the Research Period, AbbVie may exercise one or more of its exclusive development options (each, a "Development Option") to select up to a total of three Research Compounds (the "Selected Research Compounds") and their corresponding Product Candidates (the "Selected Product Candidates") to proceed to the Development Period.

Upon AbbVie's exercise of a Development Option, AbbVie will pay the Company \$80.0 million for the first Selected Research Compound and \$30.0 million each for up to two additional Selected Research Compounds. During the Development Period, the Company is obligated to use diligent efforts to conduct development activities, including Investigational New Drug application-enabling and Phase 1 clinical trial activities, for the Selected Research Compounds and corresponding Selected Product Candidates. The Company will be solely responsible for the costs and expenses during the Development Period. During a specified portion of the Development Period (the "License Option Period"), AbbVie may exercise its License Option to further develop and commercialize all of the Research Compounds (the "Licensed Compounds"), and corresponding product candidates (the "Licensed Products"). Upon AbbVie's exercise of its License Option, AbbVie will provide a one-time payment of \$75.0 million to the Company, and the Company will grant to AbbVie an exclusive, worldwide license, with the right to sublicense, under certain of the Company's intellectual property rights to develop and commercialize the Licensed Compounds and the Licensed Products for all human diagnostic, prophylactic and therapeutic uses. In addition, after AbbVie's exercise of the License Option, the Company has certain obligations to complete any remaining research and development activities that have not been completed for any Research Compounds and Product Candidates.

The Company's research and development activities will be conducted pursuant to the plans agreed to by the parties and overseen by a joint governance committee ("JGC") as detailed in the AbbVie Tau Collaboration Agreement. Any material amendment to the research or development plans must be mutually agreed to by the Company and AbbVie, which may be through the JGC.

Under the AbbVie Tau Collaboration Agreement, AbbVie is required to use commercially reasonable efforts to develop and commercialize at least one Licensed Product in each of the United States, Japan, the United Kingdom, Germany, France, Italy, and Spain. After exercise of the License Option, AbbVie is solely responsible for all development and commercialization activities relating to Licensed Compounds and Licensed Products at its sole cost and expense, subject to the agreed-upon research and development plans. The Company may elect to share in AbbVie's development costs relating to a Licensed Product on an indication-by-indication basis in exchange for a specified increase in royalties (a "Cost-Sharing Option"). If the Company exercises a Cost-Sharing Option, the Company may either reimburse AbbVie for AbbVie's applicable development costs or, in the case of certain budget overruns, AbbVie may instead deduct applicable development costs, up to a specified cap, from milestone and royalty payments owed by AbbVie to the Company.

Under the AbbVie Tau Collaboration, the Company is eligible to receive specified development and first-sale milestone payments for each Licensed Compound of up to an aggregate of \$550.0 million in the case of an Alzheimer's disease indication, up to \$230.0 million in the case of the first indication other than Alzheimer's disease and up to \$115.0 million for a subsequent non-Alzheimer's disease indication. Additionally, the Company is eligible to receive tiered, escalating royalties, in a range from a high-single digit to a mid-to-high teen (or, if the Company has exercised its Cost-Sharing Option, low-twenties) percentage of aggregate net sales of Licensed Products on a Licensed Compound by Licensed Compound basis, subject to potential reductions in certain circumstances. For each Licensed Product, AbbVie

also has the right to decrease or eliminate its royalty payments on such Licensed Product in exchange for a one-time payment by AbbVie at a fair market value to be negotiated by the parties or determined pursuant to dispute resolution procedures specified in the AbbVie Tau Collaboration Agreement.

Unless earlier terminated, the AbbVie Tau Collaboration Agreement will expire on the earliest to occur of the expiration of (i) the Development Option Period, without AbbVie's exercise of a Development Option; (ii) the License Option Period, without AbbVie's exercise of its License Option; and (iii) the last-to-expire royalty term with respect to all Licensed Products in all countries. The Company and AbbVie have customary termination rights including the right to terminate for an uncured material breach of the agreement committed by the other party, and AbbVie has the right to terminate for convenience.

### Accounting Analysis

The Company assessed the promised goods and services under the AbbVie Tau Collaboration Agreement, in accordance with ASC 606, and determined that the AbbVie Tau Collaboration Agreement includes the following performance obligations: (i) research services during the Research Period (through the delivery of the final research report) including the identification of the Research Antibodies, conduct of research activities and provision of information to AbbVie to allow AbbVie to determine whether to exercise up to three Development Options to be rendered (collectively, the "Research Services"), and (ii) a material right associated with the Development Option on the first Research Compound and associated Product Candidates ("First Development Option Material Right"). The first Development Option provides AbbVie with (i) additional development services on a selected Research Compound and (ii) the ability to exercise the License Option. The Company has concluded the option provides a material right as the consideration paid by AbbVie upon exercise of the first Development Option is less than the amount that the Company would otherwise expect to receive outside the context of the contract.

The Company has concluded that the First Development Option Material Right is a separate performance obligation under ASC 606 as AbbVie is provided additional services and a License Option for additional consideration that represents a significant discount from amounts that would otherwise be offered outside the context of the contract. The First Development Option Material Right is distinct from the other performance obligations in the arrangement as it is an option in the contract that is not required for AbbVie to obtain the benefit of the other promised goods or services in the arrangement. The First Development Option Material Right does not include the underlying goods or services that are delivered upon exercise of the option, but rather represents the value to the customer of having the right to obtain development services and the right to the License Option at an advantageous price.

The Company received a nonrefundable, upfront payment of \$69.0 million as consideration under the AbbVie Tau Collaboration Agreement, which represents the transaction price at inception. Additional consideration to be paid to the Company upon the exercise of the Development and License Options by AbbVie or upon reaching certain milestones are excluded from the transaction price as they relate to option fees and milestones that can only be achieved subsequent to the option exercise or are outside of the initial contact term.

The Company has allocated the transaction price to the separate performance obligations based on their relative standalone selling price. The Company determined the standalone selling price at contract inception based on each obligation's ESP. The Company determined the ESP for the research services obligation based on internal estimates of the costs to perform the services, including expected internal expenses and expenses with third parties for services and supplies, inclusive of a reasonable profit margin. Significant inputs used to determine the total expense of the research services include the length of time required, the internal hours expected to be incurred on the services and the number and costs of various studies that will be performed to complete the Research Plan. The ESP for the First Development Option Material Right was determined based on the fees AbbVie would pay to exercise the Development and License Options, the estimated costs to perform the development services, inclusive of a reasonable profit margin, the estimated value of the License Option using comparable transactions, and the probability that the Development and License Options would be exercised by AbbVie.

Based on the relative standalone selling price, the allocation of the transaction price to the separate performance obligations was as follows:

| Performance Obligation | Aı  | mount |
|------------------------|-----|-------|
|                        |     |       |
| F                      | -23 |       |
| -                      | 20  |       |

|   | (in th | ousands) |
|---|--------|----------|
| Research Services                       | \$     | 34,482   |
| First Development Option Material Right |        | 34,518   |
| Total                                   | \$     | 69,000   |

The Company recognizes the amounts associated with Research Services on a proportional performance basis over the period of service using input-based measurements of total cost of research incurred to estimate proportion performed and remeasures its progress towards completion at the end of each reporting period. The amount allocated to the First Development Option Material Right is recorded as deferred revenue and will be recognized either over the period in which goods and services underlying the option are transferred or upon expiry of the option.

During the year ended December 31, 2018, the Company recognized \$6.9 million of revenue associated with the AbbVie Tau Collaboration related to the Research Services performed during the period. As of December 31, 2018, there is \$62.1 million of deferred revenue related to the AbbVie Tau Collaboration Agreement, which is classified as either current or noncurrent in the accompanying balance sheet based on the period the goods or services are expected to be delivered.

Costs incurred relating to the AbbVie Tau Collaboration Agreement consist of internal and external research and development costs, which primarily include salaries and benefits, lab supplies, and preclinical research studies. All of these costs are included in research and development expenses in the Company's statement of operations during the year ended December 31, 2018.

### **MRI Interventions License and Securities Purchase Agreements**

Summary of Agreement

In September 2016, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") and a license agreement (the "MRIC License Agreement") with MRI Interventions, Inc. ("MRIC"). MRIC is the primary supplier of the ClearPoint® System, which is being used by the Company in ongoing development and clinical trials. Under the Securities Purchase Agreement, the Company paid \$2.0 million for shares of MRIC common stock and a warrant to purchase additional shares of MRIC common stock. The Company also entered into the MRIC License Agreement, which provided for certain rights to MRIC technology and for MRIC to transfer the rights and know-how to manufacture the ClearPoint System to enable the Company to utilize an alternative supplier for the ClearPoint System for use in the Company's development and clinical trials. During 2017, the Company terminated the MRIC License Agreement and all prior and future commitments and obligations under such agreement became null and void. The Company continues to hold the common stock and warrants to purchase additional shares of common stock as an available-for-sale security and non-current asset, respectively.

In May 2018, the Company entered into a master services and supply agreement with MRIC (the "MRIC Supply Agreement") which provides for MRIC to perform certain manufacturing, supply, development and services as requested by the Company, including the supply of the ClearPoint System and cannula devices.

As of December 31, 2018, the Company continued to hold the common stock and warrants to purchase additional shares of common stock as an available-for-sale security and non-current asset, respectively.

# **Other Agreements**

During 2018, 2017, and 2016, the Company entered into various agreements with contract research organizations and institutions to license intellectual property. In consideration for the licensed rights the Company generally made upfront payments, which were recorded as research and development expense as the acquired technologies were considered in-process research and development. The license agreements obligate the Company to make additional payments that are contingent upon specific clinical trial and regulatory approval milestones being achieved as well as royalties on future product sales. The agreements to license intellectual property include potential milestone payments that are dependent upon the development of products licensed under the agreements and contingent upon the achievement of clinical trial or regulatory approval milestones. As of December 31, 2018 and 2017, there have

been no milestones achieved. The Company can generally terminate the license agreements upon 30-90 days prior written notice.

Additionally, certain license agreements require the Company to reimburse the licensor for certain past and ongoing patent related expenses. During the year ended December 31, 2018, 2017, and 2016, the Company incurred \$0.6 million, \$0.8 million, and \$1.8 million of expense, respectively, related to these reimbursable patent costs which are recorded as general and administrative expense

During the year ended December 31, 2016, the Company entered into a research and development funding arrangement with a non-profit organization that provides up to \$4.0 million in funding to the Company upon the achievement of clinical and development milestones. The agreement provides that the Company repay amounts received under certain circumstances including termination of the agreement, and to pay an amount up to 2.6 times the funding received upon successful development and commercialization of any products developed. During the year ended December 31, 2017, the Company earned a milestone payment of \$1.0 million. The Company has evaluated the arrangement and has concluded that it represents a research and development financing arrangement as it is probable that the Company will repay amounts received under the arrangement. As a result, the \$1.0 million earned through the year ended December 31, 2017 is recorded as a non-current liability in the consolidated balance sheet.

### Litigation

The Company is not a party to any material legal matters or claims and does not have contingency reserves established for any litigation liabilities as of December 31, 2018 or 2017.

### 8. Preferred stock

The Company has authorized preferred stock amounting to 5,000,000 shares as of December 31, 2018 and 2017. The authorized preferred stock was classified under stockholders' equity at December 31, 2018.

### 9. Common stock

As of December 31, 2018 and 2017, the Company had authorized 120,000,000 shares of common stock, at \$0.001 par value per share.

### General

The voting, dividend and liquidation rights of the holders of the common stock are subject to and qualified by the rights, powers and preferences of the holders of preferred stock. The common stock has the following characteristics:

### Voting

The holders of shares of common stock are entitled to one vote for each share of common stock held at all meetings of stockholders and written actions in lieu of meetings.

# Dividends

The holders of shares of common stock are entitled to receive dividends, if and when declared by the Board of Directors. No dividends have been declared or paid by the Company since its inception.

### Liquidation

The holders of shares of common stock are entitled to share ratably in the Company's remaining assets available for distribution to its stockholders in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or upon occurrence of a deemed liquidation event.

#### Shares Reserved For Future Issuance

|   | As of December 31, |           |  |
|---|--------------------|-----------|--|
|   | 2018               | 2017      |  |
| Shares reserved for vesting of restricted stock awards under the Founder  |                    |           |  |
| Agreements  | 235,294            | 366,914   |  |
| Shares reserved for vesting of restricted stock awards under the 2014 Option and  |                    |           |  |
| Stock Plan  | _                  | 191,065   |  |
| Shares reserved for exercise of outstanding stock options   | 4,225,152          | 3,143,566 |  |
| Shares reserved for issuances under the 2015 Stock Option Plan  | 1,973,227          | 1,501,005 |  |
| Shares reserved for issuances under the 2015 Stock Option Plan<br>Shares reserved for issuances under the 2015 Employee Stock Purchase Plan | 963,386            | 730,860   |  |
| • •   | 7,397,059          | 5,933,410 |  |

### 10. Stock-based compensation

### 2014 Stock Option and Grant Plan

In January 2014, the Company adopted the 2014 Stock Option and Grant Plan (the "2014 Plan"), under which it could grant incentive stock options, non-qualified stock options, restricted stock awards, unrestricted stock awards, or restricted stock units to purchase up to 823,529 shares of Common Stock to employees, officers, directors and consultants of the Company.

In April 2014, the Company amended the Plan to allow for the issuance of up to 1,411,764 shares of Common Stock. In August 2014, April 2015, August 2015 and October 2015 the Company further amended the Plan to allow for the issuance of up to 2,000,000, 2,047,058, 2,669,411 and 2,998,823 shares of Common Stock, respectively. During 2014 the Company issued only restricted stock awards under the Plan and during 2015 the Company only granted stock options.

The terms of stock option agreements, including vesting requirements, were determined by the Board of Directors and were subject to the provisions of the 2014 Plan. Restricted stock awards granted by the Company generally vest based on each grantee's continued service with the Company during a specified period following grant. Stock options granted to employees generally vest over four years, with 25% vesting on the one year anniversary and 75% vesting ratably, on a monthly basis, over the remaining three years. Stock options granted to non-employee consultants generally vest monthly over a period of one to four years.

### Founder Awards

In January 2014, the Company issued 1,188,233 shares of restricted stock to its Founders at an original issuance price of \$0.0425 per share. Of the total restricted shares awarded to the Founders, 835,292 shares generally vest over one to four years, based on each Founder's continued service to the Company in varying capacity as a Scientific Advisory Board member, consultant, director, officer or employee, as set forth in each grantee's individual restricted stock purchase agreement.

The remaining 352,941 of the shares issued will begin vesting upon the achievement of certain performance objectives as well as continued service to the Company, as set forth in the agreements. These performance conditions are tied to certain milestone events specific to the Company's corporate goals, including but not limited to preclinical and clinical development milestones related to the Company's product candidates. Stock-based compensation expense associated with these performance-based awards will be recognized when the achievement of the performance condition is considered probable, using management's best estimates. Management concluded that the achievement of the performance milestone for one of the three performance-based awards had been met during 2016. Accordingly, stock-based compensation expense in the amount of \$0.3 million, \$1.4 million, and \$1.1 million was recorded in the years ended December 31, 2018, 2017, and 2016, respectively.

# 2015 Stock Option Plan

In October 2015, the Company's board of directors and stockholders approved the 2015 Stock Option and Incentive Plan "(2015 Stock Option Plan"), which became effective upon the completion of the IPO. The 2015 Stock Option Plan provides the Company with the flexibility to use various equity-based incentive and other awards as compensation tools to motivate its workforce. These tools include stock options, stock appreciation rights, restricted stock, restricted stock units, unrestricted stock, performance share awards and cash-based awards. The 2015 Stock

Option Plan replaced the 2014 Plan. Any options or awards outstanding under the 2014 Plan remained outstanding and effective. The number of shares initially reserved for issuance under the 2015 Stock Option Plan is the sum of (i) 1.311,812 shares of common stock and (ii) the number of shares under the 2014 Plan that are not needed to fulfill the Company's obligations for awards issued under the 2014 Plan as a result of forfeiture, expiration, cancellation, termination or net issuances of awards thereunder. The number of shares of common stock that may be issued under the 2015 Stock Option Plan is also subject to increase on the first day of each fiscal year by up to 4% of the Company's issued and outstanding shares of common stock on the immediately preceding December 31.

Effective January 1, 2016, 2017, 2018 and 2019, an additional 1,069,971, 1,070,635, 1,285,200, and 1,302,830 shares of common stock, respectively, were added to the Company's 2015 Stock Option Plan pursuant to its "evergreen" provision, for future issuance. During the year ended December 31, 2018, the Company granted options to purchase 2,215,891 shares of common stock to employees and directors. As of December 31, 2018, there were 1,973,227 shares available for future issuance under the 2015 Stock Option Plan.

### 2015 Employee Stock Purchase Plan

In October 2015, the Company's board of directors and stockholders approved the 2015 Employee Stock Purchase Plan (the "2015 ESPP"). Under the 2015 ESPP, all full-time employees of the Company are eligible to purchase common stock of the Company twice per year, at the end of each six-month payment period. During each payment period, eligible employees who so elect, may authorize payroll deductions in an amount of 1% to 10% (whole percentages only) of the employee's base pay for each payroll period. At the end of each payment period, the accumulated deductions are used to purchase shares of common stock from the Company at a discount. A total of 262,362 shares of common stock were initially authorized for issuance under this plan. The 2015 ESPP became effective upon the completion of the IPO. Effective January 1, 2016, 2017, 2018, and 2019, a total of 267,492, 267,658, 321,300, and 325,707 shares of common stock, respectively, were added to the 2015 ESPP, pursuant to its evergreen provision. for future issuance. The Company issued 88,774 shares of common stock under the 2015 ESPP in the year ended December 31, 2018.

### **Stock-based Compensation Expense**

Total compensation cost recognized for all stock-based compensation awards in the statements of operations and comprehensive loss is as follows:

|                                  | <br>Year ended December 31, |     |       |    |       |  |  |
|----------------------------------|-----------------------------|-----|-------|----|-------|--|--|
|                                  | <br>2018 2017 2016          |     |       |    |       |  |  |
|                                  | <br>(in thousands)          |     |       |    |       |  |  |
| Research and development         | \$<br>4,717                 | `\$ | 5,367 | \$ | 4,296 |  |  |
| General and administrative       | <br>10,993                  |     | 3,871 |    | 2,014 |  |  |
| Total stock-compensation expense | \$<br>15,710                | \$  | 9,238 | \$ | 6,310 |  |  |

### Restricted Stock

A summary of the status of and changes in unvested restricted stock was as follows:

|  | Shares    | Weighted<br>Average<br>Grant Date<br>Fair Value<br>Per Share |      |  |
|--|-----------|--|------|--|
| Unvested restricted common stock as of December 31, 2017 | 557,979   | \$   | 0.70 |  |
| Issued   |           |  |      |  |
| Vested   | (319,891) | \$   | 0.84 |  |
| Repurchased  | (2,794)   | \$   | 1.11 |  |
| Unvested restricted common stock as of December 31, 2018 | 235,294   | \$   | 0.51 |  |

The expense related to awards granted to employees and non-employees was \$0.1 million and \$0.4 million, respectively, for the year ended December 31, 2018. The expense related to awards granted to employees and non-

employees was \$0.5 million and \$2.7 million, respectively, for the year ended December 31, 2017. The expense related to awards granted to employees and non-employees was \$0.5 million and \$2.6 million, respectively, for the year ended December 31, 2016.

### **Stock Options**

A summary of the status of, and changes in, stock options was as follows:

|  | Shares    | Weighted<br>Average<br>Exercise<br>Price |       | Remaining<br>Contractual<br>Life<br>(in years) | gregate<br>itrinsic<br>Value<br>housands) |
|--|-----------|--|-------|--|---|
| Outstanding at December 31, 2017                 | 3,143,566 | \$                                       | 11.82 |  |   |
| Granted  | 2,215,891 | \$                                       | 20.78 |  |   |
| Exercised  | (384,186) | \$                                       | 10.13 |  |   |
| Cancelled or forfeited                           | (750,119) | \$                                       | 16.13 |  |   |
| Outstanding at December 31, 2018                 | 4,225,152 | \$                                       | 15.91 | 8.4  | \$<br>578                                 |
| Exercisable at December 31, 2018                 | 1,531,832 | \$                                       | 12.55 | 7.3  | \$<br>507                                 |
| Vested and expected to vest at December 31, 2018 | 4,225,152 | \$                                       | 15.91 | 8.4  | \$<br>578                                 |

Using the Black-Scholes option pricing model, the weighted average fair value of options granted to employees and directors during the year ended December 31, 2018 was \$13.87. The stock-based compensation expense related to stock option awards granted to employees and directors was \$14.9 million, \$5.5 million, and \$3.0 million for the years ended December 31, 2018, 2017, and 2016, respectively.

The fair value of each option issued to employees and directors was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

|                          | Year   | Year ended December 31, |        |  |  |  |  |
|--------------------------|--------|-------------------------|--------|--|--|--|--|
|                          | 2018   | 2017                    | 2016   |  |  |  |  |
| Risk-free interest rate  | 2.8 %  | 2.0 %                   | 1.5 %  |  |  |  |  |
| Expected dividend yield  | — %    | — %                     | — %    |  |  |  |  |
| Expected term (in years) | 6.0    | 6.0                     | 6.0    |  |  |  |  |
| Expected volatility      | 74.4 % | 73.7 %                  | 73.1 % |  |  |  |  |

There were no new options granted to non-employees during the year ended December 31, 2018. Unvested options granted to non-employees are revalued at each measurement period until they vest. The expense related to stock option awards granted to non-employees was \$0.3 million, \$0.4 million, and \$0.2 million for the years ended December 31, 2018, 2017, and 2016, respectively. As of December 31, 2018, the Company had unrecognized stock-based compensation expense related to its unvested stock options of \$26.1 million which is expected to be recognized over the remaining weighted average vesting period of 2.78 years.

The fair value of each option issued to non-employees was estimated at each vesting and reporting date using the Black-Scholes option pricing model. The reporting date fair value was determined using the following weighted-average assumptions:

|                          | A      | s of December 31, |        |
|--------------------------|--------|-------------------|--------|
|                          | 2018   | 2017              | 2016   |
| Risk-free interest rate  | 2.6 %  | 2.4 %             | 2.1 %  |
| Expected dividend yield  | — %    | — %               | — %    |
| Expected term (in years) | 7.6    | 8.5               | 9.1    |
| Expected volatility      | 73.2 % | 76.2 %            | 83.3 % |

# 11. 401(k) Savings plan

The Company has a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements, and allows participants to defer a portion of their annual compensation on a pretax basis. The Company expensed approximately \$0.8 million, \$0.5 million, and \$0.3 million related to employer contributions made during the years ended December 31, 2018, 2017, and 2016, respectively.

### 12. Income taxes

The Company accounts for income taxes using the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and for tax carryforwards, such as net operating losses. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the provision for income taxes in the period that includes the enactment date. The Company records a valuation allowance to reduce the carrying amount of deferred tax assets if it is more likely than not that such asset will not be realized. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in the law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity, and changes in facts or circumstances related to a tax position. The Company evaluates its tax positions on an annual basis.

On December 22, 2017, the U.S. federal government enacted comprehensive tax legislation with the U.S. Tax Cuts and Jobs Act ("Tax Act") that made changes to the U.S. tax code impacting the year ended December 31, 2017 and future years. Effective January 1, 2018, the Tax Act reduced the U.S. federal corporate tax rate from 35% to 21%.

For the year ended December 31, 2017, the Tax Act required a one-time transition tax on certain unrepatriated earnings of foreign subsidiaries that is payable over eight years. At December 31, 2018, the Company does not have any foreign subsidiaries and the international aspects of the Tax Act are not applicable.

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118"), which provided guidance on accounting for the tax effects of the Tax Act. SAB 118 provided a measurement period that should not extend beyond one year from the date of the Tax Act enactment for companies to complete the accounting under Accounting Standards Codification 740—Income Taxes. In accordance with SAB 118, to the extent that a company's accounting for certain income tax effects of the Tax Act is incomplete, but the company is able to determine a reasonable estimate, it must record a provisional estimate in its financial statements. The Company's accounting for the Tax Act was completed in the fourth quarter of 2018 and resulted in no adjustments to the Company's prior provisional estimates recorded in the period ended December 31, 2017.

The benefit for incomes taxes is as follows:

|                   |          | Year ended December 31, |        |  |   |  |  |  |
|-------------------|----------|-------------------------|--------|--|---|--|--|--|
|                   |          | 2018                    | 2017   |  |   |  |  |  |
|                   | ·        | (in thou                | sands) |  |   |  |  |  |
| Current           |          | · ·                     | ĺ      |  |   |  |  |  |
| Federal           | \$       | 180                     | \$     |  | _ |  |  |  |
| State             |          | _                       |        |  | _ |  |  |  |
| Total current     | <u> </u> | 180                     |        |  |   |  |  |  |
| Deferred          |          |                         |        |  |   |  |  |  |
| Federal           |          | _                       |        |  | _ |  |  |  |
| State             |          | _                       |        |  | _ |  |  |  |
| Total deferred    | ·        | _                       |        |  |   |  |  |  |
| Total tax expense | \$       | 180                     | \$     |  |   |  |  |  |

A reconciliation of the expected income tax (benefit) computed using the federal statutory income tax rate at the Company's effective tax rate is as follows:

|   | Year ended December 31, |          |         |  |  |  |  |
|---|-------------------------|----------|---------|--|--|--|--|
|   | 2018                    | 2017     | 2016    |  |  |  |  |
| Income tax computed at federal statutory tax rate | 21.0 %                  | 34.0 %   | 34.0 %  |  |  |  |  |
| State taxes, net of federal benefit               | 6.3 %                   | 6.1 %    | 5.6 %   |  |  |  |  |
| General business credit carryovers                | 3.1 %                   | 5.0 %    | 4.2 %   |  |  |  |  |
| Non-deductible expenses                           | (2.1)%                  | (4.1)%   | (4.0)%  |  |  |  |  |
| Deferred rate change                              | `—`%                    | (21.8)%  |         |  |  |  |  |
| Change in valuation allowance                     | (28.1)%                 | (19.2)%  | (40.2)% |  |  |  |  |
| Total   | 0.2 %                   | <u> </u> | (0.4)%  |  |  |  |  |

The Company has incurred net operating losses ("NOLs") since June 2013. At December 31, 2018, the Company had federal and state net operating loss carryforwards of \$162.9 million and \$163.8 million, respectively. During 2018, the company generated federal and state NOLs carryforwards of \$73.1 million and \$72.1 million, respectively. The federal net operating loss carryforward generated in 2018 is limited to 80% of taxable income and has an indefinite carryforward period. The Company's federal net operating loss carryforward generated in the period ended December 31, 2017 and prior, as well as the Company's state NOL carryforwards begin to expire in 2033. As of December 31, 2018, the Company also had federal and state research and development tax credit carryforwards of \$9.4 million and \$3.0 million, respectively, which expire beginning in 2028. As of December 31, 2018, the Company had state investment credits of \$0.4 million, which expire beginning in 2019.

Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership may result in a limitation on the amount of NOL carryforwards and research and development credit carryforwards that may be utilized annually to offset future taxable income and taxes payable. In general, an ownership change, as defined by Section 382, results from transactions that increase the ownership of 5% stockholders or public groups in the stock of a corporation by more than 50 percent in the aggregate over a three-year period. During 2016, the Company completed a study through June 30, 2016, to determine whether any ownership change has occurred since the Company's formation and has determined that transactions have resulted in three ownership changes, as defined by Section 382. There could be additional ownership changes in the future that could further limit the amount of NOLs and tax credit carryforwards that the Company can utilize.

The significant components of the Company's deferred tax assets and (liabilities) as of December 31, 2018 and 2017 are as follows:

|                                      | Year ended December 31, |          |       |          |
|--------------------------------------|-------------------------|----------|-------|----------|
|                                      |                         | 2018     |       | 2017     |
|                                      |                         | (in thou | ısarı | ıds)     |
| Deferred tax assets:                 |                         |          |       |          |
| Net operating loss carryforwards     | \$                      | 44,556   | \$    | 24,642   |
| Tax credit carryforwards             |                         | 12,021   |       | 8,832    |
| Deferred rent                        |                         | 1,560    |       | 1,458    |
| Deferred revenue                     |                         | 13,926   |       | 8,622    |
| Non-deductible accruals and reserves |                         | 1,105    |       | 817      |
| Intangibles                          |                         | 930      |       | 832      |
| Stock compensation                   |                         | 2,802    |       | 1,361    |
| Total deferred tax assets            |                         | 76,900   |       | 46,564   |
| Less valuation allowance             |                         | (75,213) |       | (44,953) |
| Net deferred tax assets              |                         | 1,687    |       | 1,611    |
| Deferred tax liabilities             |                         |          |       |          |
| Depreciation and amortization        |                         | (1,687)  |       | (1,611)  |
| Net deferred taxes                   | \$                      |          | \$    |          |

As required by ASC 740, management has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which principally comprise NOL carryforwards, research and development credit carryforwards, deferred revenue. Management has determined that it is more likely than not that the Company will not recognize the benefits of its federal and state deferred tax assets, and as a result, a valuation allowance of \$75.2 million and \$45.0 million has been established at December 31, 2018 and 2017, respectively. The change in valuation allowance was \$30.2 million for the year ended December 31, 2018, primarily due to additional operating losses incurred by the Company for the year ended December 31, 2018. The primary reason for the difference between the income tax expense recorded by the Company and the amount of income tax expense at statutory income tax rates was the change in the valuation allowance.

At December 31, 2018 and 2017, the Company had no unrecognized tax benefits. The Company has not as yet conducted a study of its research and development credit carryforwards. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed, and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheets or statements of operations if an adjustment were required.

Interest and penalty charges, if any, related to unrecognized tax benefits would be classified as income tax expense in the accompanying statements of operations. As of December 31, 2018 and 2017, the Company has no accrued interest related to uncertain tax positions. Since the Company is in a loss carryforward position, it is generally subject to examination by the U.S. federal, state, and local income tax authorities for all tax years in which a loss carryforward is available.

### 13. Related-party transactions

Since inception, the Company received consulting and management services from one of its investors. The total amount of consulting and management services provided by this investor was de minimis during the years ended December 31, 2018 and 2017.

# 14. Selected quarterly financial data (unaudited)

The following table contains quarterly financial information for 2018 and 2017. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair statement of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

|                          |    |          |     |             |     | 2018       |      |             |      |          |
|--------------------------|----|----------|-----|-------------|-----|------------|------|-------------|------|----------|
|                          |    | First    |     | Second      |     | Third      |      | Fourth      |      |          |
|                          |    | Quarter  |     | Quarter     |     | Quarter    |      | Quarter     |      | Total    |
|                          |    | (a       | moı | ınts in tho | usa | nds, excep | t pe | er share da | ıta) |          |
| Collaboration revenue    | \$ | 942      | \$  | 2,575       | \$  | 2,094      | \$   | 2,008       | \$   | 7,619    |
| Total operating expenses |    | 22,035   |     | 28,269      |     | 23,241     |      | 25,169      |      | 98,714   |
| Loss from operations     | _  | (21,093) | _   | (25,694)    | _   | (21,147)   | _    | (23,161)    |      | (91,095) |
| Net loss                 |    | (19,926) |     | (25,541)    |     | (20,289)   |      | (22,532)    |      | (88,288) |
| Net loss per share       | \$ | (0.63)   | \$  | (0.80)      | \$  | (0.63)     | \$   | (0.70)      | \$   | (2.75)   |

|                          |    |          |     |             |      | 2017       |      |            |     |          |
|--------------------------|----|----------|-----|-------------|------|------------|------|------------|-----|----------|
|                          |    | First    |     | Second      |      | Third      |      | Fourth     |     |          |
|                          |    | Quarter  |     | Quarter     |      | Quarter    |      | Quarter    |     | Total    |
|                          |    | (aı      | moι | ints in tho | usaı | ıds, excep | t pe | r share da | ta) |          |
| Collaboration revenue    | \$ | 1,464    | \$  | 1,177       | \$   | 1,148      | \$   | 6,346      | \$  | 10,135   |
| Total operating expenses |    | 18,986   |     | 19,816      |      | 24,503     |      | 18,693     |     | 81,998   |
| Loss from operations     | _  | (17,522) |     | (18,639)    |      | (23,355)   |      | (12,347)   |     | (71,863) |
| Net loss                 |    | (16,648) |     | (18,876)    |      | (23,346)   |      | (11,828)   |     | (70,698) |
| Net loss per share       | \$ | (0.65)   | \$  | (0.73)      | \$   | (0.89)     | \$   | (0.40)     | \$  | (2.64)   |

# 15. Subsequent events

### Neurocrine Collaboration

In January 2019, the Company entered into a collaboration and license agreement with Neurocrine for the research, development and commercialization of four programs including the Company's Parkinson's disease program, the Company's Friedreich's ataxia program, and two programs to be determined by the Company and Neurocrine at a later date. Under the terms of the agreement, the Company will receive an upfront payment of \$165.0 million, inclusive of \$50.0 million for the sale of 4,179,728 shares of its common stock, funding of development costs under the Parkinson's and Friedreich's ataxi programs, and may receive future development and regulatory milestones and royalties.

### AbbVie Alpha-Synuclein Collaboration

In February 2019, the Company entered into a separate collaboration agreement with AbbVie, the AbbVie Alpha-Synuclein Collaboration Agreement, for the research, development, and commercialization of AAV and other virus based gene therapy products directed against pathological species of alpha-synuclein for the potential treatment of Parkinson's disease and other synucleinopathies. Under the terms of the AbbVie Alpha-Synuclein Collaboration Agreement, the Company will receive an upfront payment of \$65.0 million and may receive option exercise payments, future regulatory and commercial milestone payments and royalties.

# EXHIBIT INDEX

|                |   | Incorporated by Reference to: |                |                            |                    |                   |  |  |  |
|----------------|---|-------------------------------|----------------|----------------------------|--------------------|-------------------|--|--|--|
| Exhibit<br>No. | Description   | Form or<br>Schedule           | Exhibit<br>No. | Filing<br>Date with<br>SEC | SEC File<br>Number | Filed<br>Herewith |  |  |  |
| 1.1            | Sales Agreement by and between the Registrant and Cowen and Company, LLC, dated as of December 1, 2016.   | S-3                           | 1.2            | 12/01/2016                 | 333-<br>207367     |                   |  |  |  |
| 3.1            | Amended and Restated Certificate of Incorporation of the Registrant.  | 8-K                           | 3.1            | 11/16/2015                 | 001-<br>37625      |                   |  |  |  |
| 3.2            | Amended and Restated By-Laws of the Registrant.   | 8-K                           | 3.2            | 11/16/2015                 | 001-<br>37625      |                   |  |  |  |
| 4.1            | Specimen Common Stock Certificate of the Registrant.  | 10-K                          | 4.1            | 3/14/18                    | 001-<br>37625      |                   |  |  |  |
| 4.2            | Form of Indenture to be entered into between the Registrant and Trustee.  | S-3/A                         | 4.2            | 12/19/2016                 | 333-<br>207367     |                   |  |  |  |
| 4.3            | Second Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated as of April 10, 2015. | S-1/A                         | 4.2            | 10/28/2015                 | 333-<br>207367     |                   |  |  |  |
| 10.1#          | 2014 Stock Option and Grant Plan and forms of award agreements thereunder.  | S-1/A                         | 10.1           | 10/28/2015                 | 333-<br>207367     |                   |  |  |  |
| 10.2#          | 2015 Stock Option and Incentive Plan and forms of award agreements thereunder.  | S-1/A                         | 10.2           | 10/28/2015                 | 333-<br>207367     |                   |  |  |  |
| 10.3†          | Collaboration Agreement by and between the Registrant and Sanofi Genzyme Corporation, dated February 11, 2015.                                    | S-1/A                         | 10.3           | 11/06/2015                 | 333-<br>207367     |                   |  |  |  |
| 10.4†          | Exclusive License Agreement by and between the Registrant and the University of Massachusetts, dated January 30, 2014.                            | S-1                           | 10.4           | 10/09/2015                 | 333-<br>207367     |                   |  |  |  |
| 10.5           | Lease Agreement by and between the Registrant and UP 45/75 Sidney Street, LLC, dated as of April 1, 2014.   | S-1/A                         | 10.5           | 10/28/2015                 | 333-<br>207367     |                   |  |  |  |
| 10.6           | First Amendment to Lease Agreement by and between the Registrant and 45/75 Sidney Street, LLC, dated as of December 23, 2015.                     | 10-Q                          | 10.5           | 05/12/2016                 | 001-<br>37625      |                   |  |  |  |
| 10.7#          | Offer Letter by and between the Registrant and Bernard Ravina, M.D., dated January 15, 2014.  | S-1/A                         | 10.6           | 10/28/2015                 | 333-<br>207367     |                   |  |  |  |
|                |   | F-33                          |                |                            |                    |                   |  |  |  |

| 10.9#   | Offer Letter by and between the Registrant and Steven Paul, M.D., dated July 24,  | S-1/A | 10.8  | 10/28/2015 | 333-<br>207367 |
|---------|---|-------|-------|------------|----------------|
| 10.10   | 2014.  Form of Indemnification Agreement to be entered into between the Registrant and its directors.   | S-1/A | 10.9  | 10/28/2015 | 333-<br>207367 |
| 10.11   | Form of Indemnification Agreement to be entered into between the Registrant and its executive officers.                                       | S-1/A | 10.10 | 10/28/2015 | 333-<br>207367 |
| 10.12†  | License Agreement, by and between the Registrant and ReGenX Biosciences, LLC, dated May 28, 2014.   | S-1/A | 10.11 | 11/04/2015 | 333-<br>207367 |
| 10.13#  | 2015 Employee Stock Purchase Plan.  | S-1/A | 10.12 | 10/28/2015 | 333-<br>207367 |
| 10.14#  | Employment Agreement by and between the Registrant and Steven M. Paul, Dated May 11, 2016.  | 10-Q  | 10.1  | 05/12/2016 | 001-37625      |
| 10.16#  | Employment Agreement by and between the Registrant and Dinah Sah, dated May 11, 2016.   | 10-Q  | 10.3  | 05/12/2016 | 001-37625      |
| 10.17   | Lease Agreement by and between the Registrant and UP 64 Sidney Street, LLC, dated as of December 23, 2015.                                    | 10-Q  | 10.6  | 05/12/2016 | 001-37625      |
| 10.18   | First Amendment to Lease Agreement, by and between Voyager Therapeutics, Inc. and UP 64 Sidney Street, LLC, dated June 1, 2018.               | 8-K   | 10.2  | 06/05/2018 | 001-37625      |
| 10.19#  | Employment Agreement by and between the Registrant and Jane Pritchett Henderson, dated January 1, 2017.                                       | 8-K   | 10.1  | 01/03/2017 | 001-37625      |
| 10.20#  | Employment Agreement by and between the Registrant and Matthew Ottmer, dated September 11, 2017.  | 8-K   | 10.1  | 9/18/2017  | 001-37625      |
| 10.21   | Second Amendment to the Lease<br>Agreement by and between the Registrant<br>and UP 45/75 Sidney Street, LLC, dated as<br>of February 5, 2018. | 8-K   | 10.1  | 02/07/2018 | 001-<br>37625  |
| 10.22#  | Amendment No. 1 to 2015 Employee Stock Purchase Plan.   | 10-K  | 10.21 | 03/14/2018 | 001-37625      |
| 10.23†† | Collaboration Agreement by and between the Registrant and AbbVie Biotechnology Ltd, dated as of February 16, 2018.                            | 10-K  | 10.22 | 03/14/2018 | 001-37625      |
|         |   | F-34  |       |            |                |

| 10.24#  | Retirement Agreement, by and between Voyager Therapeutics, Inc. and Steven M. Paul, dated June 28, 2018.                           | 8-K  | 10.1 | 06/29/2018 | 001-37625 |   |
|---------|--|------|------|------------|-----------|---|
| 10.25#  | Employee Agreement, by and between<br>Voyager Therapeutics, Inc. and G. Andre<br>Turenne, dated June 28, 2018.                     | 8-K  | 10.2 | 06/29/2018 | 001-37625 |   |
| 10.26#  | Consulting Agreement, by and between Voyager Therapeutics, Inc. and Steven M. Paul, M.D., dated August 2, 2018.                    | 10-Q | 10.5 | 08/07/2018 | 001-37625 |   |
| 10.27#  | Form of Non-Qualified Stock Option<br>Agreement for Inducement Grant.  |      |      |            |           | X |
| 10.28†† | Collaboration and License Agreement, by and between the Registrant and Neurocrine Biosciences, Inc., dated January 28, 2019.       |      |      |            |           | X |
| 10.29   | Stock Purchase Agreement, by and between the Registrant and Neurocrine Biosciences, Inc., dated January 28, 2019.                  |      |      |            |           | X |
| 10.30   | Investor Agreement, by and between the Registrant and Neurocrine Biosciences, Inc., dated January 28, 2019.                        |      |      |            |           | X |
| 10.31†† | Collaboration and Option Agreement, by and between the Registrant and AbbVie Ireland Unlimited Company, dated February 21, 2019.   |      |      |            |           | X |
| 10.32#  | Employment Agreement, by and between Voyager Therapeutics, Inc. and Allison Dorval, dated November 7, 2018.                        | 10-Q | 10.3 | 11/07/2018 | 001-37625 |   |
| 10.33#  | Form of Restricted Stock Unit Agreement for Inducement Grant.  |      |      |            |           | X |
| 10.34   | Third Amendment to Lease Agreement, by and between Voyager Therapeutics, Inc. and UP 45/75 Sidney Street, LLC, dated June 1, 2018. | 8-K  | 10.1 | 06/05/2018 | 001-37625 |   |
| 21.1    | Subsidiaries of the Registrant.  |      |      |            |           | X |
| 23.1    | Consent of Ernst & Young, Independent Registered Public Accounting Firm.   |      |      |            |           | X |
| 24.1    | Power of Attorney (see signature page of this Annual Report on Form 10-K).   |      |      |            |           | X |
|         |  | F-35 |      |            |           |   |

| Table of Contents |  |   |  |
|-------------------|--|---|--|
| 31.1              | Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14 or 15d-14.  | X |  |
| 31.2              | Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14 or 15d-14.  | X |  |
| 32.1+             | Certifications of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act Rules 13a- 14(b) or 15d-14(b) and 18 U.S.C. Section 1350. | X |  |
| 101.INS           | XBRL Instance Document.  |   |  |
| 101.SCH           | XBRL Taxonomy Extension Schema<br>Document.  |   |  |
| 101.CAL           | XBRL Taxonomy Extension Calculation Document.  |   |  |
| 101.LAB           | XBRL Taxonomy Extension Definition Linkbase Document.  |   |  |

Management contract or compensatory plan or arrangement filed in response to Item 15(a)(3) of the Instructions to the Annual Report on Form 10-K.

† Confidential treatment has been granted as to certain portions, which portions have been omitted and separately filed with the Securities and Exchange Commission.
†† Confidential treatment has been requested as to certain portions, which portions have been omitted and separately filed

Linkbase Document.

Link Document.

XBRL Taxonomy Extension Labels

XBRL Taxonomy Extension Presentation

101.PRE

101.DEF

with the Securities and Exchange Commission.

The certification furnished in Exhibit 32.1 hereto is deemed to be furnished with this Annual Report on Form 10-K and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

## **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

February 26, 2019

# VOYAGER THERAPEUTICS, INC.

By: /s/ G. Andre Turenne

G. Andre Turenne Chief Executive Officer, President, and Director

#### SIGNATURES AND POWER OF ATTORNEY

We, the undersigned directors and officers of Voyager Therapeutics, Inc. (the "Company"), hereby severally constitute and appoint G. Andre Turenne and Allison Dorval, and each of them singly, our true and lawful attorneys, with full power to them, and to each of them singly, to sign for us and in our names in the capacities indicated below, any and all amendments to this Annual Report on Form 10-K, and to file or cause to be filed the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as each of us might or could do in person, and hereby ratifying and confirming all that said attorneys, and each of them, or their substitute or substitutes, shall do or cause to be done by virtue of this Power of Attorney.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed by the following persons in the capacities and on the dates indicated.

| Name  | Title  | Date              |
|---|--|-------------------|
| /s/ G. Andre Turenne<br>G. Andre Turenne                  | Chief Executive Officer, President, and Director (Principal Executive Officer) | February 26, 2019 |
| /s/Allison Dorval<br>Allison Dorval                       | Chief Financial Officer (Principal Financial and Accounting Officer)           | February 26, 2019 |
| /s/Mark Levin<br>Mark Levin                               | Director   | February 26, 2019 |
| /s/Jim Geraghty<br>Jim Geraghty                           | Director   | February 26, 2019 |
| /s/Michael Higgins Michael Higgins                        | Director   | February 26, 2019 |
| /s/Perry A. Karsen<br>Perry A. Karsen                     | Director   | February 26, 2019 |
| /s/Steven Hyman, M.D. Steven Hyman, M.D.                  | Director   | February 26, 2019 |
| /s/Wendy Dixon, Ph.D.<br>Wendy Dixon, Ph. D.              | Director   | February 26, 2019 |
| /s/Steve Paul, M.D.<br>Steve Paul, M.D.                   | Director   | February 26, 2019 |
| /s/Glenn Pierce, M.D., Ph.D.<br>Glenn Pierce, M.D., Ph.D. | Director   | February 26, 2019 |
|   |  |                   |

## **VOYAGER THERAPEUTICS, INC.**

# NON-QUALIFIED STOCK OPTION AGREEMENT

#### INDUCEMENT GRANT PURSUANT TO NASDAQ STOCK MARKET RULE 5635(C)(4)

| Name of Optionee:                | []                  |
|----------------------------------|---------------------|
| No. of Option Shares:            | []                  |
| Option Exercise Price per Share: | [\$]                |
|                                  | [FMV on Grant Date] |
| Grant Date:                      | []                  |
| Expiration Date:                 | []                  |
|                                  | [up to 10 years]    |

This agreement (the "Agreement") evidences the grant by Voyager Therapeutics, Inc. (the "Company") to the Optionee named above, an employee of the Company, of an option (the "Stock Option") to purchase, on the terms provided herein, all or part of the number of shares of common stock, par value \$0.001 per share, of the Company (the "Stock") specified above at the Option Exercise Price per Share specified above. Except as otherwise indicated by the context, the term "Optionee", as used herein, shall be deemed to include any person who acquires the right to exercise the Stock Option validly under its terms.

- 1. <u>Inducement Grant.</u> This Stock Option was granted to the Optionee pursuant to the inducement grant exception under NASDAQ Stock Market Rule 5635(c)(4), and not pursuant to the Company's 2014 Stock Option and Grant Plan, 2015 Stock Option and Incentive Plan or any other equity incentive plan of the Company, as a material inducement to the Optionee's employment with the Company.
- 2. <u>Non-Qualified Option</u>. It is intended that the Stock Option shall not be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code").
- 3. <u>Exercisability Schedule</u>. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as set forth below, and subject to the discretion of the Administrator (as defined in Section 10) to accelerate the exercisability schedule hereunder, this Stock Option shall be exercisable with respect to the following number of Option Shares on the dates indicated so long as the Optionee remains an employee of the Company or a Subsidiary (as defined below) on such dates:

| Incremental Number of Option Shares Exercisable | Exercisability Date |
|---|---------------------|
| ( )%  |                     |
| ( )%  |                     |
| ( )%  |                     |
| ( )%  |                     |

Once exercisable, this Stock Option, unless earlier terminated, shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof. "Subsidiary" means any corporation or other entity (other than the Company) in which the Company has at least a 50% interest, either directly or indirectly.

### 4. Manner of Exercise.

a. The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written notice to the Administrator of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Administrator; (ii) through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that are beneficially owned by the Optionee and are not then subject to any restrictions under any Company plan and that otherwise satisfy any holding periods as may be required by the Administrator (such Stock to be valued at Fair Market Value, as defined below, on the exercise date); (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; (iv) in the discretion of the Administrator, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; or (v) a combination of (i), (ii), (iii) and (iv) above. Payment instruments will be received subject to collection. For purposes of this Agreement, "Fair Market Value" shall mean the fair market value of the Stock determined in good faith by the Administrator; provided, however, that for so long as the Stock is admitted to quotation on the NASDAQ Global Select Market, such determination shall be made by reference to the closing price of the Stock on the NASDAQ Global Select Market on the relevant date. If there is no closing price for the relevant date, the determination shall be made by reference to the last date preceding such date for which there is a closing price.

The transfer to the Optionee on the records of the Company or of the transfer agent of the Option Shares will be contingent upon (i) the Company's receipt from the Optionee of the full purchase price for the Option Shares, as set forth above, (ii) the fulfillment of any other

requirements contained herein or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of this Stock Option and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the Shares attested to. In the event that the Company establishes, for itself or using the services of a third party, an automated system for the exercise of options, such as a system using an internet website or interactive voice response, then the paperless exercise of the Stock Option will be permitted through the use of such an automated system.

- b. The shares of Stock purchased upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Administrator with all requirements under applicable laws or regulations in connection with such transfer and with the requirements hereof. The determination of the Administrator as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company or the transfer agent shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.
- c. The minimum number of shares with respect to which this Stock Option may be exercised at any one time shall be 100 shares, unless the number of shares with respect to which this Stock Option is being exercised is the total number of shares subject to exercise under this Stock Option at the time.
- d. Notwithstanding any other provision hereof, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.
- 5. <u>Termination of Employment</u>. If the Optionee's service as an employee of the Company or a Subsidiary is terminated, the period within which to exercise the Stock Option may be subject to earlier termination as set forth below.
- a. <u>Termination Due to Death</u>. If the Optionee's employment terminates by reason of the Optionee's death, any portion of this Stock Option outstanding on such date, to the extent exercisable on the date of death, may thereafter be exercised by the Optionee's legal representative or legatee for a period of 12 months from the date of death or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of death shall terminate immediately and be of no further force or effect.
- b. <u>Termination Due to Disability</u>. If the Optionee's employment terminates by reason of the Optionee's disability (as determined by the Administrator), any portion of this Stock Option outstanding on such date, to the extent exercisable on the date of such disability, may thereafter be exercised by the Optionee for a period of 12 months from the date of disability

or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of disability shall terminate immediately and be of no further force or effect.

- c. <u>Termination for Cause</u>. If the Optionee's emplomnet terminates for Cause, any portion of this Stock Option outstanding on such date shall terminate immediately and be of no further force and effect. For purposes hereof, "Cause" shall mean, unless otherwise provided in an employment or other agreement between the Company and the Optionee, a determination by the Administrator that the Optionee shall be dismissed as a result of (i) the Optionee's dishonest statements or acts with respect to the Company or any affiliate of the Company, or any of the Company's current or prospective customers, suppliers, vendors or other third parties with which such entity does business; (ii) the Optionee's commission of (A) a felony or (B) any misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) the Optionee's failure to perform his assigned duties and responsibilities to the reasonable satisfaction of the Company which failure continues, in the reasonable judgment of the Company, after written notice given to the Optionee by the Company; (iv) the Optionee's gross negligence, willful misconduct or insubordination with respect to the Company or any affiliate of the Company; or (v) the Optionee's material violation of any provision of any agreement(s) between the Optionee and the Company relating to noncompetition, nondisclosure and/or assignment of inventions.
- d. Other Termination. If the Optionee's employment terminates for any reason other than the Optionee's death, the Optionee's disability, or Cause, and unless otherwise determined by the Administrator, any portion of this Stock Option outstanding on such date may be exercised, to the extent exercisable on the date of termination, for a period of three months from the date of termination or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of termination shall terminate immediately and be of no further force or effect. The following events shall not be deemed a termination of employment: (i) a transfer to the employment of the Company from a Subsidiary of the Company or from the Company to a Subsidiary of the Company, or from one Subsidiary of the Company to another; or (ii) an approved leave of absence for military service or sickness, or for any other purpose approved by the Company, if the Optionee's right to employment is guaranteed either by a statute or by contract or under the policy pursuant to which the leave of absence was granted or if the Administrator otherwise so provides in writing.

The Administrator's determination of the reason for termination of the Optionee's employment shall be conclusive and binding on the Optionee and his or her representatives or legatees.

6. <u>Transferability</u>. This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution or pursuant to a domestic relations order. During the Optionee's lifetime, this Stock Option shall be exercisable only by the Optionee or by the Optionee's legal representative or guardian in the event of the Optionee's incapacity. Upon the Optionee's death, this Stock Option shall be exercisable only by the Optionee's legal representative or legatee. The Optionee may designate a beneficiary or beneficiaries to exercise the Stock Option on or after the Optionee's death. Any such designation shall be on a form provided for the purpose by the Administrator and shall not be effective until received by the Administrator. This Stock Option

shall not be subject, in whole or in part, to attachment, execution, or levy of any kind, and any purported transfer in violation hereof shall be null and void.

- 7. Tax Withholding. The Optionee shall, not later than the date as of which the exercise of this Stock Option becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Administrator for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Company shall, to the extent permitted by law, have the right to deduct any such taxes from any payment of any kind otherwise due to the Optionee. The Company's obligation to deliver evidence of book entry (or stock certificates) to the Optionee is subject to and conditioned on tax withholding obligations being satisfied by the Optionee. The Company shall have the authority to cause the minimum required tax withholding obligation to be satisfied, in whole or in part, by withholding from shares of Stock to be issued to the Optionee a number of shares of Stock with an aggregate Fair Market Value that would satisfy the minimum withholding amount due.
  - 8. <u>Adjustments for Changes in Stock and Sale Events</u>.

## a. <u>Definitions</u>.

- i. "Sale Event" shall mean (i) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity, (ii) a merger, reorganization or consolidation pursuant to which the holders of the Company's outstanding voting power and outstanding stock immediately prior to such transaction do not own a majority of the outstanding voting power and outstanding stock or other equity interests of the resulting or successor entity (or its ultimate parent, if applicable) immediately upon completion of such transaction, (iii) the sale of all of the Stock of the Company to an unrelated person, entity or group thereof acting in concert, or (iv) any other transaction in which the owners of the Company's outstanding voting power immediately prior to such transaction do not own at least a majority of the outstanding voting power of the Company or any successor entity immediately upon completion of the transaction other than as a result of the acquisition of securities directly from the Company.
- ii. "Sale Price" shall mean the value as determined by the Administrator of the consideration payable, or otherwise to be received by stockholders, per share of Stock pursuant to a Sale Event.
- b. <u>Changes in Stock</u>. Subject to Section 8(c) hereof, if, as a result of any reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar change in the Company's capital stock, the outstanding shares of Stock are increased or decreased or are exchanged for a different number or kind of shares or other securities of the Company, or additional shares or new or different shares or other securities of the Company or other non-cash assets are distributed with respect to such shares of Stock or other securities, or, if, as a result of any merger or consolidation, sale of all or substantially all of the assets of the Company, the outstanding shares of Stock are converted into or exchanged for securities of the Company or any successor entity (or a parent or subsidiary thereof), the Administrator shall make an appropriate or proportionate adjustment in (i) the number and kind of shares or other securities subject to this Stock Option, and (ii) the Option Exercise Price per

Share, without changing the aggregate exercise price (i.e., the Option Exercise Price per Share multiplied by the Number of Option Shares) as to which the Stock Option remains exercisable. The Administrator shall also make equitable or proportionate adjustments in the Number of Option Shares and the Option Exercise Price per Share and the terms of the Stock Option to take into consideration cash dividends paid other than in the ordinary course or any other extraordinary corporate event. The adjustment by the Administrator shall be final, binding and conclusive. No fractional shares of Stock shall be issued under the Stock Option resulting from any such adjustment, but the Administrator in its discretion may make a cash payment in lieu of fractional shares.

c. <u>Sale Events</u>. In the case of and subject to the consummation of a Sale Event, the parties thereto may cause the assumption or continuation of this Stock Option, or the substitution of the Stock Option with a new award of the successor entity or parent thereof, with appropriate adjustment as to the number and kind of shares and, if appropriate, the per-share exercise price, as such parties shall agree. To the extent the parties to such Sale Event do not provide for the assumption, continuation or substitution of the Stock Option, upon the effective time of the Sale Event, the Stock Option shall terminate. In such case, if the Stock Option is not exercisable immediately prior to the effective time of the Sale Event, the Stock Option shall become fully exercisable as of the effective time of the Sale Event in the Administrator's discretion. In the event of such termination, (i) the Company shall have the option (in its sole discretion) to make or provide for a cash payment to the Optionee in exchange for the cancellation of the Stock Option in an amount equal to the difference between (A) the Sale Price multiplied by the Number of Option Shares (to the extent then exercisable at prices not in excess of the Sale Price) and (B) the aggregate exercise price of the Stock Option; or (ii) the Optionee shall be permitted, within a specified period of time prior to the consummation of the Sale Event as determined by the Administrator, to exercise all outstanding shares of Stock under the Stock Option (to the extent then exercisable).

If the Stock Option is assumed, continued or substituted in connection with a Sale Event, the Stock Option shall become fully vested and nonforfeitable if the Optionee is terminated without Cause by the Company (or its successor) in connection with, or within 12 months following, the Sale Event.

- 9. <u>No Obligation to Continue Employment</u>. Neither the Company nor any Subsidiary is obligated by or as a result of this Agreement to continue the Optionee's employment and this Agreement shall not interfere in any way with the right of the Company or any Subsidiary to terminate the employment of the Optionee at any time.
- 10. <u>Administrator</u>. This Agreement shall be administered by either the Board of Directors of the Company (the "Board"), the Compensation Committee of the Board, or a similar committee performing the functions of the compensation committee and which is comprised of not less than two non-employee directors who are independent (the "Administrator"). The Administrator shall have the power and authority to: (i) determine and modify from time to time the terms and conditions, including restrictions, of this Stock Option; (ii) accelerate at any time the exercisability or vesting of all or any portion of the Stock Option; (iii) amend this Agreement to provide that this Stock Option shall vest and be exercisable based on service to the Company or a Subsidiary other than employment (such as service as a consult, advisor or director); (iv)

extend at any time the period in which the Stock Option may be exercised, provided that such period shall not be extended beyond the Expiration Date; (v) interpret the terms and provisions of the Stock Option (including related written instruments); (vi) make all determinations it deems advisable for the administration of the Stock Option; (vii) decide all disputes arising in connection with the Stock Option; and (viii) otherwise supervise the administration of the Stock Option. All decisions and interpretations of the Administrator shall be binding on all persons, including the Company and the Optionee.

- 11. <u>Stockholder Rights</u>. Until Stock is deemed delivered in accordance with Section 16, no right to vote or receive dividends or any other rights of a stockholder will exist with respect to shares of Stock to be issued in connection with this Stock Option, notwithstanding the exercise of the Stock Option or any other action by the Optionee with respect thereto.
- 12. <u>Integration</u>. This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.
- 13. <u>Amendment</u>. The Administrator may, at any time, amend or cancel this Stock Option for the purpose of satisfying changes in law or for any other lawful purpose, but no such action shall adversely affect the Optionee's rights under the Stock Option without the Optionee's consent. Except as provided in Section 8, without prior stockholder approval, in no event may the Administrator exercise its discretion to reduce the exercise price of the Stock Option or effect repricing through cancellation and re-grant or cancellation of the Stock Option in exchange for cash. Nothing in this Section 13 shall limit the Administrator's authority to take any action permitted pursuant to Section 8.
- 14. Compliance with Section 409A of the Code. To the extent this Stock Option is determined to constitute "nonqualified deferred compensation" within the meaning of Code Section 409A, the Stock Option shall be subject to such additional rules and requirements as specified by the Administrator from time to time in order to comply with Section 409A. In this regard, if any amount under the Stock Option is payable upon a "separation from service" (within the meaning of Section 409A) to the Optionee and the Optionee is considered a "specified employee" (within the meaning of Section 409A), then no such payment shall be made prior to the date that is the earlier of (i) six months and one day after the Optionee's separation from service, or (ii) the Optionee's death, but only to the extent such delay is necessary to prevent such payment from being subject to interest, penalties and/or additional tax imposed pursuant to Section 409A.
- 15. <u>Indemnification</u>. Neither the Board nor the Administrator, nor any member of either or any delegate thereof, shall be liable for any act, omission, interpretation, construction or determination made in good faith in connection with this Stock Option, and the members of the Board and the Administrator (and any delegate thereof) shall be entitled in all cases to indemnification and reimbursement by the Company in respect of any claim, loss, damage or expense (including, without limitation, reasonable attorneys' fees) arising or resulting therefrom to the fullest extent permitted by law and/or under the Company's articles of incorporation or bylaws or any directors' and officers' liability insurance coverage which may be in effect from time to time and/or any indemnification agreement between such individual and the Company.

- Delivery of Stock Certificates. Stock certificates to the Optionee under the Stock Option shall be 16. deemed delivered for all purposes when the Company or a stock transfer agent of the Company shall have mailed such certificates in the United States mail, addressed to the Optionee, at the Optionee's last known address on file with the Company. Uncertificated Stock shall be deemed delivered for all purposes when the Company or a Stock transfer agent of the Company shall have given to the Optionee by electronic mail (with proof of receipt) or by United States mail, addressed to the Optionee, at the Optionee's last known address on file with the Company, notice of issuance and recorded the issuance in its records (which may include electronic "book entry" records). Notwithstanding anything herein to the contrary, the Company shall not be required to issue or deliver any certificates evidencing shares of Stock pursuant to the exercise of the Stock Option, unless and until the Administrator has determined, with advice of counsel (to the extent the Administrator deems such advice necessary or advisable), that the issuance and delivery of such certificates is in compliance with all applicable laws, regulations of governmental authorities and, if applicable, the requirements of any exchange on which the shares of Stock are listed, quoted or traded. All Stock certificates delivered pursuant to the Stock Option shall be subject to any stop-transfer orders and other restrictions as the Administrator deems necessary or advisable to comply with federal, state or foreign jurisdiction, securities or other laws, rules and quotation system on which the Stock is listed, quoted or traded. The Administrator may place legends on any Stock certificate to reference restrictions applicable to the Stock. In addition to the terms and conditions provided herein, the Administrator may require that an individual make such reasonable covenants, agreements, and representations as the Administrator, in its discretion, deems necessary or advisable in order to comply with any such laws, regulations, or requirements. The Administrator shall have the right to require any individual to comply with any timing or other restrictions with respect to the exercise of the Stock Option, including a window-period limitation, as may be imposed in the discretion of the Administrator. The Administrator may require each person acquiring Stock pursuant to the Stock Option to represent and agree with the Company in writing that such person is acquiring the shares without a view to distribution thereof.
- 17. <u>Trading Policy Restrictions</u>. The exercise of this Stock Option shall be subject to the Company's insider trading policies and procedures, as in effect from time to time.
- 18. <u>Clawback Policy</u>. This Stock Option shall be subject to the Company's clawback policy, as in effect from time to time.
- 19. <u>Data Privacy Consent</u>. In order to administer this Agreement, the Company, its Subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Agreement (the "Relevant Information"). By entering into this Agreement, the Optionee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Optionee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Optionee shall have access to, and the right to

change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

- 20. <u>Status of Stock Option</u>. With respect to any portion of the Stock Option that has not been exercised, the Optionee shall have no rights greater than those of a general creditor of the Company unless the Administrator shall otherwise expressly determine. In its discretion, the Administrator may authorize the creation of a trust or other arrangement to meet the Company's obligation to deliver Stock, provided that the existence of such trusts or other arrangements is consistent with the foregoing sentence.
- 21. <u>Governing Law</u>. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, applied without regard to conflict of law principles.
- 22. <u>Notices</u>. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

|   | VOYAGER THERAPEUTICS, INC.   |  |
|---|------------------------------|--|
|   | By:                          |  |
|   | Title:                       |  |
|   |                              |  |
| The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Optionee (including through an online acceptance process) is acceptable. |                              |  |
| Dated:  |                              |  |
|   | Optionee's Signature         |  |
|   | Optionee's name and address: |  |
|   |                              |  |

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

# **COLLABORATION AND LICENSE**

**AGREEMENT** 

By and between

VOYAGER THERAPEUTICS, INC.

**AND** 

NEUROCRINE BIOSCIENCES, INC.

# TABLE OF CONTENTS

| ARTICLE 1 | DEFINITIONS   | 1  |
|-----------|---|----|
| ARTICLE 2 | COLLABORATION; PRE-TRANSITION DEVELOPMENT               | 19 |
| 2.1       | Collaboration and Programs                              | 19 |
| 2.2       | Development Costs                                       | 22 |
| 2.3       | Records of Activities                                   | 23 |
| 2.4       | No Representation                                       | 23 |
| 2.5       | Subcontracting  | 23 |
| 2.6       | Academic Collaborators                                  | 23 |
| ARTICLE 3 | MANAGEMENT OF THE COLLABORATION                         | 24 |
| 3.1       | Joint Steering Committee and Subcommittees              | 24 |
| 3.2       | Formation and Dissolution of Subcommittee(s)            | 26 |
| 3.3       | Working Groups  | 26 |
| 3.4       | Membership  | 27 |
| 3.5       | Meetings  | 28 |
| 3.6       | Decision-Making   | 28 |
| 3.7       | Alliance Managers                                       | 30 |
| 3.8       | Authority   | 30 |
| ARTICLE 4 | POST-TRANSITION ACTIVITIES                              | 30 |
| 4.1       | Co-Development and Co-Commercialization                 | 30 |
| 4.2       | Neurocrine Development and Commercialization            | 34 |
| 4.3       | Program Transition                                      | 35 |
| 4.4       | Transition Activities                                   | 35 |
| ARTICLE 5 | GRANT OF LICENSES                                       | 36 |
| 5.1       | License Grant   | 36 |
| 5.2       | In-License Agreements                                   | 37 |
| 5.3       | Obligations Under In-Licenses                           | 39 |
| 5.4       | Genzyme Agreement                                       | 40 |
| 5.5       | Neurocrine's Sublicensing Rights                        | 41 |
| 5.6       | Licenses to Voyager                                     | 41 |
| 5.7       | No Other Rights   | 41 |
| 5.8       | Section 365(n) of the Bankruptcy Code                   | 42 |
| ARTICLE 6 | MANUFACTURING   | 42 |
| 6.1       | Manufacturing Responsibilities Prior to Transition Date | 42 |
| 6.2       | Manufacturing After Transition Date                     | 42 |
| ARTICLE 7 | GENERAL PROVISIONS RELATING TO ACTIVITIES               | 43 |
| 7.1       | Compliance  | 43 |
| 7.2       | Regulatory Activities                                   | 43 |
| 7.3       | Sale of Priority Review Voucher                         | 44 |

| 7.4        | Records and Audits   | 44 |
|------------|--|----|
|            | INITIAL FEE; MILESTONES AND ROYALTIES; PAYMENTS                      | 45 |
| 8.1        | Initial Consideration  | 45 |
| 8.2        | Milestone Payments   | 45 |
| 8.3        | Royalties  | 49 |
| 8.4        | Royalty Period   | 52 |
| 8.5        | Royalty Adjustments  | 52 |
| 8.6        | Reports; Payment of Royalty  | 53 |
| 8.7        | Accounting; Audit  | 54 |
| 8.8        | Currency Conversion  | 55 |
| 8.9        | Books and Records  | 55 |
| 8.10       | Methods of Payments  | 55 |
| 8.11       | Taxes  | 55 |
| 8.12       | Late Payments  | 56 |
| ARTICLE 9  | EXCLUSIVITY  | 56 |
| 9.1        | Exclusivity  | 56 |
| 9.2        | Exception for Basic Research   | 57 |
| 9.3        | Acquisitions   | 57 |
|            | INTELLECTUAL PROPERTY RIGHTS   | 58 |
| 10.1       | Ownership of Inventions; Disclosure                                  | 58 |
| 10.2       | Patent Prosecution and Maintenance                                   | 59 |
| 10.3       | Enforcement and Defense  | 63 |
| 10.4       | Infringement Claimed by Third Parties                                | 65 |
| 10.5       | Marking  | 65 |
| 10.6       | Trademarks   | 66 |
|            | CONFIDENTIALITY  | 66 |
| 11.1       | Confidentiality; Exceptions  | 66 |
| 11.2       | Authorized Disclosure  | 67 |
| 11.3       | Press Release; Disclosure of Agreement                               | 67 |
| 11.4       | Publications   | 69 |
| 11.5       | Remedies   | 69 |
| 11.6       | [**] Agreement   | 69 |
| ARTICLE 12 | REPRESENTATIONS AND WARRANTIES                                       | 70 |
| 12.1       | Representations and Warranties of Both Parties                       | 70 |
| 12.2       | Representations, Warranties and Covenants, as applicable, of Voyager | 70 |
| 12.3       | Mutual Covenants   | 74 |
| 12.4       | Disclaimer   | 75 |
|            | INDEMNIFICATION; INSURANCE   | 75 |
| 13.1       | Indemnification by Neurocrine  | 75 |
| 13.2       | Indemnification by Voyager   | 76 |
| 13.3       | Procedure  | 76 |
| 13.4       | Insurance  | 77 |

|                                | Limitation of Liability  | 77 |
|--------------------------------|--|----|
|                                | TERM AND TERMINATION   | 78 |
| 14.1                           | Term   | 78 |
| 14.2                           | Termination by Neurocrine  | 78 |
| 14.3                           | Termination for Breach   | 78 |
| 14.4                           | Termination for Failure to Make Equity Purchase                    | 79 |
| 14.5                           | Termination for Patent Challenge                                   | 79 |
| 14.6                           | Effects of Termination Other than by Neurocrine for Voyager Breach | 79 |
| 14.7                           | Effects of Termination by Neurocrine for Voyager Breach            | 81 |
| 14.8                           | HSR Filing; Termination Upon HSR Denial                            | 82 |
| 14.9                           | Accrued Rights; Surviving Provisions of the Agreement              | 82 |
| ARTICLE 15                     | MISCELLANEOUS  | 83 |
| 15.1                           | Governing Law  | 83 |
| 15.2                           | Dispute Resolution   | 83 |
| 15.3                           | Arbitration Request  | 83 |
| 15.4                           | Assignment   | 85 |
| 15.5                           | Change of Control  | 85 |
| 15.6                           | Performance by Affiliates and Sublicensees                         | 85 |
| 15.7                           | Force Majeure  | 85 |
| 15.8                           | Notices  | 86 |
| 15.9                           | Export Clause  | 87 |
| 15.10                          | Waiver   | 87 |
| 15.11                          | Severability   | 87 |
| 15.12                          | Entire Agreement   | 87 |
| 15.13                          | Independent Contractors  | 87 |
| 15.14                          | CREATE Act   | 88 |
| 15.15                          | Headings; Construction; Interpretation                             | 88 |
| 15.16                          | Further Actions  | 88 |
| 15.17                          | Parties in Interest  | 89 |
| 15.18                          | Counterparts   | 89 |
| 15.10                          | Counterparts   | 03 |
|                                |  |    |
| SCHEDULES                      |  |    |
| Schedule 1.37                  | Existing In License Agreements                                     |    |
| Schedule 1.57<br>Schedule 1.68 |  |    |
| Schedule 5.2.1                 |  |    |
|                                |  |    |
| Schedule 5.2.4<br>Schedule 8.1 | 4(a) Certain Intellectual Property Allocation of Initial Fee       |    |
| Schedule 6.1                   | Allocation of filling ree  |    |
| EXHIBITS                       |  |    |

Stock Purchase Agreement Voyager Licensed Patent Rights Schedule of Exceptions

Exhibit A Exhibit B Exhibit C This COLLABORATION AND LICENSE AGREEMENT (the "<u>Agreement</u>") is entered into as of January 28, 2019 (the "<u>Execution Date</u>"), by and between Voyager Therapeutics, Inc., a Delaware corporation, having its principal place of business at 75 Sidney Street, Cambridge, MA 02139 ("<u>Voyager</u>"), and Neurocrine Biosciences, Inc., a Delaware corporation, having its principal place of business at 12780 El Camino Real, San Diego, CA 92130 ("<u>Neurocrine</u>"). Voyager and Neurocrine shall be referred to herein individually as a "<u>Party</u>" and collectively as the "Parties".

#### **RECITALS**

WHEREAS, Voyager is a gene therapy company focused on the research and development of products for the treatment of diseases of the central nervous system and other neurodegenerative diseases;

WHEREAS, Neurocrine is a biopharmaceutical company focused on developing and commercializing treatments for neurological and endocrine-related disorders, and possesses expertise in the research, development, manufacturing and commercialization of human therapeutics;

WHEREAS, Voyager and Neurocrine desire to engage in a collaborative effort in which Voyager will carry out certain preclinical research activities and clinical development activities relating to the identification and development of Development Candidates (as defined herein), and pursuant to which Neurocrine will have certain rights to further develop and commercialize Collaboration Products (as defined herein); and

WHEREAS, Voyager and Neurocrine believe that combining their respective expertise will allow them to identify and develop more Development Candidates and bring Collaboration Products to market more quickly than they could without this Agreement, as well as to take advantage of other efficiencies stemming from their complementary expertise.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

# ARTICLE 1 DEFINITIONS

As used in this Agreement, the following terms will have the meanings set forth in this Article 1 unless context dictates otherwise:

- 1.1 "<u>AADC</u>" means the enzyme aromatic L-amino acid decarboxylase, which is defined by the ENSEMBL Gene ID ENSG0000132437, or any naturally occurring variant thereof.
- 1.2 "<u>AADC Program</u>" means all activities under this Agreement directed to the Development, Manufacture and Commercialization of Gene Therapy Products intended to treat Parkinson's disease by delivery of a gene encoding AADC, which gene is the Target of the AADC Program (it being understood that the foregoing does not limit the rights granted to Neurocrine with respect to the Field).

- 1.3 "AADC Program Development Plan" means the plan and budget for the Development of VY-AADC through completion of Voyager's ongoing Pivotal Clinical Trial (1105) therefor (the "Existing Pivotal Trial"), as such plan and budget may be updated by the JSC from time to time in accordance with Section 2.1.3(a). The initial AADC Program Development Plan will be mutually agreed to by the Parties within [\*\*] of the Effective Date.
  - 1.4 "AAV" means a recombinant adeno-associated Virus Vector.
- 1.5 "<u>Accounting Standards</u>" means (a) GAAP (United States Generally Accepted Accounting Principles) or (b) IFRS (International Financial Reporting Standards), in either case, consistently applied, as reported in the applicable financial statements.
- 1.6 "Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with a Party to this Agreement, regardless of whether such Affiliate is or becomes an Affiliate on or after the Effective Date, but only for so long as such control exists. A Person shall be deemed to "control" another Person if it (a) owns, directly or indirectly, beneficially or legally, more than fifty percent (50%) of the outstanding voting securities or capital stock of such other Person, or has other comparable ownership interest with respect to any Person other than a corporation; or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of such other Person.
- 1.7 "<u>Annual Net Sales</u>" means, on a Collaboration Product-by-Collaboration Product basis, the total Net Sales of such Collaboration Product in the U.S. or in the Territory outside the U.S., as applicable, in a particular Calendar Year.
- 1.8 "<u>Antitrust Laws</u>" means any law relating to competition that is enforced by the U.S. Federal Trade Commission or the Antitrust Division of the U.S. Department of Justice.
- 1.9 "Biosimilar Product" means, with respect to a particular Collaboration Product in a particular country in the Territory, any Gene Therapy Product sold by a Third Party not authorized by or on behalf of Neurocrine, its Affiliates, or Sublicensees, that targets the same Target as the Collaboration Product and, on the basis of a prior Regulatory Approval granted to a Collaboration Product, (a) is approved by the FDA pursuant to Section 351(k) of the PHSA or successor thereto, (b) is approved by the EMA pursuant to EU Directive 2001/83/EC or successor thereto in the European Union or any member state thereof citing such Collaboration Product as the reference product, or (c) has received abbreviated Regulatory Approval from the applicable Regulatory Authority in another foreign jurisdiction.
- 1.10 "<u>BLA</u>" means a Biologics License Application submitted to the FDA pursuant to 21 U.S.C. §601.2 (or successor regulation thereto), for purposes of obtaining Regulatory Approval for a new biologic in the United States, or any equivalent filing in a country or regulatory jurisdiction other than the United States.
- 1.11 "<u>Business Day</u>" means a day on which banking institutions in Boston, Massachusetts or San Diego, California are open for business, excluding any Saturday or Sunday.

- 1.12 "<u>Calendar Quarter</u>" means a period of three (3) consecutive months ending on the last day of March, June, September, or December, respectively; provided that, the first Calendar Quarter starts on the Effective Date and ends on March 31, 2019.
- 1.13 "<u>Calendar Year</u>" means a period of twelve (12) consecutive months beginning on January 1 and ending on December 31; provided that the first Calendar Year starts on the Effective Date and ends on December 31, 2019.
- 1.14 "[\*\*] <u>License Agreement</u>" means that certain license agreement by and between Voyager and [\*\*], dated [\*\*]as of the Execution Date.
- 1.15 "<u>cGMP</u>" means the current Good Manufacturing Practices as provided for (and as amended from time to time) in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Harmonized Tripartite Guideline, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, Q7 (ICH Q7), and the United States Code of Federal Regulations 21 CFR Parts 210 and 211, or any similar regulation in other applicable jurisdictions.
- 1.16 "Change of Control" means, with respect to a Party, (a) the acquisition of beneficial ownership, directly or indirectly, by any Third Party of securities or other voting interest of such Party representing a majority or more of the combined voting power of such Party's then outstanding securities or other voting interests, (b) any merger, consolidation or business combination involving such Party with a Third Party that results in the holders of beneficial ownership (other than by virtue of obtaining irrevocable proxies) of the voting securities or other voting interests of such Party (or, if applicable, the ultimate parent of such Party) immediately prior to such merger, consolidation or business combination ceasing to hold beneficial ownership of more than fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, consolidation or business combination, or (c) any sale, lease, exchange, contribution or other transfer to a Third Party (in one transaction or a series of related transactions) of all or substantially all of the assets of such Party to which this Agreement relates. The acquiring or combining Third Party in any of clause (a), (b) or (c), is referred to herein as the "Acquirer".
- 1.17 "<u>Clinical Trial</u>" means a Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial or any other study in which human subjects or patients are dosed with a drug, whether approved or investigational.
- 1.18 "Collaboration Candidate" means (a) with respect to the AADC Program, VY-AADC and all other Gene Therapy Products Developed in the AADC Program and (b) with respect to each other Program, any form, formulation, or dosage of a Gene Therapy Product that is Developed by or on behalf of Voyager under such Program, or in the case of the FA Program, was Developed by Voyager prior to the Effective Date and is directed to the Target for the FA Program.
- 1.19 "Collaboration Product" means, with respect to each Program, a product containing a Collaboration Candidate in such Program, alone or in combination with other active or inactive components or ingredients, in any formulation, dosage or form. Except where the context otherwise requires, the term "Collaboration Product" includes any Co-Co Product.

- 1.20 "<u>Commercialization</u>" and "Commercialize" means any and all activities undertaken relating to the marketing, obtaining pricing and reimbursement approvals, promotion (including advertising, detailing or continuing medical education), any other offering for sale or any sale of a product, including any distribution, importation, exportation or transport of a product for sales purposes. "Commercialization" shall not include Development, but may include Manufacturing to the extent applicable.
  - 1.21 "Commercial Milestones" means the Milestone Events described in Section 8.2.4.
- 1.22 "Commercially Reasonable Efforts" means, with respect to the efforts to be expended by a Party with respect to an agreed objective, such reasonable, diligent, and good faith efforts that a biopharmaceutical company of similar size would normally use taking into account the reasonable allocation of such company's resources under the circumstances to accomplish a similar objective for its own internally developed product that is of similar market potential at a similar stage in its Development, Commercialization or product life, taking into account all relevant factors, including (a) the potential profitability of the product, (b) the costs and risks of Developing, Manufacturing, having Manufactured, using and Commercializing the product, (c) scientific, safety and regulatory concerns, (d) product profile, (e) the competitiveness of the marketplace and (f) the proprietary position of the product. In addition, "Commercially Reasonable Efforts" shall be determined on a country-by-country or market-by-market basis (as most applicable) for a particular Collaboration Product, and it is anticipated that the level of effort will change over time, including to reflect changes in the status of the Collaboration Product and the countries (or markets) involved. For the avoidance of doubt, where a Party has an obligation to use Commercially Reasonable Efforts, the efforts of such Party and its Affiliates, subcontractors and Sublicensees shall be considered in determining whether such Party has satisfied such obligation.
- 1.23 "Competitive Product" means, with respect to a Program, a Gene Therapy Product (other than a Collaboration Product under the Collaboration) that is directed to the Target to which Collaboration Products in such Program are directed, provided, however, that to the extent such Target is a derivative or fragment of a gene that is (i) the same derivative or fragment of a different gene and (ii) is a potential Target for a Gene Therapy Product in a different indication, a Gene Therapy Product that is directed to such Target for use in such different indication shall not be a Competitive Product.
- 1.24 "Control" means, subject to Section 5.2.3, with respect to a Person and any Know-How or Patent Right, the possession by such Person of the right (whether through ownership or license (other than by a license under this Agreement) or control (as defined in Section 1.6) over an Affiliate with such right) to grant the licenses or sublicenses as provided herein without violating the terms of any agreement or other arrangement with any Third Party.
- 1.25 "Cover" means, in the absence of ownership of or a license granted under a Valid Claim, (a) with respect to a Collaboration Product, that the manufacture, use or sale of such Collaboration Product and (b) with respect to any other invention, that the practice of such invention, in each case (a) and (b) would infringe such Valid Claim (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue).

- 1.26 "Develop" or "Development" means non-clinical, pre-clinical and clinical research and development activities, including discovery, identification, research, engineering, characterization, development, modification, optimization, drug metabolism and pharmacokinetics, translational research, toxicology, pharmacology toxicology studies, statistical analysis and report writing, formulation development and optimization, Clinical Trials, regulatory affairs (including preparation for a Regulatory Approval Application submission and other submission-related activities), product approval and registration activities, and all other activities necessary to conduct IND-enabling studies, conduct Clinical Trials, or seek, obtain and maintain Regulatory Approval. "Development" shall not include Commercialization, but may include Manufacturing to the extent applicable.
- 1.27 "Development Candidate" means (a) with respect to the AADC Program, VY-AADC, (b) with respect to the FA Program, initially, VY-FXN01, and (c) on a Program-by-Program basis, other than with respect to the AADC Program, a Gene Therapy Product that (i) is Developed by or on behalf of Voyager in the course of such Program, (ii) has been nominated as a development candidate by either Voyager or Neurocrine in accordance with Section 2.1.9(a) and (iii) either (A) has been determined to meet the development candidate criteria developed by the JSC (the "Development Candidate Criteria") or (B) has otherwise been selected by the JSC as a Development Candidate notwithstanding its failure to meet the Development Candidate Criteria, in each case (A) and (B) pursuant to Section 2.1.9(b).
- 1.28 "<u>Development Costs</u>" means the FTE Costs (at the then-current FTE Rate) and the Out-of-Pocket Costs (without markup) incurred by or on behalf of a Party or any of its Affiliates in the conduct of the Development of a Collaboration Product.
  - 1.29 "Development Milestones" means the Milestone Events described in Sections 8.2.1, 8.2.2 and 8.2.3.
- 1.30 "<u>Development Plan</u>" means an Existing Program Development Plan or a Discovery Program Development Plan, as applicable.
- 1.31 "<u>Discovery Program</u>" means, with respect to each Discovery Target, all activities under this Agreement directed to the Development, Manufacture and Commercialization of Gene Therapy Products directed to such Discovery Target.
- 1.32 "<u>Discovery Target</u>" means each of two Targets approved for the Discovery Programs by the JSC pursuant to Section 2.1.2.
  - 1.33 "Dollars" or "\$" means the legal tender of the U.S.
  - 1.34 "Effective Date" means the HSR Clearance Date.
  - 1.35 "EMA" means the European Medicines Agency, and any successor entity thereto.
- 1.36 "<u>Executive Officers</u>" means the Chief Executive Officer, or his or her designee, in the case of Voyager, and the Chief Executive Officer, or his or her designee, in the case of Neurocrine.

- 1.37 "<u>Existing In-License Agreement</u>" means those in-licenses of Voyager or any of its Affiliates set forth on <u>Schedule 1.37</u> attached hereto.
  - 1.38 "Existing Program" means each of (a) the AADC Program and (b) the FA Program.
- 1.39 "<u>Existing Program Development Plan</u>" means each of (a) the AADC Program Development Plan and (b) the FA Program Development Plan.
- 1.40 "Exploit" or "Exploitation" means to make, have made, import, use, sell, or offer for sale, Develop, Manufacture or Commercialize.
  - 1.41 "FA" means Friedreich's Ataxia.
- 1.42 "<u>FA Program</u>" means all activities under this Agreement directed to the Development, Manufacture and Commercialization of Gene Therapy Products intended to treat FA. The Target of the FA Program is the gene encoding Frataxin.
- 1.43 "<u>FA Program Development Plan</u>" means the plan and budget for the Development of VY-FXN01 (or any successor Development Candidate in the FA Program) through completion of the Phase 1 Clinical Trial therefor, the initial version of which will be mutually agreed to by the Parties within [\*\*] of the Effective Date, as such plan and budget may be updated by the JSC from time to time in accordance with Section 2.1.3(a).
  - 1.44 "FDA" means the U.S. Food and Drug Administration, and any successor entity thereto.
  - 1.45 "Field" means all human and veterinary diagnostic, prophylactic, and therapeutic uses.
- 1.46 "<u>First Commercial Sale</u>" means, with respect to a Collaboration Product and a country in the Territory, the first sale for end use or consumption of such Collaboration Product in such country after all Regulatory Approvals and pricing and reimbursement approvals legally required for such sale have been granted by the applicable Regulatory Authority of such country or, if Regulatory Approval is not required, after the date on which sales are permitted by applicable Law.
- 1.47 "<u>Frataxin</u>" means the protein encoded by the *FXN* gene which is defined by ENSEMBL Gene ID ENSG00000165060, or any naturally occurring variant thereof.
- 1.48 "FTE" means one (1) person (or the equivalent of one (1) person) working full time for one (1) twelve (12) month period in a Development, regulatory or other relevant capacity (excluding persons employed in general and administrative, non-technical management or other non-technical capacities) employed by Voyager or Neurocrine or any of their respective Affiliates and assigned to perform specified work, with such commitment of time and effort to constitute one (1) employee performing such work on a full-time basis, which for purposes hereof shall be [\*\*] hours per year. No additional payment shall be made with respect to any person who works more than [\*\*] hours per year (which person shall be deemed one (1) FTE) and any person who

devotes less than [\*\*] hours per year shall be treated as an FTE on a pro rata basis based upon the actual number of hours worked divided by [\*\*].

- 1.49 "<u>FTE Costs</u>" means the FTE Rate multiplied by the applicable number of FTEs who perform a specified activity pursuant to this Agreement.
- 1.50 "FTE Rate" means \$[\*\*] per FTE for the period commencing on the Effective Date and ending December 31, 2019. On January 1, 2020 and on January 1st of each subsequent Calendar Year, the foregoing rate shall be increased for the Calendar Year then commencing by the percentage increase, if any, in the Consumer Price Index ("CPI") as of December 31 of the then most recently completed Calendar Year with respect to the level of the CPI on December 31, 2019. Consumer Price Index or CPI means the Consumer Price Index Urban Wage Earners and Clerical Workers, US City Average, All Items, 1982-84 = 100, published by the United States Department of Labor, Bureau of Labor Statistics (or its successor equivalent index).
- 1.51 "<u>Future In-License Agreement</u>" means any agreement between Voyager (or any of its Affiliates), on the one hand, and a Third Party, on the other hand, entered into after the Effective Date, pursuant to which Voyager or any of its Affiliates acquires Control of any Know-How or Patent Right that, subject to Section 5.2, would be Voyager IP.
- 1.52 "GCP" means the then-current good clinical practice standards for clinical trials for pharmaceuticals, as set forth in the United States Food, Drug and Cosmetic Act, as amended from time to time (the "Act"), or other applicable law, and such standards of good clinical practice as are required by the Regulatory Authorities of the EU and other organizations and Governmental Authorities in countries for which the applicable Collaboration Candidate or Collaboration Product is intended to be developed, to the extent such standards are not less stringent than United States GCP.
- 1.53 "<u>Gene Therapy Product</u>" means a Virus Vector, including without limitation AAV, that delivers a polynucleotide to certain cells of a patient for a purpose in the Field. Gene Therapy Products include, but are not limited to, Development Candidates, other Collaboration Candidates and Collaboration Products.
- 1.54 "<u>Genzyme Agreement</u>" means that certain Collaboration Agreement by and between Voyager and Genzyme Corporation ("<u>Genzyme</u>") dated February 11, 2015, as amended March 28, 2017, including the Post-Termination Under Collaboration Agreement dated December 8, 2017.
- 1.55 "<u>GLP</u>" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, or comparable regulatory standards in jurisdictions outside the United States.
- 1.56 "<u>Governmental Authority</u>" means any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority or functions of any nature pertaining to government.

- 1.57 "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended from time to time.
- 1.58 "HSR Clearance Date" means the expiration or termination of all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act in the U.S.
- 1.59 "<u>HSR Filing</u>" means filings by Neurocrine and Voyager with the U.S. Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto.
- 1.60 "<u>In-License Agreement</u>" means (a) any Existing In-License Agreement and (b) any Future In-License Agreement.
- 1.61 "IND" means an investigational new drug application submitted to the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations, including any amendments thereto. References herein to IND shall include, to the extent applicable, any comparable filing(s) outside the U.S. for the investigation of any product in any other country or group of countries.
- 1.62 "<u>Initiation</u>" means, with respect to a Clinical Trial, the first dosing of the first subject enrolled in such Clinical Trial with a Collaboration Product.
- 1.63 "<u>Invention</u>" means any new invention, discovery, process, method, machine, manufacture, design, composition of matter, material or improvement thereof (whether patentable or not).
  - 1.64 "Joint IP" means the Joint Know-How and Joint Patent Rights.
- 1.65 "<u>Joint Know-How</u>" means Joint Inventions and other Know-How that is jointly invented, discovered, conceived or generated by one or more employees, agents or consultants of Voyager, on the one hand, and one or more employees, agents or consultants of Neurocrine, on the other hand, in the conduct of activities under this Agreement, including in the conduct of the Development, Manufacture or Commercialization of Collaboration Products.
  - 1.66 "Joint Patent Right" means any Patent Right that Covers Joint Know-How.
- 1.67 "Know-How" means all information, know-how and data, including trade secrets, inventions (whether patentable or not), discoveries, methods, specifications, processes, expertise, technology, other non-clinical, pre-clinical and clinical data, documentation and results (including pharmacological, toxicological, biological, chemical, physical, safety and manufacturing data and results), analytical and quality control data and results, Regulatory Filings and other technical information. "Know-How" excludes in any event any Patent Rights.
- 1.68 "Knowledge" means (a) with respect to Voyager, the knowledge after reasonable investigation of the individuals set forth on Schedule 1.68, and (b) with respect to Neurocrine, the knowledge after reasonable investigation of the individuals set forth on Schedule 1.68.

- 1.69 "<u>Law</u>" means any law, statute, rule, regulation, order, judgment or ordinance having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision.
  - 1.70 "[\*\*]" means any of the following: [\*\*].
- 1.71 "Manufacture" or "Manufacturing" means all activities related to the manufacturing of a Collaboration Candidate and/or Collaboration Product, including test method development and stability testing, formulation, process development, manufacturing scale-up, manufacturing for use in non-clinical and clinical studies, manufacturing for commercial sale, packaging, release of product, quality assurance/quality control development, quality control testing (including in-process, in-process release and stability testing) and release of product or any component or ingredient thereof, and regulatory activities related to all of the foregoing. "Manufacturing" may be included as part of Development or Commercialization, to the extent applicable.
- 1.72 "Net Sales" means, with respect to any Collaboration Product, the gross amount invoiced by Neurocrine, any of its Affiliates and or any Sublicensee (each, a "Selling Party") to a Third Party (including a customer, distributor, wholesaler or end user) for sales of such Collaboration Product, less the following deductions as calculated in accordance with the applicable Accounting Standard as consistently applied:
- 1.72.1 normal trade, cash, quantity and other customary discounts actually given to customers in the ordinary course of business;
- 1.72.2 rebates, credits and allowances given by reason of rejections, returns, damaged or defective product or recalls;
- 1.72.3 government-mandated rebates and any other compulsory payments, credits, adjustments and rebates actually paid or deducted;
- 1.72.4 price adjustments, allowances, credits, chargeback payments, discounts, rebates, fees and reimbursements or similar payments granted or made to managed care organizations, group purchasing organizations or other buying groups, pharmacy benefit management companies, health maintenance organizations and any other providers of health insurance coverage, health care organizations or other health care institutions (including hospitals), health care administrators, patient assistance or other similar programs, or to federal state/provincial, local and other governments, including their agencies, or to wholesalers, distributors or other trade customers;
- 1.72.5 reasonable and customary freight, shipping, insurance and other transportation expenses, if actually borne by the applicable Selling Party without reimbursement from any Third Party;
- 1.72.6 reasonable distributors' and inventory management fees, including fees for services provided by wholesalers and warehousing chains, in connection with the sale and distribution of such Collaboration Product;

- 1.72.7 that portion of administrative fees paid to group purchasing organizations, pharmacy benefit managers, Medicare prescription drug plans or any other facilitator of drug access for patients relating specifically to such Collaboration Product;
- 1.72.8 uncollectible amounts or reasonable reserves accrued therefor (it being understood that any subsequent reductions in such accrual amounts due to collections in subsequent periods shall be included in Net Sales when such reductions occur);
- 1.72.9 that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) and reasonably allocable to sales of such Collaboration Product;
- 1.72.10 sales, value-added, excise taxes, tariffs and duties, and other taxes and government charges directly related to the sale, delivery or use of such Collaboration Product (but not including taxes assessed against the net income derived from such sale); and
- 1.72.11 any other similar and customary deductions that are consistent with Accounting Standards, as agreed by the Parties in writing or, if the Parties fail to agree on any such deductions proposed by Neurocrine, as determined by a mutually agreed independent accounting expert, whose decision will be final and binding on the Parties.

If non-monetary consideration is received for any Collaboration Product, Net Sales will be calculated based on the average price charged for such Collaboration Product during the preceding Calendar Quarter in the relevant country, or in the absence of such sales, the fair market value of the Collaboration Product, as determined by the Parties in good faith.

Resales or sales of a Collaboration Product made in good faith between or among Neurocrine, any of its Affiliates or any Sublicensee shall not be included in the calculation of Net Sales as long as, with respect to such resales or sales, the first sale thereafter to a non-Sublicensee Third Party is included in the calculation of Net Sales.

Net Sales shall not include any amounts received for Collaboration Products supplied for use in clinical trials, or supplied at or below the fully-burdened cost of good thereof under early access, compassionate use, named patient, indigent access, patient assistance or other reduced pricing programs.

In the event that a Collaboration Product under this Agreement is sold by a Selling Party in combination (a "<u>Combination Product</u>") with one or more therapeutically active compound(s) that are not Collaboration Products ("<u>Supplemental Ingredient(s)</u>"), then "Net Sales" of the Combination Product shall be calculated using one of the following methods:

(x) By multiplying the Net Sales of the Combination Product (calculated prior to the application of this formula) by the fraction A/(A+B), where A is the average gross selling price, during the applicable Calendar Quarter in the country concerned, of the Collaboration Product when sold separately, and B is the average gross selling price, during the applicable Calendar Quarter in the country concerned, of the Supplemental Ingredient(s) when sold separately; or

- (y) In the event that no such separate sales are made of the Collaboration Product or any of the Supplemental Ingredients in such Combination Product during the applicable Calendar Quarter in the country concerned, Net Sales shall be calculated using the above formula where A is the reasonably estimated commercial value of the Collaboration Product sold separately and B is the reasonably estimated commercial value of the Supplemental Ingredient(s) sold separately. Any such estimates shall be determined using criteria to be mutually agreed upon by the Parties. If the Parties are unable to agree on the criteria for determining such estimates, the Parties will submit such dispute for resolution to a mutually agreed independent accounting expert, whose decision will be final and binding on the Parties.
- 1.73 "Neurocrine IP" means the Neurocrine Know-How and the Neurocrine Patent Rights.
- 1.74 "Neurocrine Know-How" means (a) all Know-How that (i) is Controlled by Neurocrine or any of its Affiliates on the Effective Date or during the Term, (ii) prior to any disclosure to Voyager hereunder or under the Existing Confidentiality Agreement was not generally known to the public and (iii) is necessary or reasonably useful to Exploit in the Field in the Territory any Collaboration Product; and (b) Neurocrine's interest in the Joint Know-How. Notwithstanding anything in this Agreement to the contrary, Neurocrine Know-How shall not include any Know-How to the extent Controlled by any Person that acquires all or any part of Neurocrine or an Affiliate of Neurocrine, or any affiliates of such Person, in each case (x) which is Controlled by such Person immediately prior to the effective date of the acquisition (and such Control was not acquired through acquisition) or (y) which is Controlled by such Person on or after the effective date of acquisition but is not Controlled by Neurocrine or an Affiliate of Neurocrine (excluding for purposes of this provision, such Person and Affiliates of Neurocrine that are such Affiliates by virtue of controlling, being controlled by or under common control with such Person and were not Affiliates of Neurocrine prior to the acquisition) and was developed, invented or obtained without the direct or indirect use of any non-public Neurocrine Know-How.
- 1.75 "Neurocrine Patent Rights" means (a) all Patent Rights Controlled by Neurocrine or any of its Affiliates as of the Effective Date or during the Term, that Cover any Collaboration Product; and (b) Neurocrine's interest in the Joint Patent Rights. Notwithstanding anything in this Agreement to the contrary, Neurocrine Patent Rights shall not include any Patents to the extent owned or Controlled by any Person that acquires all or any part of Neurocrine or an Affiliate of Neurocrine, or any affiliates of such Person, in each case (x) which is Controlled by such Person immediately prior to the effective date of the acquisition (and such Control was not acquired through acquisition or license from Neurocrine or any Affiliate of Neurocrine in existence prior to the effective date of such acquisition) or (y) which is Controlled by such Person on or after the effective date of acquisition but is not Controlled by Neurocrine or an Affiliate of Neurocrine (excluding for purposes of this provision, such Person and Affiliates of Neurocrine that are such Affiliates by virtue of controlling, being controlled by or under common control with such Person and were not Affiliates of Neurocrine prior to the acquisition) and was developed, invented, or obtained without the direct or indirect use of any non-public Neurocrine Know-How.

- 1.76 "[\*\*] Agreement" means that certain [\*\*] Agreement by and between [\*\*] and Voyager, dated [\*\*].
- 1.77 "Out-of-Pocket Costs" means actual out-of-pocket costs and expenses paid by a Party or any of its Affiliates to Third Parties, including to a consultant or contractor of such Party.
- 1.78 "Patent Right" means (a) any patent or patent application (including any provisional application) in any country or multinational jurisdiction in the Territory (including any converted application, continuation, continuation-in-part, continued prosecution application or divisional of any such application, any reissue, renewal, extension, substitution, reexamination, supplementary protection certificate, pediatric exclusivity period or the like of any such patent); (b) any foreign equivalent of any patent or patent application described in clause (a); and (c) all rights of priority in any of the foregoing.
- 1.79 "<u>PHSA</u>" means the Public Health Service Act as set forth in 42 U.S.C. Chapter 6A, as may be amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).
- 1.80 "PMDA" means the Pharmaceuticals and Medical Devices Agency in Japan, and any successor entity thereto.
- 1.81 "Person" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Governmental Authority, or any other entity not specifically listed in this Section 1.81.
- 1.82 "<u>Phase 1 Clinical Trial</u>" means a human clinical trial (or a portion of a human clinical trial) of a product in any country, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients, that would satisfy the requirements of 21 C.F.R. 312.21(a), or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States.
- 1.83 "Phase 2 Clinical Trial" means a human clinical trial (or a portion of a human clinical trial) of a product in any country that would satisfy the requirements of 21 C.F.R. 312.21(b) and whose design is intended to explore a variety of doses, dose response, and duration of effect, and to generate initial evidence of clinical safety and activity in a target patient population, or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States.
- 1.84 "Phase 3 Clinical Trial" means a human clinical trial (or a portion of a human clinical trial) of a product in any country that would satisfy the requirements of 21 C.F.R. 312.21(c) and whose design is intended to (a) establish that the product is safe and efficacious for its intended use, (b) define warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support Regulatory Approval for such product.
- 1.85 "Pivotal Clinical Trial" means a Clinical Trial that is designed to be sufficient to support the filing of a BLA for such product.

- 1.86 "<u>Program</u>" means, with respect to a Target, all activities under this Agreement directed to the Development, Manufacture and Commercialization of Collaboration Products directed to such Target. The Term "Program" includes any Existing Program or Discovery Program or Co-Co Program, but specifically excludes any Terminated Program.
- 1.87 "<u>Proof of Mechanism</u>" means, with respect to the FA Program and each Discovery Program, achievement of the milestones or metrics determined by the JSC and identified as such in the applicable Development Plan.
- 1.88 "Prosecution and Maintenance" or "Prosecute and Maintain" means, with regard to a Patent Right, the preparation, filing, prosecution and maintenance of such Patent Right, as well as re-examinations, reissues, appeals, and requests for patent term adjustments and patent term extensions with respect to such Patent Right. For clarification, "Prosecution and Maintenance" or "Prosecute and Maintain" shall not include any enforcement actions taken with respect to a Patent Right.
- 1.89 "<u>Public Official or Entity</u>" means (a) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality or subdivision of any government, military or international governmental organization, including any ministry or department of health or any state-owned or affiliated company or hospital, or (b) any candidate for political office, any political party or any official of a political party.
- 1.90 "<u>Regulatory Approval</u>" means all approvals of the applicable Regulatory Authority necessary for the commercial marketing and sale of a product in a country(ies), excluding any pricing and reimbursement approvals that may be required.
- 1.91 "<u>Regulatory Approval Application</u>" means (a) a BLA, or (b) any other application to seek Regulatory Approval of a product in any country or multinational jurisdiction, as defined in applicable Laws and filed with the relevant Regulatory Authorities of such country or jurisdiction.
- 1.92 "<u>Regulatory Authority</u>" means the FDA in the United States or any Governmental Authority in another country or regulatory jurisdiction in the Territory that is a counterpart to the FDA and holds responsibility for granting Regulatory Approval for a product in such country or regulatory jurisdiction, including the EMA and PMDA, and any successor(s) thereto.
- 1.93 "<u>Regulatory Exclusivity</u>" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to any Collaboration Product, excluding Patent Rights, that precludes the use of any clinical data collected and filed for such Collaboration Product for the benefit of any Regulatory Approval for a generic or biosimilar product (for any use), including orphan or pediatric exclusivity where applicable.
- 1.94 "<u>Regulatory Filing</u>" means, with respect to a product, any documentation comprising any filing or application with any Regulatory Authority with respect to such product, or its use or potential use in the Field, any document submitted to any Regulatory Authority, including any IND and any Regulatory Approval Application, and any correspondence to, from or

with any Regulatory Authority with respect to such product (including minutes of any meetings, telephone conferences or discussions with any Regulatory Authority).

- 1.95 "<u>Target</u>" means a gene as defined by a specific gene ID, all mutants of such gene, derivatives or fragments with similar functional properties to such gene, or allelic variants of such gene, (a) whose DNA is delivered, replaced, substituted for, or altered upon administration of a Gene Therapy Product; (b) whose level of expressed RNA (including mRNA) or protein is modulated, silenced, augmented or eliminated upon administration of a Gene Therapy Product; or (c) whose protein expression product serves in whole or in part as an antigen and whereby, upon binding by an immunoglobulin encoded by a Gene Therapy Product such protein is neutralized or destroyed. All of the Gene Therapy Products described in the preceding clauses (a), (b) and (c) are considered "directed to" such Target.
- 1.96 "<u>Terminated Program</u>" shall mean a Program that is terminated by the JSC pursuant to Section 3.1.2(q), by the mutual agreement of the Parties or pursuant to Article 14.
- 1.97 "<u>Territory</u>" means (a) with respect to the AADC Program and each Discovery Program, all countries in the world (excluding any countries for which this Agreement has been terminated with respect to such Program) and (b) with respect to the FA Program, the United States and, upon expiration of Genzyme's option to the FA Program without exercise thereof, all countries in the world (excluding any countries for which this Agreement has been terminated with respect to such Program).
  - 1.98 "Third Party" means any Person that is neither a Party nor an Affiliate of a Party.
  - 1.99 "Transition Date" means the date upon which the applicable Transition Event occurs.
- 1.100 "<u>Transition Event</u>" means (a) with respect to the AADC Program, Voyager's receipt of topline data with respect to the Existing Pivotal Trial, (b) with respect to the FA Program, Voyager's receipt of topline data with respect to the first Phase 1 Clinical Trial for a Product in the FA Program, and (c) with respect to the Discovery Programs, preparation by Voyager and approval by Neurocrine of the IND to be filed by Neurocrine for the first Development Candidate in each such Discovery Program.
- 1.101 "<u>United States</u>" or "<u>U.S.</u>" means the United States of America and all of its territories and possessions.
- 1.102 "Valid Claim" means (a) a claim of an issued and unexpired patent, which claim has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction and that has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise, or (b) a claim of a patent application that has been pending less than [\*\*] from the date of filing of the earliest patent application from which such patent application claims priority, which claim has not been cancelled, withdrawn or abandoned or finally rejected by an administrative agency action from which no appeal can be taken.

- 1.103 "Vectorization IP" means all Vectorization Know-How and Vectorization Patent Rights.
- 1.104 "<u>Vectorization Know-How</u>" means all Know-How, including Inventions, that is conceived, discovered, developed or otherwise made or acquired under any Program during the Term (a) by or on behalf of either Party (or its Affiliates or its or their (sub)licensees/Sublicensees) or (b) jointly by or on behalf of Neurocrine (or its Affiliates or its or their Sublicensees), on the one hand, and Voyager (or its Affiliates or its or their licensees), on the other hand, in each case ((a) and (b)), that is directed to Vectorization Technology. Vectorization Know-How shall be considered the Confidential Information of Voyager.
  - 1.105 "Vectorization Patent Rights" means any Patent Rights that Cover Vectorization Know-How.
- 1.106 "<u>Vectorization Technology</u>" means Voyager's proprietary Virus Vector platform, including any of the following aspects of such platform: (a) Virus Capsids or (b) Know-How regarding the design, Manufacture or optimization of Virus Capsids for the creation of vectorized payloads, including (i) Voyager's system of manufacturing recombinant adeno-associated virus ("<u>rAAV</u>"), comprising molecular materials and methods of generating baculovirus expression vectors (BEVs) that express AAV structural and non-structural proteins essential for replication; (ii) processes for purifying rAAV from the cell culture; (iii) genetic modifications to the Spodoptera frugiperda (Sf9) cell line and baculovirus and (d) Know-How regarding the administration or delivery of any Virus Vectors as therapeutics. For clarity, Vectorization Technology shall not include Know-How related to specific Collaboration Products or Targets or the manufacture of specific Collaboration Products.
- 1.107 "<u>Vector Genome</u>" means a polynucleotide, whether single stranded (ss) or self-complementary (sc), having a configuration capable of selectively encoding one (1) or more payloads or including one or more transgenes when encapsulated by a Virus Capsid.
- 1.108 "<u>Virus Capsid</u>" means an engineered or naturally occurring capsid protein or proteins (or the encoding nucleic acid sequence thereof), including, but not limited to, from an AAV, that is capable of encapsulating a Vector Genome.
  - 1.109 "Virus Vector" means a virus comprising a Virus Capsid and Vector Genome encapsulated therein.
- 1.110 "<u>Voyager IP</u>" means the Voyager Know-How, Voyager Licensed Patent Rights and all Vectorization IP.
- 1.111 "<u>Voyager Know-How</u>" means (a) all Know-How that (i) is Controlled by Voyager or any of its Affiliates on the Effective Date or during the Term, (ii) prior to any disclosure to Neurocrine hereunder or under the Existing Confidentiality Agreement was not generally known to the public and (iii) is necessary or reasonably useful to Exploit in the Field in the Territory any Collaboration Product; (b) Vectorization Know-How; and (c) Voyager's interest in the Joint Know-How. Notwithstanding anything in this Agreement to the contrary, Voyager Know-How shall not include any Know-How to the extent Controlled by any Person that acquires all or any part of Voyager or an Affiliate of Voyager, or any affiliates of such Person, in each case (x) which

is Controlled by such Person immediately prior to the effective date of the acquisition (and such Control was not acquired through acquisition or license from Voyager or any Affiliate of Voyager in existence prior to the effective date of such acquisition) or (y) which is Controlled by such Person on or after the effective date of acquisition but is not Controlled by Voyager or an Affiliate of Voyager (excluding for purposes of this provision, such Person and Affiliates of Voyager that are such Affiliates by virtue of controlling, being controlled by or under common control with such Person and were not Affiliates of Voyager prior to the acquisition) and was developed, invented or obtained without the direct or indirect use of any non-public Voyager Know-How.

- "Voyager Licensed Patent Rights" means (a) all Patent Rights Controlled by Voyager or any of its Affiliates as of the Effective Date or during the Term, that claim or Cover any Collaboration Product; and (b) Voyager's interest in the Joint Patent Rights. Notwithstanding anything in this Agreement to the contrary, Voyager Licensed Patent Rights shall not include any Patents to the extent owned or Controlled by any Person that acquires all or any part of Voyager or an Affiliate of Voyager, or any affiliates of such Person, in each case (x) which is Controlled by such Person immediately prior to the effective date of the acquisition (and such Control was not acquired through acquisition or license from Voyager or any Affiliate of Voyager in existence prior to the effective date of such acquisition) or (v) which is Controlled by such Person on or after the effective date of acquisition but is not Controlled by Voyager or an Affiliate of Voyager (excluding for purposes of this provision, such Person and Affiliates of Voyager that are such Affiliates by virtue of controlling, being controlled by or under common control with such Person and were not Affiliates of Voyager prior to the acquisition) and was developed, invented, or obtained without the direct or indirect use of any non-public Voyager Know-How. Notwithstanding the foregoing, the Voyager Licensed Patent Rights exclude any Patent Rights licensed to Voyager under that certain License Agreement between Voyager and ReGenX Biosciences, LLC, dated May 28, 2014 (the "ReGenX Agreement"), which will not be considered an Existing In-License Agreement unless and until Neurocrine requests in writing that the ReGenX Agreement becomes an Existing In-License Agreement. Notwithstanding the foregoing, the Voyager Licensed Patent Rights exclude any Patent Rights licensed to Voyager under the [\*\*] License Agreement, which Patent Rights will not be considered sublicensed hereunder unless and until Neurocrine requests in writing that such Patent Rights be so sublicensed following the naming of a Development Candidate with respect to the FA Program or either Discovery Program. Notwithstanding the foregoing, the Voyager Licensed Patent Rights exclude any Patent Rights licensed to Voyager under the [\*\*] Agreement, which Patent Rights will not be considered sublicensed hereunder unless and until [\*\*] consents to the sublicense of such Patent Rights, at which time such Patent Rights shall be considered sublicensed hereunder without any further action by either Party.
- 1.113 "<u>Voyager Licensed Platform Patent Rights</u>" means all Voyager Licensed Patent Rights that are not Voyager Target-Specific Patent Rights.
- 1.114 "<u>Voyager Target-Specific Patent Rights</u>" means those Voyager Licensed Patent Rights that contain claims (a) directed specifically toward a particular Collaboration Candidate, Collaboration Product, or its formulation, manufacture or use, (b) directed toward a method of treatment or use relating to any Program or (c) that relate to modulation of a Target in a Program, its expression or activity of its gene products.

- 1.115 "<u>VY-AADC</u>" means the Gene Therapy Product under Development by Voyager for the treatment of Parkinson's disease prior to the execution of this Agreement that will be utilized initially in the AADC Program as a Development Candidate, as described in IND Nos. [\*\*], the Development of which is afforded a right of reference to the Avigen/Genzyme IND, [\*\*].
- 1.116 "<u>VY-FXN01</u>" means the Gene Therapy Product under Development by Voyager for the treatment of FA prior to the execution of this Agreement that will be utilized initially in the FA Program as a Development Candidate.
- 1.117 <u>Additional Definitions</u>. Each of the following definitions is set forth in the section of this Agreement indicated below:

| Definition:                        | Section:      |
|------------------------------------|---------------|
| Acquired Affiliate                 | 9.3.1         |
| Acquired Competing Product         | 9.3.1         |
| Acquired Competing Program         | 9.3.1         |
| Acquirer                           | 1.16          |
| Acquisition Party                  | 9.3.1         |
| Act                                | 1.52          |
| Agreement                          | Preamble      |
| Alliance Manager                   | 3.7           |
| Allocation Schedule                | 8.1.1         |
| Alternative Method                 | 5.2.4         |
| [**]                               | 7.3           |
| [**]                               | 1.14          |
| [**] Indemnitees                   | 13.1.2        |
| Co-Co Agreement                    | 4.1.1         |
| Co-Co Option                       | 4.1.1         |
| Co-Co Product                      | 4.1.1         |
| Co-Co Program                      | 4.1.1         |
| Co-Co Rate                         | 4.1.3         |
| Co-Co Territory                    | 4.1.1         |
| Co-Co Trigger Date                 | 4.1.1         |
| Collaboration                      | 2.1.1         |
| Collaboration IP Working Group     | 3.3.1(b)      |
| Combination Product                | 1.72          |
| Committee                          | 3.3.1         |
| Competitive Infringement           | 10.3.1        |
| Confidential Information           | 11.1          |
| CPI                                | 1.50          |
| Defense Proceeding                 | 10.2.1(a)(ii) |
| Delivery Event                     | 5.8           |
| Development Candidate Criteria     | 1.27          |
| Discovery Program Development Plan | 2.1.3(b)      |
| Disclosing Party                   | 11.1          |
| Dispute                            | 15.2          |
| Execution Date                     | Preamble      |
|                                    |               |

| Existing Confidentiality Agreement | 11.1     |
|------------------------------------|----------|
| Existing Pivotal Trial             | 1.3      |
| ICC                                | 15.3.2   |
| Genzyme                            | 1.54     |
| Inbound Licensor                   | 5.2.1    |
| Indemnified Party                  | 13.3     |
| Indemnifying Party                 | 13.3     |
| Initial Fee                        | 8.1.1    |
| Joint CMC Working Group            | 3.3.1(c) |
| Joint Invention                    | 10.1.1   |
| Joint R&D Working Group            | 3.3.1(a) |
| JRA Exception                      | 15.14    |
| JSC                                | 3.1.1    |
| Losses                             | 13.1     |
| Major Market Countries             | 4.2.2    |
| Milestone Event                    | 8.2(a)   |
| Milestone Payment                  | 8.2(a)   |
| Neurocrine                         | Preamble |
| Neurocrine Plan                    | 4.2.3    |
| Neurocrine Product Marks           | 10.6     |
| Neurocrine PRV Use                 | 7.3      |
| Parties                            | Preamble |
| Party                              | Preamble |
| Patent Challenge                   | 14.5     |
| Payee                              | 8.7.1    |
| Payor                              | 8.7.1    |
| Potential Target List              | 2.1.2    |
| PRV                                | 7.3      |
| PRV Sale                           | 7.3      |
| rAAV                               | 1.106    |
| Rate-Shifting Fee                  | 4.1.3    |
| Receiving Party                    | 11.1     |
| Redacted Version                   | 11.3.2   |
| ReGenX Agreement                   | 1.112    |
| Royalty Term                       | 8.4      |
| Secondary Market Countries         | 4.2.2(b) |
| Selling Party                      | 1.72     |
| Stock Purchase Agreement           | 8.1.2    |
| Subcommittee                       | 3.1.1    |
| Sublicense                         | 5.5      |
| Sublicensee                        | 5.5      |
| Supplemental Ingredient(s)         | 1.72     |
| Target Nomination Period           | 2.1.2    |
| Term                               | 14.1     |
| Title 11                           | 5.8      |
| Third Party Claims                 | 13.1     |
|                                    |          |

Transition Plan 4.3
Voyager Preamble
Withholding Tax Action 8.11.3
Working Group 3.3.1

# ARTICLE 2 COLLABORATION; PRE-TRANSITION DEVELOPMENT

### 2.1 <u>Collaboration and Programs</u>.

2.1.1 <u>Collaboration</u>. The Parties agree to collaborate on the conduct of four (4) Programs under this Agreement: the AADC Program, the FA Program and two (2) Discovery Programs. The Development, Manufacturing and Commercialization activities for Collaboration Candidates and Collaboration Products conducted pursuant to this Agreement under all four Programs, as well as any such activities conducted pursuant to any Co-Co Agreement, together, shall constitute the "<u>Collaboration</u>".

2.1.2 <u>Selection of Targets for Discovery Programs</u>. Within [\*\*] after the Effective Date, the Parties shall agree to a list of up to eight (8) Targets (the "Potential Target List") from which Neurocrine will have the right, after consultation with Voyager, to nominate Targets for the two (2) Discovery Programs by written notice to the JSC, which nomination shall occur within [\*\*] after the Parties' designation of the Potential Target List (the "Target Nomination Period"). Promptly following each such nomination by Neurocrine, Voyager shall provide Neurocrine with an analysis of such proposed Target, including technological feasibility, intellectual property protection, whether any In-License Agreement would be applicable to such Discovery Program, preliminary development timelines and a preliminary budget. Promptly thereafter, the JSC shall hold a meeting to discuss each proposed Target and determine whether to approve such proposed Target as a Discovery Target. Each Discovery Target must be approved by consensus of the JSC (or, if applicable, consensus of the Executive Officers), and upon approval by the JSC or Executive Officers of a Target nominated by Neurocrine, such Target will become a Discovery Target. Promptly thereafter, Voyager shall update <u>Schedule 1.37</u> to include any Existing In-License Agreements applicable to such Discovery Program. Voyager may not withhold approval of any proposed Discovery Target selected from the Potential Target List unless Voyager has a bona fide technical reason or other substantial concern that the proposed Discovery Target is not suitable for conducting a Discovery Program. If Voyager withholds its approval of any Target from the Potential Target List proposed by Neurocrine as a Discovery Target, then (a) Voyager shall concurrently provide a written description of its technical reason or other substantial concern to Neurocrine and (b) Voyager shall not, during the [\*\*] period after the end of the Target Nomination Period, conduct any activities, itself or with or through a Third Party, or grant a Third Party a license or otherwise enable a Third Party to conduct any activities, related to the development or commercialization of a Gene Therapy Product directed to such Target. If following the JSC's approval of any Discovery Target, the JSC fails to approve an initial Development Plan therefor, such Discovery Target will no longer be a Discovery Target, the restriction in the preceding clause (b) will apply thereto, and Neurocrine shall within [\*\*] nominate an additional Target from the Potential Target List as a Discovery Target pursuant to this Section 2.1.2. Until the JSC's approval of two (2) Discovery Targets and Development Plans therefor,

Voyager shall not conduct any activities, itself or with or through a Third Party, or grant a Third Party a license or otherwise enable a Third Party to conduct any activities, related to the development or commercialization of a Gene Therapy Product directed to a Target on the Potential Target List. The foregoing restriction shall terminate upon the JSC's approval of the second Discovery Target and Development Plan therefor.

# 2.1.3 Conduct of Programs.

- (a) <u>Existing Programs</u>. Voyager shall conduct each Existing Program pursuant to the applicable Existing Program Development Plan. The JSC shall, prior to the end of each Calendar Year prior to the applicable Transition Date, review the Existing Program Development Plans and determine whether to update such plans, including to prepare a detailed budget for the subsequent Calendar Year. A Party may also develop and submit to the JSC from time to time proposed substantive amendments to the AADC Program Development Plan or the FA Program Development Plan. The JSC shall review such proposed amendments and may approve such proposed amendments or any other proposed amendments that the JSC may consider from time to time in its discretion and, upon any such approval by the JSC, the AADC Program Development Plan or FA Program Development Plan, as applicable, shall be amended accordingly.
- Discovery Programs. Each Discovery Program shall be conducted pursuant to a (b) research plan and associated budget (each such research plan, including the associated budget, a "Discovery Program Development Plan"). Each Discovery Program Development Plan shall set forth the activities to be conducted with respect to the applicable Discovery Program prior to the applicable Transition Date, and, subject to any mutually agreed contributions from Neurocrine pursuant to Section 2.1.7, shall assign to Voyager responsibility for all Development and associated Manufacturing activities with respect to such Discovery Program until filing by Neurocrine of the IND with respect to such Discovery Program. Following the JSC's approval of a Target as a Discovery Target, Voyager shall prepare the initial draft of the applicable Discovery Program Development Plan and submit it to the JSC for review and approval. The JSC shall approve each initial Discovery Program Development Plan with respect to each Discovery Program in accordance with Section 3.1.2(d). The JSC shall, prior to the end of each Calendar Year prior to the applicable Transition Date, review and update, as appropriate, each Discovery Program Development Plan, including preparing a detailed budget for the subsequent Calendar Year. A Party may also develop and submit to the JSC from time to time proposed substantive amendments to any Discovery Program Development Plan. The JSC shall review such proposed amendments and may approve such proposed amendments or any other proposed amendments that the JSC may consider from time to time in its discretion and, upon any such approval by the JSC, the applicable Discovery Program Development Plan shall be amended accordingly.
- 2.1.4 <u>Voyager Program Responsibilities</u>. Except as otherwise provided in this Agreement or the applicable Development Plan, Voyager shall have sole responsibility for the conduct of each Program (including any Clinical Trials and Manufacture of Collaboration Candidates and Collaboration Products) until the Transition Date with respect to such Program (and responsibility for any post-Transition Date activities that the Parties mutually agree in accordance with this Agreement). Subject to the terms and conditions of this Agreement, until the earlier of (i) the Transition Date or (ii) termination of the applicable Program by the JSC or by a

Party pursuant to Article 14, Voyager shall use Commercially Reasonable Efforts to Develop VY-AADC, VY-FXN01 and each other Development Candidate and to identify Development Candidates in the Discovery Programs and FA Program, and shall conduct all Development of Collaboration Candidates, including Development Candidates, in accordance with the applicable Development Plan. There shall be no more than two (2) Development Candidates per Program in each of the FA Program and each Discovery Program, unless otherwise mutually agreed by the Parties. Voyager shall conduct all activities allocated to it under the Development Plans and shall use Commercially Reasonable Efforts to comply with the timelines and budgets therein.

- 2.1.5 <u>Voyager Development Breach</u>. If Voyager materially breaches its obligations with respect to the conduct of activities under the Development Plan for a Discovery Program and fails to cure such breach within [\*\*] after written notice of such breach from Neurocrine, then Neurocrine shall have the right, but not the obligation, to assume the conduct of the applicable Program, itself or through an Affiliate or Third Party contractor (other than a competitor of Voyager), by written notice to Voyager. If Neurocrine elects to assume the conduct of any Program, then Voyager shall conduct all activities and provide all assistance reasonably necessary to transition the Program to Neurocrine or its permitted designee, including the transfer of Voyager Know-How and the provision of materials. Notwithstanding anything the contrary herein, in such event, Neurocrine shall not be responsible to reimburse any Development Costs incurred by Voyager to conduct any activities that were not properly conducted by Voyager or whose conduct Neurocrine has assumed.
- 2.1.6 <u>Voyager Reporting Obligations</u>. On a Calendar Quarterly basis until all four Transition Events have occurred, in advance of each regularly-scheduled JSC meeting, Voyager shall provide Neurocrine with a reasonably detailed report describing the activities undertaken and accomplishments achieved under each Development Plan, setting forth the Development Costs incurred to conduct such activities and including a copy of all results generated by Voyager in the performance of such Development Plan, in each case since the last such report. Voyager shall promptly respond to Neurocrine's reasonable requests for more information with respect to each such Calendar Quarterly report with respect to any Program. In addition, at Neurocrine's request in between such quarterly reports, Voyager shall provide all information reasonably requested by Neurocrine, including results and Development Costs incurred.
- 2.1.7 <u>Neurocrine Program Responsibilities</u>. On a Program-by-Program basis with regard to each Program, prior to the Transition Date with respect to such Program, Neurocrine shall, at Neurocrine's cost and expense, (a) contribute Development expertise to such Program as determined by the JSC and (b) provide reasonable Development assistance to Voyager during the conduct of such Program, where such assistance is reasonably requested by Voyager and approved by the JSC based on particular Neurocrine expertise.
- 2.1.8 <u>Neurocrine Reporting Obligations</u>. On a Calendar Quarterly basis for the AADC Program and the FA Program and on an annual basis for the Discovery Programs, following the Transition Event on a Program-by-Program basis, in advance of the regularly-scheduled JSC meeting, Neurocrine shall provide Voyager with a reasonably detailed report describing the activities undertaken and accomplishments achieved under each Program, including a summary of all results generated by Neurocrine under each Program, in each case since the last such report. In addition, prior to the Transition Event on a Program-by-Program basis, to the extent Neurocrine

has conducted any activities under a Development Plan since the preceding JSC meeting, Neurocrine shall provide Voyager with a reasonably detailed report describing all activities undertaken and accomplishments achieved under each Development Plan, including a copy of all results generated by Neurocrine in the performance of such Development Plan, in each case since the last such report. Neurocrine shall promptly respond to Voyager's reasonable requests for more information with respect to each such Calendar Quarterly or annual report with respect to any Program.

## 2.1.9 <u>Development Candidates</u>.

- (a) On a Program-by-Program basis with respect to the FA Program and each Discovery Program, prior to the applicable Transition Date, Voyager shall notify Neurocrine of potential Development Candidates that are Developed by or on behalf of Voyager under such Program. Based upon the Development Candidate Criteria and the results of Development activities with respect to the FA Program or any Discovery Program, either Party may nominate a development candidate for such Program by providing written notification thereof to the JSC.
- (b) Following nomination of a development candidate by either Party, the JSC shall determine whether such nominated development candidate meets the Development Candidate Criteria. Voyager shall respond to reasonable requests from the JSC for additional information regarding each nominated development candidate. If the JSC agrees that a nominated development candidate meets the Development Candidate Criteria, or if the JSC otherwise decides to designate a Collaboration Candidate as a Development Candidate notwithstanding its failure to achieve the Development Candidate Criteria, then such nominated development candidate shall thereafter be deemed to be a Development Candidate hereunder.

## 2.2 <u>Development Costs</u>.

- 2.2.1 <u>In General</u>. Neurocrine shall be responsible for all Development Costs incurred by Voyager in connection with Voyager's performance under each applicable Development Plan in accordance with the terms of this Agreement, provided that such Development Costs are in accordance with the budget set forth in such Development Plan, subject to Section 2.2.2.
- 2.2.2 <u>Payment</u>. Within [\*\*] following the end of each Calendar Quarter in which Voyager conducts activities under a Development Plan, Voyager shall provide Neurocrine with a preliminary report detailing, on a Program-by-Program basis, all Development Costs actually incurred by Voyager in such Calendar Quarter to conduct its activities under each Development Plan in accordance with the budget in such Development Plan. Within [\*\*] following the end of each Calendar Quarter in which Voyager conducts activities under a Development Plan, Voyager shall provide Neurocrine with an invoice detailing, on a Program-by-Program basis, all Development Costs actually incurred by Voyager in such Calendar Quarter to conduct its activities under each Development Plan in accordance with the budget in such Development Plan. Voyager shall include with each invoice documentation for any individual Out-of-Pocket Costs in excess of [\*\*] Dollars (\$[\*\*]). To the extent that the invoiced amounts for each activity are less than or equal to [\*\*] percent ([\*\*]%) of the corresponding amounts set forth in the budget in the applicable Development Plan, Neurocrine shall pay each such invoice, unless subject to a bona fide dispute,

within [\*\*] after receipt thereof. Neurocrine shall have the right to conduct an audit of Voyager's books and records to verify the amount of Development Costs pursuant to Section 8.7. Such audit shall not be performed more frequently than [\*\*] period. If Voyager anticipates that the FTE Costs or Out-of-Pocket Costs it incurs to conduct any activity under a Development Plan will exceed, or if any such costs do exceed, the amount set forth in the applicable budget for such activity by more than [\*\*] percent ([\*\*]%), Voyager shall promptly notify the JSC, and the JSC shall discuss in good faith and decide whether to increase such budget.

- 2.3 Records of Activities. Each Party shall maintain complete, current and accurate records of all Development activities conducted by it under the Collaboration, and all data and other information resulting from such activities. Such records shall fully and properly reflect all work done and results achieved in the performance of such Development activities in good scientific manner appropriate for regulatory and patent purposes. Each Party shall document all non-clinical studies and clinical trials for Programs in formal written study records according to applicable Laws, including national and international guidelines such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, GCP, GLP and cGMP. Neurocrine shall have the right to review and copy such records maintained by Voyager at reasonable times, as reasonably requested by Neurocrine.
- 2.4 <u>No Representation</u>. No Party makes any representation, warranty or guarantee that the Collaboration will be successful, or that any other particular results will be achieved with respect to the Collaboration, any Program or any Collaboration Product.
- Subcontracting. Subject to the terms of this Agreement, each Party shall have the right to engage 2.5 Affiliates or Third-Party subcontractors (including contract manufacturing organizations) Development or Manufacturing obligations under this Agreement. Any such Affiliate or subcontractor shall meet the qualifications typically required by such Party for the performance of work similar in scope and complexity to the subcontracted activity and perform such work consistent with the terms of this Agreement; provided, however, that a Party engaging an Affiliate or subcontractor hereunder shall remain fully responsible and obligated for all activities performed by such Affiliate or subcontractor. Unless otherwise agreed by the Parties, each Party will obligate each of its Third-Party subcontractors hereunder to agree in writing to assign to such Party ownership of, or, solely after using reasonable efforts to obtain such an assignment and being unable to obtain such an assignment, grant to such Party an exclusive, royalty-free, worldwide, perpetual and irrevocable license (with the right to freely grant sublicenses through multiple tiers) to, any inventions arising under its agreement with such Third Party to the extent related to or resulting from the Development, Manufacture or Commercialization of Collaboration Products; and such Party shall structure such assignment or exclusive license so as to enable such Party to license or sublicense such Third Party inventions to the other Party pursuant to the applicable provisions of this Agreement (including permitting such other Party to grant further sublicenses in accordance with this Agreement).
- 2.6 <u>Academic Collaborators</u>. If any Party collaborates with an academic institution or one or more individuals at an academic institution to Develop Collaboration Products, such Party shall be required to obligate such academic collaborator to agree in writing to grant the same rights specified in Section 2.5 with respect to ownership or licenses to inventions; it being understood and agreed that, solely in the case of academic collaborations to Develop Collaboration Products

which are not reasonably expected by the applicable Party to result in inventions related to composition of matter or methods of use, in lieu of the rights specified in Section 2.5, it shall be sufficient for such Party to obtain a non-exclusive, worldwide, royalty-free, perpetual license (with the right to freely grant sublicenses through multiple tiers) to, and a right to negotiate for an exclusive license, with the right to grant sublicenses to, any such inventions, which sublicensing rights must permit sublicensing to the other Party pursuant to the applicable provisions of this Agreement (including permitting such other Party to grant further sublicenses in accordance with this Agreement).

# ARTICLE 3 MANAGEMENT OF THE COLLABORATION

### 3.1 Joint Steering Committee and Subcommittees.

- 3.1.1 The Parties hereby establish the Joint Steering Committee (the "JSC") to serve as the oversight and decision-making body for the activities to be conducted by the Parties pursuant to this Agreement, as more fully described in this Article 3. The Parties anticipate that the JSC will not be involved in day-to-day implementation of the activities under this Agreement but shall have the responsibilities and decision-making authority set forth herein or as mutually agreed by the Parties in writing from time to time. The JSC may establish subcommittees as set forth in Section 3.2 (each a "Subcommittee").
- 3.1.2 <u>Responsibilities</u>. The JSC shall perform the following functions with respect to the Collaboration, subject to the final decision-making authority of the respective Parties as set forth in Section 3.6:
- (a) serve as an information transfer vehicle, from time to time, to facilitate discussions regarding the Development of Collaboration Products;
- (b) review and determine whether to update the Existing Program Development Plans or Discovery Program Development Plans (including related budgets) at the end of each Calendar Year in accordance with Sections 2.1.3(a);
- (c) discuss and approve as a Discovery Target any Target proposed by Neurocrine under Section 2.1.2;
- (d) within [\*\*] after submission by Voyager pursuant to Section 2.1.3(b), review, provide comments on and approve each Discovery Program Development Plan;
- (e) review and approve any substantive amendments to a Development Plan proposed by a Party, including any amendments to the budget therein;
- (f) establish the Development Candidate Criteria for the FA Program promptly after the Effective Date and for each Discovery Program promptly after approval of the Development Plan therefor;
- (g) review and approve the designation of each Development Candidate in accordance with Section 2.1.9(b);

- (h) discuss and determine what CMC and Development expertise, if any, Neurocrine shall contribute to each Program in accordance with Section 2.1.7;
- (i) review and discuss progress reports on the Development activities submitted by each Party, including the reports submitted by Voyager under Section 2.1.6 and by Neurocrine under Section 2.1.8;
- (j) address any issues or disputes arising from the conduct of the Development activities hereunder;
- (k) determine whether Proof of Mechanism has been established for the FA Program and for each Discovery Program;
- (l) on a Program-by-Program basis for those Programs for which Voyager has exercised the Co-Co Option, review and approve plans for co-Development and co-Commercialization in accordance with the Co-Co Agreements to be entered into by the Parties;
- (m) on a Program-by-Program basis for the Discovery Programs and those Programs for which Voyager has a Co-Co Option but has not exercised such Co-Co Option (i) review and, to the extent related to Development of Collaboration Products, approve the Neurocrine Plan, (ii) review and approve any amendments to the Neurocrine Plan to the extent related to the Development of Collaboration Products, and (iii) review (but not approve) any amendments to the Neurocrine Plan related to the Commercialization of Collaboration Products;
- (n) if Voyager exercises its Co-Co Option with respect to the AADC Program, review and approve branding decisions with respect to the Co-Co Products thereunder;
  - (o) resolve disputes between the Parties with respect to the Co-Co Programs;
- (p) review the progress reports on the Development and Commercialization activities submitted by Neurocrine in accordance with Section 4.2.4;
- (q) determine that successful Development under a Development Plan is not commercially or scientifically viable, and terminate such Program, thereby deeming such program a Terminated Program;
  - (r) review and discuss Collaboration Product formulation and formulation optimization;
- (s) periodically review and provide comments on the Development and post-approval status of each Collaboration Product;
- (t) review and discuss manufacturing scale-up, validation and Collaboration Product supply;
- (u) review and discuss any potential Future In-License Agreements and reports or recommendations of the JSC;

- (v) discuss patent term extensions in accordance with Section 10.2.7;
- (w) review and discuss any reports or recommendations of the Joint R&D Working Group;
- (x) review and discuss any reports or recommendations of the Collaboration IP Working Group;
- (y) review and discuss any reports or recommendations of the Joint CMC Working Group;
- (z) review and resolve any disputes of the Joint R&D Working Group, the Collaboration IP Working Group, the Joint CMC Working Group or any other Subcommittee or Working Group;
- (aa) form such Subcommittees and additional Working Groups as it deems necessary to achieve the objectives and intent of this Agreement;
- (bb) assign responsibilities that may fall within the purview of more than one Subcommittee to a particular Subcommittee or more than one Working Group to a particular Working Group; and
- (cc) perform such other responsibilities as may be assigned to the JSC pursuant to this Agreement or as may be mutually agreed upon by the Parties in writing from time to time.

Except with respect to Co-Co Products in the Co-Co Territory as set forth in Section 4.1.2(a), the JSC will not have any decision-making authority with respect to Commercialization of Collaboration Products, including the content of the Neurocrine Plans to the extent related to Commercialization. For clarity, the JSC shall not have any authority beyond the specific matters set forth in this Section 3.1.2, and in particular shall not have any power to amend or modify the terms of this Agreement or waive a Party's compliance with this Agreement.

3.2 <u>Formation and Dissolution of Subcommittee(s)</u>. The JSC may, in its discretion, establish Subcommittees from time to time to handle specific matters within the scope of the JSC's area of authority and responsibility, and no Subcommittee's authority and responsibility may be greater than that of the JSC itself. Each Subcommittee shall have such authority and responsibility as determined by the JSC from time to time, and decisions and recommendations of any Subcommittee shall be made in accordance with Section 3.6. The JSC shall determine when each Subcommittee it forms shall be dissolved.

### 3.3 Working Groups.

3.3.1 <u>Formation of Working Groups</u>. From time to time, the Parties, the JSC or any Subcommittee (each, a "<u>Committee</u>") may establish a working group (each, a "<u>Working Group</u>") to oversee particular projects or activities. Each Working Group shall undertake the activities allocated to it herein or delegated to it by the Committee to which it reports. During the process of establishing a Working Group, such Working Group and the Committee to which it

reports shall agree regarding which matters such Working Group will resolve on its own and which matters such Working Group will advise the Committee regarding (and with respect to which such advice-specific matters the Committee will resolve); provided that the Parties acknowledge and agree that each Working Group is intended to function primarily in a supporting role providing advice to the Committee to which it reports, but that each Working Group will be best positioned to provide expedited guidance and decisions regarding certain operational matters as determined by the Committee to which such Working Group reports.

- (a) <u>Joint R&D Working Group</u>. The Parties shall establish a joint research and development working group (the "<u>Joint R&D Working Group</u>") within [\*\*] following the Effective Date. The Joint R&D Working Group will be responsible for the oversight of the day-to-day implementation of (i) the Development activities conducted prior to the applicable Transition Event under this Agreement and (ii) providing the JSC with all relevant information and any recommendations necessary for the JSC to exercise its decision-making authority set forth in Section 3.6 with respect to such Development activities. The Joint R&D Working Group will report to the JSC.
- (b) <u>Collaboration IP Working Group</u>. The Parties shall establish an intellectual property working group (the "<u>Collaboration IP Working Group</u>") within [\*\*] following the Effective Date. The Collaboration IP Working Group will be responsible for providing the JSC and the Parties with guidance with respect to matters relating to (i) the preparation, filing, prosecution and maintenance of Voyager Licensed Patent Rights and Joint Patent Rights, (ii) freedom-to-operate matters, (iii) discussing any challenges to any Third Party's Patent Rights that may Cover any Collaboration Products, and (iv) advising the JSC regarding which of the Existing In-License Agreements are relevant to any Collaboration Products. The Collaboration IP Working Group will report to the JSC.
- (c) <u>Joint CMC Working Group</u>. The Parties shall establish a joint Manufacturing working group (the "<u>Joint CMC Working Group</u>") within [\*\*] following the Effective Date. The Joint CMC Working Group will be responsible for providing the JSC and the Parties with guidance with respect to matters relating to the generation and maintenance of chemistry, manufacturing and controls (CMC) data required by applicable Law to be included or referenced in, or otherwise support, an IND or Regulatory Approval Application and coordinating the sharing and exchange of such data between Voyager and Neurocrine. The Joint CMC Working Group will report to the JSC.
- 3.4 <u>Membership</u>. Each Committee shall be composed of an equal number of representatives appointed by each of Voyager and Neurocrine. The JSC shall be comprised of [\*\*] representatives of each Party, and each other Committee shall be comprised of such number of representatives of each Party as is agreed upon by the Parties. Each Party shall appoint at least one (1) representative to each Working Group and shall have the right, but not the obligation, to appoint the same number of representatives to any Working Group as are appointed by the other Party to such Working Group. Each individual appointed by a Party as a representative to the JSC shall be an employee of such Party. Each individual appointed by a Party as a representative to any Subcommittee or Working Group shall be an employee of such Party, an employee of such Party's Affiliate or, upon the other Party's approval, a contractor to such Party or its Affiliate; <u>provided that</u>, with respect to the Collaboration IP Working Group, either Party may appoint

outside intellectual property counsel as a representative. Each Party may replace any of its Committee or Working Group representatives at any time upon written notice to the other Party, which notice may be given by e-mail sent to the other Party's co-chairperson of such Committee and, with respect to a change of representatives to any Working Group, to the other Party's co-chairperson of the Committee to which such Working Group reports. Each Committee and Working Group shall be co-chaired by one designated representative of each Party. Any member of a Committee or Working Group may designate a substitute who is an employee of the applicable Party to attend and perform the functions of that member at any meeting of such Committee, as applicable. Notwithstanding the foregoing, each Party shall ensure at all times during the existence of a Committee or Working Group that its representatives (including any replacements or substitutes therefor) on such Committee or Working Group are appropriate in terms of seniority, experience, expertise and decision-making authority and are subject to obligations of confidentiality and non-use with respect to the other Party's Confidential Information that are no less stringent than those set forth in Article 11.

### 3.5 Meetings.

- 3.5.1 The co-chairpersons shall be responsible, with respect to their Committee or Working Group, as applicable, for (a) calling meetings; (b) preparing and circulating an agenda in advance of each meeting; provided that the co-chairpersons shall include any agenda items proposed by either Party on such agenda; (c) ensuring that all decision-making is carried out in accordance with the voting and dispute resolution mechanisms set forth in this Agreement; and (d) preparing and issuing minutes of each meeting within [\*\*] (or such shorter time as is agreed by the relevant Committee or Working Group) thereafter. The location of regularly scheduled meetings shall alternate between Voyager's offices located in Cambridge, Massachusetts and Neurocrine's offices located in San Diego, California, unless otherwise agreed by such Committee or Working Group. Such Committee or Working Group may also determine that a meeting will instead be held telephonically, by video conference or by any other media; provided, however, that the JSC shall hold at least one (1) meeting in person each Calendar Year. For the avoidance of doubt, each Party may designate the same individual as a representative on more than one Committee or Working Group. Each Party will bear all expenses it incurs in regard to participating in all meetings of each Subcommittee and Working Group, including all travel and living expenses.
- 3.5.2 The JSC shall meet at least once each Calendar Quarter prior to the time of First Commercial Sale of a Collaboration Product from all Programs, and annually thereafter, or more or less frequently as the Parties mutually deem appropriate, on such dates and at such places and times as provided herein or as the Parties shall agree.

### 3.6 <u>Decision-Making</u>.

3.6.1 <u>Escalation to JSC</u>. Except as otherwise provided herein, all decisions of each Committee and each Working Group shall be made by consensus, with all of a Party's voting members collectively having one (1) vote. If a Committee or Working Group other than the JSC is incapable of reaching unanimous agreement on a matter before it within [\*\*] after first attempting to decide such matter, the matter shall be referred to the JSC for resolution. If the JSC is incapable of reaching unanimous agreement on a matter before it within [\*\*] after first attempting to decide such matter and after having at least [\*\*], unless agreed otherwise in writing

by the Parties, such agreement not to be unreasonably withheld, conditioned or delayed, the matter shall be resolved in accordance with Section 3.6.2.

- 3.6.2 <u>Escalation to the Executive Officers</u>. If the JSC cannot agree on a matter within [\*\*] after it has first attempted to reach such decision and, unless agreed otherwise pursuant to Section 3.6.1, after having at least [\*\*], then either Party may, by written notice to the other, have such issue referred to the Executive Officers for resolution. The Parties' respective Executive Officers shall meet within [\*\*] after such matter is referred to them, after having at least [\*\*], unless agreed otherwise in writing by the Parties, and shall negotiate in good faith to resolve the matter.
- 3.6.3 <u>Escalation to the Parties</u>. If the Executive Officers are unable to resolve the matter within [\*\*] after the matter is referred to them, then:
  - (a) <u>Existing Programs</u>. With respect to each Existing Program:
- (i) Prior to the exercise by Voyager of its Co-Co Option for such Program, Neurocrine shall have the right to decide such unresolved matter;
- (ii) From and after the timely exercise by Voyager of its Co-Co Option for such Program, (A) to the extent the unresolved matter relates to the Development or Manufacturing prior to commercial launch in the Co-Co Territory of Collaboration Products in such Program, neither Party shall have the right to decide such unresolved matter and such unresolved matter shall be deadlocked until resolved by mutual agreement of the Parties or the JSC, (B) to the extent the unresolved matter relates to the Manufacturing or Commercialization in the Co-Co Territory of the Collaboration Products in such Program, Neurocrine shall have the right to decide such unresolved matter; and (C) to the extent the unresolved matter relates to the Development, Manufacturing following commercial launch or Commercialization outside of the Co-Co Territory of Collaboration Products in such Program, Neurocrine shall have the right to decide such unresolved matter; and
- (iii) If Voyager does not timely exercise its Co-Co Option with respect to such Program, then Neurocrine shall have the right to decide such unresolved matter.

Notwithstanding the foregoing, in no event shall any Committee or Working Group, without Voyager's explicit agreement, or Neurocrine alone have the power or authority to (1) cause Voyager to deviate from its hiring plan for the AADC Program through completion of the Existing Pivotal Trial as it pertains to work through the Transition Date for the AADC Program, (2) cause Voyager to deviate from its hiring plan for the FA Program through completion of the first Phase 1 Clinical Trial for the FA Program as it pertains to work through the Transition Date for the FA Program, or (3) cause Voyager to reallocate or realign its existing personnel as of the Effective Date in relation to any Existing Program.

(b) <u>Discovery Programs</u>. Neurocrine shall have the right to resolve all unresolved matters relating to the Discovery Programs, provided that Neurocrine shall not have the right to approve (i) any proposed Target as a Discovery Target, (ii) the initial Discovery Program Development Plan for each Discovery Program or (iii) any Development Plan or amendment thereto that would require Voyager to conduct any activities thereunder for which

Voyager does not have, and is not able to obtain with the exercise of Commercially Reasonable Efforts, sufficient personnel or resources, or to conduct any activities that are not included in the budget in such Development Plan;

provided, however, that in no event shall any Committee, Working Group or any Party alone have the power or authority to (1) amend this Agreement, (2) determine whether a Party has fulfilled or breached its obligations under this Agreement, (3) impose any requirements on either Party to undertake obligations beyond those for which it is responsible, or to forgo any of its rights, under this Agreement, (4) make a decision that is expressly stated under this Section 3.6.3 to require the mutual agreement of the Parties or of the JSC, (5) make a decision that could reasonably be expected to cause Voyager to breach an In-License Agreement or give rise to the right of the applicable Inbound Licensor to take any action under such In-License Agreement, or (6) require any Party to perform any act that it reasonably believes to be inconsistent with any Law. Any decision made by the Executive Officers in accordance with Section 3.6.2 or by a Party in accordance with this Section 3.6.3 shall be considered a decision made by the JSC.

- 3.7 <u>Alliance Managers</u>. Promptly after the Effective Date, each Party shall appoint an individual (who may not be a then-current member of the JSC) to act as alliance manager for such Party (each, an "<u>Alliance Manager</u>"). Each Alliance Manager shall thereafter be permitted to attend meetings of the JSC as a nonvoting observer, subject to the confidentiality provisions of Article 11. The Alliance Managers shall be the primary point of contact for the Parties regarding the activities contemplated by this Agreement. The Alliance Managers shall also be responsible for assisting the JSC in performing its oversight responsibilities. The name and contact information for each Party's Alliance Manager, as well as any replacement chosen by such Party, in its sole discretion, from time to time, shall be promptly provided to the other Party in accordance with Section 15.8.
- 3.8 <u>Authority</u>. Each Party will retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion will be delegated to or vested in the JSC or any other Subcommittee or any Working Group unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing.

# ARTICLE 4 POST-TRANSITION ACTIVITIES

### 4.1 Co-Development and Co-Commercialization.

4.1.1 <u>Voyager's Opt-In Right</u>. On an Existing Program-by-Existing Program basis, Voyager shall have the right to elect to co-develop and co-commercialize Collaboration Products that are the subject of such Existing Program in the United States (the "<u>Co-Co Option</u>") by providing Neurocrine with written notice of such election within [\*\*] following the applicable Co-Co Trigger Date. Upon such exercise, the Parties shall negotiate in good faith and enter into an agreement, which shall be based on terms and conditions substantially the same as those set forth in this Section 4.1 and otherwise consistent with this Agreement (each such agreement, a "<u>Co-Co Agreement</u>"), pursuant to which the Parties will jointly Develop and Commercialize and share in the Development Costs, Commercialization costs and profit or loss resulting from the Development and Commercialization of such Collaboration Products in the United States (the

"<u>Co-Co Territory</u>"). Once Voyager exercises the Co-Co Option with respect to an Existing Program, each Collaboration Product in such Existing Program shall be designated a "<u>Co-Co Product</u>" hereunder and such Existing Program shall be designated a "<u>Co-Co Program</u>" hereunder, and the Parties will share Development Costs incurred thereafter. The "<u>Co-Co Trigger Date</u>" shall mean (a) with respect to the AADC Program, Voyager's receipt of topline data with respect to the Existing Pivotal Trial, which data Voyager shall submit to Neurocrine promptly after availability thereof and (b) with respect to the FA Program, the date upon which the JSC determines that Proof of Mechanism has been achieved.

- 4.1.2 <u>Co-Co Agreement General Principles</u>. It is the intent of the Parties that Development and Commercialization of each Co-Co Product in the Co-Co Territory under the applicable Co-Co Agreement will be conducted in accordance with the following principles, except as otherwise mutually agreed by the Parties in writing. The Parties shall take into account and attempt to implement the following principles in their decision-making, including preparation, review and approval of any updates to and amendments of the Development plan and Commercialization plan under such Co-Co Agreement:
- Development and Commercialization of each Co-Co Product in and for the Co-Co (a) Territory shall be conducted according to a mutually agreed Development plan and Commercialization plan, respectively, prepared and updated periodically by Neurocrine, in consultation with Voyager, and submitted to the JSC for review and approval. Such plans shall (i) set forth the Development activities and Commercialization activities, respectively, to be undertaken by the Parties with respect to the applicable Co-Co Product in and for the Co-Co Territory in the subsequent [\*\*], (ii) be updated at least [\*\*] and (iii) include a related detailed budget. Either Party may propose amendments to a Development plan or Commercialization plan to the JSC for review and approval. No Development or Commercialization activities shall be delegated to a Party in the Development plan or Commercialization plan (or any amendment thereto) without such Party's prior Each Party will use Commercially Reasonable Efforts to perform the Development and Commercialization activities delegated to such Party in the Development plan and Commercialization plan, as applicable. Each Party's Development Costs for the Co-Co Program shall be calculated in a manner consistent with Development Costs calculation under this Agreement (including related definitions). FTE Costs with respect to Commercialization costs for the Co-Co Program shall be calculated in a manner consistent with this Agreement. Notwithstanding the foregoing, the terms of the Co-Co Agreement (i) shall not require any realignment or decrease in the size of the then Neurocrine field forces, and (ii) shall be reasonably directed to maximize sales of the Co-Co Product.
- (b) The Development plan and the Commercialization plan under the Co-Co Agreement shall each include an allocation of responsibilities between the Parties reasonably and equitably determined after taking into consideration each Party's expertise, capabilities, staffing and available resources to take on such activities. Notwithstanding the foregoing, but subject to the last sentence of Section 4.1.2(a), the Development plan and the Commercialization plan under the Co-Co Agreement shall include meaningful participation in Development activities, Commercialization activities (including participation in field sales and detailing), preparation for Commercialization, and medical affairs activities by Voyager (unless otherwise agreed by Voyager), provided that in all cases Neurocrine will be responsible for booking sales of Collaboration Products.

- Party or its Affiliates in accordance with the applicable budgets in conducting activities for the Co-Co Territory in accordance with the applicable Co-Co Rate pursuant to the Development plan and Commercialization plan under the Co-Co Agreement. The Co-Co Agreement shall provide that (i) if either Party incurs Development Costs or Commercialization costs in excess of [\*\*] percent ([\*\*]%) of the Development Costs or Commercialization costs, as applicable, budgeted for activities assigned to such Party in the budget of the then-current version of the Development plan or Commercialization plan, as applicable, then such Party shall be solely responsible for such excess costs unless such Party has received the other Party's written approval to share such excess costs and (ii) global Development Costs incurred for Development activities that support Regulatory Approval in the Co-Co Territory and in other countries of the Territory shall be reasonably and equitably allocated to the Co-Co Program in accordance with the reasonably expected proportion of Co-Co Product sales in the Co-Co Territory as compared with other countries in the Territory, as mutually agreed by the Parties.
- (d) All profit or loss (which shall be defined in the Co-Co Agreement in a customary manner) and any amounts due to any Inbound Licensor under an In-License Agreement from and after the exercise of the Co-Co Option (including royalty, milestone, and sublicense income payments) with respect to the Co-Co Products shall be shared between the Parties at the Co-Co Rate, to the extent such amounts are allocable to the Co-Co Territory. Proceeds of the sale of any PRV granted to Neurocrine in connection with the approval of the BLA for a Co-Co Product shall be considered Net Sales for the Co-Co Program and costs and expenses associated with any Third Party engaged to facilitate such sale shall be considered a cost for the Co-Co Program, but only if Voyager approves of the engagement of such Third Party prior to such sale. Notwithstanding Sections 13.1.1(c) or 13.2.3, and regardless of the Parties' respective insurance coverages, any losses incurred by either Party arising from Third Party Claims related to Exploitation of the Co-Co Products in or for the Co-Co Territory, including Third Party Claims based on intellectual property infringement, product liability or personal injury, shall be shared between the Parties at the Co-Co Rate, except to the extent resulting from the gross negligence, recklessness or intentional misconduct of a Party or any of its Affiliates or its or their respective directors, officers, employees, agents or representations or a Party's breach of this Agreement.
- (e) Neurocrine's obligation to pay the royalty set forth in Sections 8.3.1(a) and 8.3.2(a) shall terminate, and Neurocrine's obligation to make milestone payments with respect to such Co-Co Products shall be modified as set forth in Section 8.2(b).
- (f) Regardless of the specific division of responsibility between the Parties for particular activities at any particular time, the JSC shall serve as a conduit for sharing information, knowledge and expertise relating to the Development and Commercialization of each Co-Co Product.
- (g) The Co-Co Agreement shall specify that the mutual consent of both Parties shall be required to Develop and Commercialize each Co-Co Product with any Third Party in the Co-Co Territory, including the sale, licensing or divestiture of marketing rights or product assets as to such Co-Co Product in the Co-Co Territory.

- (h) The dispute resolution provisions in the Co-Co Agreement shall mirror Sections 15.2 and 15.3 of this Agreement and the Parties shall agree that any arbitration brought under a Co-Co Agreement may be consolidated with an arbitration brought under another Co-Co Agreement or this Agreement.
- 4.1.3 <u>Co-Co Rate</u>. Each Party shall receive (in the case of profits) or pay (in the case of losses), as applicable, its allocable share of profit and losses with respect to each Co-Co Product in the Co-Co Territory. The rate at which the Parties shall share in such profit and losses is referred to herein as the "<u>Co-Co Rate</u>". The Co-Co Rate for the FA Program shall be 60% for Neurocrine and 40% for Voyager, and the Co-Co Rate for the AADC Program shall initially be 50% for each of Neurocrine and Voyager; provided that, Neurocrine may elect, by delivery of written notice and payment to Voyager of the Rate-Shifting Fee within [\*\*] of BLA acceptance for filing by the FDA with respect to the Co-Co Product for the AADC Program, to change the Co-Co Rate for the AADC Program to 55% for Neurocrine and 45% for Voyager. The "<u>Rate-Shifting Fee</u>" shall be Thirty-Five Million Dollars (\$35,000,000). If Neurocrine so elects, the Co-Co Rate shall be adjusted effective as of the first day of the month following Neurocrine's election, and there shall be no credit or accounting for profit and losses shared by the Parties prior to such date. If Neurocrine does not notify Voyager of its election and pay the Rate-Shifting Fee within such [\*\*] period, then the Co-Co Rate for Co-Co Products in the AADC Program shall remain 50% for each of Neurocrine and Voyager for the term of the applicable Co-Co Agreement.

### 4.1.4 <u>Termination of Co-Co Agreement</u>.

- (a) Voyager shall have the right to terminate any Co-Co Agreement for any or no reason on [\*\*] prior written notice. For the avoidance of doubt, following termination of a Co-Co Agreement as set forth in this subsection (a), Voyager shall not be entitled to any refund or credit for amounts that it may have paid under such Co-Co Agreement prior to termination (other than amounts that may be payable or creditable to Voyager as a final reconciliation of its share of profits and losses through termination).
- (b) Neurocrine shall have the right to terminate any Co-Co Agreement upon a Change of Control of Voyager if the Acquirer is Developing or Commercializing a branded product that directly competes with a product being Developed or Commercialized by Neurocrine. In such event, the Parties will negotiate in good faith a reasonable royalty to Voyager (in excess of the applicable royalties in Section 8.3) that would approximate Voyager's share (at the Co-Co Rate) of profit under the Co-Co Agreement, and if the Parties fail to agree on such share, the dispute will be submitted to an independent mutually agreed expert for determination, whose decision will be final and binding on the Parties.
- (c) If a Co-Co Agreement is terminated, as set forth above in this Section 4.1.4 or in accordance with the terms of such Co-Co Agreement, then (i) the Co-Co Products from such Co-Co Program shall be deemed Collaboration Products (and not Co-Co Products) hereunder for the remainder of the Term, (ii) the Parties shall cease to share profit and loss with respect to such Collaboration Products and Neurocrine's obligation to pay the royalties set forth in Sections 8.3.1(a) and 8.3.2(a), as applicable, shall be reinstated from and after the effective date of termination and (iii) Neurocrine's obligations to make milestone payments with respect to such Collaboration Products shall thereafter be as set forth in Section 8.2(b) for

Collaboration Products that are not Co-Co Products; <u>provided</u>, <u>that</u> Neurocrine shall not have any obligation to make milestone payments with respect to milestones that occurred prior to the effective date of termination of the Co-Co Agreement.

## 4.2 <u>Neurocrine Development and Commercialization</u>.

4.2.1 <u>Neurocrine Responsibilities</u>. From and after the Transition Date with respect to a Program that is not a Co-Co Program, Neurocrine shall be solely responsible at Neurocrine's cost and expense for all Development, Manufacturing and Commercialization activities in connection with the Collaboration Products that are the subject of such Program in the Field in the Territory, which activities shall be conducted in accordance with the Neurocrine Plan and this Agreement; provided that Voyager shall provide reasonable Development assistance to Neurocrine as reasonably requested by Neurocrine and reasonably agreed by Neurocrine in connection with activities for which Voyager has expertise. Neurocrine shall reimburse Voyager for all Development Costs incurred by Voyager under this Section 4.2.1 within [\*\*] of Voyager's submission of an invoice therefor.

## 4.2.2 Neurocrine Diligence.

- (a) <u>Major Market Countries</u>. Neurocrine shall use Commercially Reasonable Efforts (i) to Develop, seek Regulatory Approval for and Commercialize at least one (1) Collaboration Product in each Program in each of [\*\*] (collectively, the "<u>Major Market Countries</u>") and (ii) to Commercialize at least one (1) Collaboration Product in each Program in each Major Market Country in which it receives Regulatory Approval and, if applicable, pricing and reimbursement approval for such Collaboration Product.
- (b) <u>Secondary Market Countries</u>. Neurocrine shall use Commercially Reasonable Efforts (i) to Develop, seek Regulatory Approval for and Commercialize Collaboration Products in [\*\*] (collectively, the "<u>Secondary Market Countries</u>") and (ii) to Commercialize such Collaboration Products in the Secondary Market Countries for which it receives Regulatory Approval and, if applicable, pricing and reimbursement approval for such Collaboration Products to the extent sufficient commercial opportunities exist in such countries and such activities do not impede Development or Commercialization of Collaboration Products in any Major Market Countries.

Notwithstanding the foregoing or any other provision under this Agreement, it will be consistent with the exercise of Commercially Reasonable Efforts for Neurocrine to prioritize one Program over all other Programs at any given time, and it will not be consistent with the exercise of Commercially Reasonable Efforts for Neurocrine to prioritize another Program over the AADC Program, and Neurocrine may not give priority to another Program over the AADC Program without Voyager's written agreement.

4.2.3 <u>Neurocrine Plan</u>. Within [\*\*] after the Transition Date with respect to a Program, Neurocrine shall submit a written plan, prepared in good faith, (such plan, as each may be amended from time to time in accordance with this Agreement, the "<u>Neurocrine Plan</u>") to the JSC for review and approval (to the extent set forth in Section 3.1.2(m)), which Neurocrine Plan shall include a description and overall summary of the Development, Manufacturing and

Commercialization activities that Neurocrine intends to conduct in order to obtain Regulatory Approval for each Collaboration Product that is the subject of such Program in the Territory, which shall specifically include such activities in each of the [\*\*]. Neurocrine shall use Commercially Reasonable Efforts to execute the activities specified in the Neurocrine Plan. Neurocrine may submit to the JSC proposed amendments to the Neurocrine Plan from time to time during the term of this Agreement. All amendments to the Neurocrine Plan shall be reviewed and, to the extent provided in Section 3.1.2, approved by the JSC.

- 4.2.4 <u>Neurocrine Reports.</u> Neurocrine shall, within [\*\*] after the end of each of the first and second halves of each Calendar Year prior to First Commercial Sale of a Collaboration Product in all Programs, and annually thereafter, provide Voyager with written progress reports on the status of the Development and Commercialization activities under the applicable Neurocrine Plan with respect to each Collaboration Product in such Calendar Year. Notwithstanding the foregoing, Neurocrine agrees that to the extent that an In-License Agreement applicable to a given Program requires more thorough or more frequent reporting or requires that reports be provided on a different timeline than that set forth in this Section 4.2.4, Voyager shall notify Neurocrine of the deadline and content of such reports, and Neurocrine shall provide such reports to Voyager as requested by Voyager no less than [\*\*] prior to the date that Voyager is required to submit such report pursuant to the applicable In-License Agreement.
- 4.3 <u>Program Transition</u>. On a Program-by-Program basis, no later than [\*\*] before the reasonably anticipated Transition Date with respect to such Program, the Parties shall commence preparing in good faith and prior to such Transition Date shall agree to a plan to transfer to Neurocrine (or its designee (other than a competitor of Voyager who is developing or commercializing a gene therapy, gene editing or anti-sense oligonucleotide product)) all Development and Manufacturing activities relating to Collaboration Product(s) in such Program then being undertaken by Voyager (the "<u>Transition Plan</u>"). Voyager shall transition all such activities to Neurocrine, at Neurocrine's cost and expense, and shall conduct all transition activities in accordance with the Transition Plan as soon as reasonably practicable. As part of each such Transition Plan, Voyager shall provide to Neurocrine all Voyager Know-How relevant to the applicable Program and not previously provided to Neurocrine.
- 4.3.1 <u>Reimbursement</u>. To the extent that Neurocrine is required to reimburse Voyager hereunder for any costs incurred by Voyager or pursuant to the activities under the Transition Plan, Voyager shall submit an invoice itemizing such costs and expenses Voyager has incurred, on a Calendar Quarter basis, together with any written evidence of such costs. Neurocrine shall pay such invoice, unless subject to a bona fide dispute, within [\*\*] of receipt. For the avoidance of doubt, any such costs shall be calculated by Voyager as Development Costs.
- 4.4 <u>Transition Activities</u>. In connection with the transition of each Program to Neurocrine, and as further detailed in the Transition Plan, Voyager shall conduct the following activities for no additional consideration:
- 4.4.1 Voyager shall provide all assistance reasonably necessary for Neurocrine or its designees to continue the Manufacture and Development of all Collaboration Products in such Program;

- 4.4.2 Upon Neurocrine's request, Voyager shall assign to Neurocrine any agreements (including any agreement with any Third Party manufacturer with respect to a Collaboration Candidate or Collaboration Product) solely relating to the Development or Manufacture of any Collaboration Candidate or Collaboration Product to which Voyager or any of its Affiliates is a party; provided that if any such agreement is not assignable to Neurocrine (because consent is required or because it relates to products that are not Collaboration Products), Voyager shall take all actions reasonably requested by Neurocrine so that Neurocrine may receive the benefits of such agreement applicable to Collaboration Candidates and Collaboration Products, which may include assigning a statement of work or work order to Neurocrine and facilitating a discussion of the terms of a services agreement between Neurocrine and the applicable counterparty;
- 4.4.3 Voyager shall transfer to Neurocrine copies of all data, reports, records, materials and other information arising out of the applicable Program, including all non-clinical and clinical data relating to any Collaboration Candidate or Collaboration Product, and all adverse event or other safety data resulting from such Program, as well as any chemistry, manufacturing and controls (CMC) or other Manufacturing data generated in connection with such Program; and
- 4.4.4 Voyager shall provide Neurocrine with a written summary of its inventory of Collaboration Candidates and Collaboration Products, and Voyager shall, at Neurocrine's election, promptly destroy such inventory or deliver such inventory to Neurocrine. Voyager represents and warrants that, at the time of delivery, all clinical supply of Collaboration Candidates and Collaboration Products (a) will have been Manufactured in accordance with applicable Law, including cGMP, (b) will not be adulterated or misbranded under the Act and may be introduced into interstate commerce pursuant to the Act, (c) will comply with the specifications therefor, and (d) will comply with the quality agreement to be entered into between the Parties. In the event that Voyager cannot make such representations with respect to any such inventory, Voyager shall destroy such inventory and certify such destruction to Neurocrine, unless requested otherwise by Neurocrine; provided that if any such non-compliance results from either (i) Voyager's gross negligence or willful misconduct in the Manufacture of such inventory, Voyager shall reimburse the amounts paid by Neurocrine under the Development Plan for the Manufacture of such inventory.

# ARTICLE 5 GRANT OF LICENSES

5.1 <u>License Grant</u>. Subject to the terms and conditions of this Agreement, Voyager hereby grants to Neurocrine, and Neurocrine accepts, an exclusive, royalty-bearing, non-transferable (except in accordance with Section 15.4), sublicenseable (subject to Section 5.5) license under the Voyager IP to Develop, Commercialize, Manufacture, have Manufactured and use Collaboration Candidates and Collaboration Products in the Field in the Territory during the Term; provided, however, that, such license shall be subject to Voyager's retained rights under the Voyager IP to conduct the activities allocated to Voyager under any Development Plan or Co-Co Agreement or otherwise under this Agreement. The license granted under this Section 5.1 shall automatically convert to a fully paid-up, non-royalty bearing, perpetual, irrevocable, exclusive license on a country-by-country and Collaboration Product-by-Collaboration Product basis upon

the expiration of the Royalty Term applicable to such Collaboration Product in such country (but not upon an earlier termination of this Agreement with respect thereto).

#### 5.2 In-License Agreements.

- 5.2.1 Neurocrine acknowledges that the license granted by Voyager to Neurocrine in Section 5.1 includes sublicenses under certain Voyager IP that is licensed to Voyager pursuant to In-License Agreements, and that such sublicenses are subject to the applicable terms of the In-License Agreements, the scope of the licenses granted to Voyager or the applicable Affiliate thereunder and the rights granted to or retained by the Third Party counterparties and any other Third Parties (including Governmental Authorities) (each, an "Inbound Licensor") set forth therein. To the extent Patent Rights under the In-License Agreements are sublicensed to Neurocrine hereunder, Neurocrine covenants to comply with, and to cause its sublicensed Affiliates and to require its Sublicensees to comply with, the In-License Agreements, pursuant to their terms, including Sections 5.1, 5.2, 8.1, 10.1, 10.2, 12.5, and 13.7-13.9 of the [\*\*] Agreement the text of which Sections are set forth on Schedule 5.2.1 in compliance with Section 4.2 of the [\*\*] Agreement and if the Patent Rights under the [\*\*] Agreement are sublicensed to Neurocrine hereunder, Section 2.3 of the [\*\*] Agreement. To the extent there is a conflict between any of the terms of any In-License Agreement and the rights granted to Neurocrine hereunder (including with respect to any sublicensing rights, Prosecution and Maintenance, enforcement and defense rights) the terms of such In-License Agreement shall control with respect to the Know-How and Patent Rights licensed to Voyager under such In-License Agreement.
- If either Party becomes aware of any Third Party's Know-How that would be necessary or reasonably useful for the Development, Manufacturing or Commercialization of a Collaboration Product or any Third Party's Patent Right that Covers in the Territory any Collaboration Product, such Party shall promptly notify the other Party, and the Parties shall discuss whether to seek a license under such Know-How or Patent Rights. Voyager shall have the first right to enter into Third Party licenses related to Know-How, Patent Rights, or other intellectual property rights related to any Vectorization Technology, in Voyager's sole discretion. If Voyager determines to enter into such a license, then prior to doing so Voyager shall provide written notice to Neurocrine and, if Neurocrine expresses a desire to obtain a sublicense to such license pursuant to Section 5.2.3, Voyager shall thereafter provide Neurocrine with a reasonable opportunity to review and comment on the proposed terms of such license that are applicable to Neurocrine as a sublicensee thereunder. Voyager shall use reasonable efforts to negotiate the terms of such license accordingly. Neurocrine shall have the first right to seek any other Third Party license related to Know-How, Patent Rights, or other intellectual property rights. If Neurocrine elects not to seek any other such license, and if Voyager seeks such license, and if Neurocrine expresses a desire to obtain a sublicense to such license pursuant to Section 5.2.3, Voyager shall thereafter provide Neurocrine with a reasonable opportunity to review and comment on the proposed terms of such license that are applicable to Neurocrine as a sublicensee thereunder. Voyager shall use reasonable efforts to negotiate the terms of such license accordingly. For the avoidance of doubt, nothing contained in this Section 5.2.2 creates an obligation for Voyager to obtain any Third Party license.
- 5.2.3 If, after the Effective Date, subject to Section 5.2.2, Voyager or any of its Affiliates enters into a Future In-License Agreement with a Third Party pursuant to which Voyager

(or, subject to the last sentence of this Section 5.2.3, any of its Affiliates) obtains Control over a Third Party's Know-How that is necessary or reasonably useful for the Development, Manufacturing or Commercialization of a Collaboration Product or any Patent Right that Covers in the Territory any Collaboration Product, Voyager shall promptly provide such Future In-License Agreement to Neurocrine and provide any information reasonably requested by Neurocrine with respect thereto, and such Third Party's Know-How and Patent Rights shall be included in the license granted to Neurocrine under Section 5.1 and considered Voyager IP hereunder, only if Neurocrine agrees in writing to pay the share of the payments due to Inbound Licensors applicable to the Collaboration Product(s), as well as a reasonably allocable share of any other payments due to Inbound Licensors not specific to a compound or product, as set forth in Section 5.2.4.

- 5.2.4 As between the Parties, the amounts payable under all In-License Agreements shall be allocated as follows:
- (a) With respect to an Existing Program (unless and until such Existing Program becomes a Co-Co Program), (i) Voyager shall be responsible for any payment required under applicable Existing In-License Agreements and (ii) each of Voyager and Neurocrine shall be responsible for fifty percent (50%) of all payments under any applicable Future In-License Agreement that are specifically related to a Collaboration Product, it being agreed that if Voyager's fifty percent (50%) share of royalties payable under the Future In-License Agreement exceed the royalties payable by Neurocrine to Voyager with respect to the applicable Collaboration Product in the applicable country in the applicable Calendar Quarter, then Neurocrine shall bear such excess. Notwithstanding the foregoing, Voyager shall be solely responsible for all payments under any potential In-License Agreements for intellectual property referenced on Schedule 5.2.4(a) for Existing Programs.
- (b) With respect to the Discovery Programs, (i) each of Voyager and Neurocrine shall be responsible for fifty percent (50%) of all payments under any Existing In-License Agreement and Future In-License Agreement that are specifically related to Vectorization Technology, it being agreed that if Voyager's fifty percent (50%) share of royalties payable under the Existing In-License Agreement or Future In-License Agreement exceed the royalties payable by Neurocrine to Voyager with respect to the applicable Collaboration Product in the applicable country in the applicable Calendar Quarter, then Neurocrine shall bear such excess and (ii) Neurocrine shall be responsible for 100% of all payments under any Future In-License Agreement that are not specifically related to Vectorization Technology.
- (c) With respect to any Co-Co Program, from and after the exercise of the Co-Co Option, pursuant to Section 4.1.2(d), any amounts due to any Inbound Licensor under an In-License Agreement (including royalty, milestone and sublicense income payments) with respect to the Co-Co Products shall be shared between the Parties at the Co-Co Rate, to the extent such amounts are allocable to the Co-Co Product in the Co-Co Territory.

Notwithstanding the fact that Voyager has obtained a license related to Know-How, Patent Rights or other intellectual property rights Covering Vectorization Technology and that such intellectual property rights may be included within Neurocrine's license to Existing In-License Agreements or that Neurocrine may elect, under Section 5.2.3 to take a sublicense to Know-How, Patent Rights or other intellectual property rights Covering Vectorization Technology under a Future In-License

Agreement, to the extent that Voyager demonstrates that an alternative methodology or approach that is not Covered by such licensed intellectual property rights (an "Alternative Method") yields results that are of materially equivalent or superior quality, and Voyager proposes to Neurocrine that such Alternative Method be deployed in a Collaboration Program on a timeline that is practicable and does not introduce unreasonable risk to the success of a Program, then Neurocrine shall reasonably consider deploying such Alternative Method for the relevant Collaboration Program; provided that if, notwithstanding Voyager's proposal for the use of the Alternative Method, Neurocrine exercises its final-decision making authority pursuant to Section 3.6 to decline the use of the Alternative Method, then any payments under the Existing Licensed Agreement or Future In-License Agreement implicated by Neurocrine's refusal to adopt the Alternative Method shall be allocated between the Parties as set forth in Section 5.2.4(a) (without giving effect to the last sentence thereof).

5.2.5 Neurocrine shall prepare and deliver to Voyager any additional reports required under the applicable In-License Agreements of Voyager, in each case to the extent requested by Voyager, and, provided that Voyager has notified Neurocrine reasonably sufficiently in advance of the applicable deadline, to enable Voyager to comply with its obligations under the applicable In-License Agreements.

### 5.3 <u>Obligations Under In-Licenses</u>.

- 5.3.1 Voyager shall not take (or fail to take) any action, including failure to pay any amounts when due (except that any such failure to pay that was caused by Neurocrine's failure to make a payment required to be made by Neurocrine under Section 5.2.4 will not be considered an action or failure to take action by Voyager for purposes of this Section 5.3.1), that constitutes a material breach under any In-License Agreement. Voyager will not, without the consent of Neurocrine (a) take any action with respect to any In-License Agreement (including amending, terminating or otherwise modifying) that diminishes the rights granted to Neurocrine under this Agreement; or (b) fail to take any action with respect to an In-License Agreement that is reasonably necessary to avoid diminishing the rights granted to Neurocrine under this Agreement.
- 5.3.2 Voyager shall reasonably enforce, or otherwise take all actions necessary to enable Neurocrine to enforce, at Voyager's expense, Voyager's rights and benefits and the obligations of the counterparty under each In-License Agreement that may affect the rights, benefits and obligations of Neurocrine hereunder, including taking such actions as Neurocrine may request, and will inform Neurocrine of any action it takes under any In-License Agreement to the extent such action may affect Neurocrine's rights under this Agreement.
- 5.3.3 Voyager shall not (and shall cause its Affiliates not to) assign (except an assignment to a party to which this Agreement has been assigned as permitted under Section 15.4) any In-License Agreement without the prior written consent of Neurocrine.
- 5.3.4 Voyager shall (and shall cause its Affiliates to) provide Neurocrine with prompt notice of any claim of a breach under any In-License Agreement or notice of termination of any In-License Agreement, made by any of Voyager, its Affiliate or the Inbound Licensor, and shall promptly send to Neurocrine (or cause its Affiliates promptly to send to Neurocrine) copies

of all material correspondence regarding each In-License Agreement, to the extent relevant to the rights or obligations of Neurocrine under this Agreement.

- 5.3.5 In the event that Voyager or its Affiliate receives written notice of an alleged breach by Voyager or its Affiliate under any In-License Agreement, where termination of such In-License Agreement or any diminishment of the licenses granted to Neurocrine under the Voyager IP is being or could be sought by the Inbound Licensor, then Voyager will promptly, but in no event less than [\*\*] thereafter, provide written notice thereof to Neurocrine and grant Neurocrine the right (but not the obligation) to cure such alleged breach, and if Neurocrine elects to and does cure such breach, then Neurocrine may offset any Out-of-Pocket Costs and expenses incurred by or on behalf of Neurocrine or any of its Affiliates in connection with curing such breach against Neurocrine's future payment obligations to Voyager under this Agreement. Each Party shall notify the other Party if it intends to cure such breach and again promptly after curing such breach.
- Neurocrine acknowledges and agrees that, if any license granted to Voyager under an In-License Agreement is terminated then Neurocrine's sublicense under such terminated license shall automatically terminate, subject to Neurocrine's right to receive a direct license from any Inbound Licensor of such In-License Agreement to the extent specified in the applicable In-License Agreement. In the event that any In-License Agreement is terminated by the applicable Inbound Licensor, and such In-License Agreement does not permit the sublicense to survive (or Neurocrine to receive a direct license), then Voyager will take all reasonable actions requested by Neurocrine to facilitate Neurocrine's entry into a direct license agreement with the applicable Inbound Licensor. In the event that any In-License Agreement is terminated by the applicable Inbound Licensor, and such In-License Agreement permits the sublicense to survive (or Neurocrine to receive a direct license), Neurocrine will have the right, at Neurocrine's election, to convert the applicable sublicenses granted under this Agreement by Voyager to a direct license from the applicable Inbound Licensor to Neurocrine on the terms and conditions contained in such In-License Agreement, or such other terms and conditions as may be negotiated by Neurocrine and the applicable Inbound Licensor, and Voyager will reasonably cooperate with Neurocrine and its Affiliates to effectuate such direct license and assist Neurocrine in discussions with Inbound Licensors to accomplish such direct license. In the event Neurocrine enters into any such direct license with an Inbound Licensor, Neurocrine may offset any Out-of-Pocket Costs and expenses incurred by or on behalf of Neurocrine or any of its Affiliates or Sublicensees in connection with entering into and exercising its rights or performing under such direct license, against Neurocrine's future payment obligations to Voyager under this Agreement.
- 5.4 <u>Genzyme Agreement</u>. Voyager shall notify Neurocrine within [\*\*] after Genzyme's rights to the FA Program outside the United States expire and shall provide written confirmation thereof from Genzyme. Upon such expiration, the Territory with respect to the FA Program will automatically expand to include all countries in the world. If instead Genzyme exercises its option with respect to the FA Program, then promptly thereafter Voyager will use Commercially Reasonable Efforts to facilitate negotiation of a cooperation agreement among Genzyme, Neurocrine and Voyager including provisions related to data sharing, license grants and coordination of development activities for Collaboration Candidates and Collaboration Products in the FA Program.

Neurocrine's Sublicensing Rights. Neurocrine shall have the right to grant and authorize sublicenses under the rights granted to it under Section 5.1 to any of its Affiliates and Third Parties through multiple tiers (each such Third Party, a "Sublicensee"). Neurocrine shall provide Voyager with a fully-executed copy of any agreement (redacted as necessary to protect confidential or commercially sensitive information that is not necessary for Voyager to determine Neurocrine's compliance with this Agreement or for Voyager to comply with any applicable In-License Agreement) reflecting any such sublicense to a Third Party promptly after the execution thereof (a "Sublicense"). If Neurocrine or any Affiliate or Sublicensee grants a sublicense, the terms and conditions of this Agreement that are applicable to Sublicensees shall apply to such Sublicensee to the same extent as they apply to Neurocrine. Neurocrine will itself pay and account to Voyager for all payments due under this Agreement by reason of operation of any such sublicense. Each Sublicense must be consistent with, and require the Sublicensee to meet, all applicable obligations and requirements of the In-License Agreements. Notwithstanding the foregoing, unless and until the receipt of written agreement by the applicable Inbound Licensor to permit further sublicensing to a Third Party, Neurocrine shall not have the right to grant any sublicenses to the extent not permitted under the applicable In-License Agreement; provided that upon Neurocrine's request, Voyager will use Commercially Reasonable Efforts to obtain the right for Neurocrine to grant sublicenses to the extent not already permitted by an In-License Agreement.

### 5.6 Licenses to Voyager.

- 5.6.1 <u>Development License</u>. Subject to the terms and conditions of this Agreement, Neurocrine hereby grants to Voyager, and Voyager accepts, a non-exclusive, royalty-free, non-transferable (except in accordance with Section 15.4), sublicenseable (only to its permitted subcontractors under Section 2.5) license under the Neurocrine IP to conduct the Development and Manufacturing activities allocated to Voyager under the Development Plans in the Field in the Territory in accordance with this Agreement.
- 5.6.2 <u>Co-Co License</u>. Subject to the terms and conditions of this Agreement and each applicable Co-Co Agreement, on a Program-by-Program basis, upon Voyager's exercise of the Co-Co Option with respect to such Program in accordance with Section 4.1.1, Neurocrine grants to Voyager, and Voyager accepts, a non-exclusive, non-transferable (except in accordance with Section 15.4), sublicenseable (solely as set forth in the applicable Co-Co Agreement) license under the Neurocrine IP to conduct those Development, Commercialization and Manufacturing activities that are allocated to Voyager under such Co-Co Agreement with respect to Co-Co Products in such Program in the Field in and for the Co-Co Territory during the term of such Co-Co Agreement.
- 5.7 <u>No Other Rights</u>. Except as otherwise expressly provided in this Agreement, under no circumstances shall a Party, as a result of this Agreement, obtain any ownership interest, license right or other right in any Know-How, Patent Rights or other intellectual property rights of the other Party or any of its Affiliates, including items owned, controlled, developed or acquired by the other Party or any of its Affiliates, or provided by the other Party to the first Party at any time pursuant to this Agreement.

Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to this Agreement by a Party to the other, including those set forth in Sections 5.1 and 5.6, are and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the U.S. Bankruptcy Code ("Title 11"), licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code and any foreign counterpart thereto. Without limiting the Parties' rights under Section 365(n) of Title 11, if a case under Title 11 is commenced by or against either Party, the other Party shall be entitled to a copy of any and all such intellectual property and all embodiments of such intellectual property, and the same, if not in the possession of such other Party, shall be promptly delivered to it (a) before this Agreement is rejected by or on behalf of such Party, within [\*\*] after such other Party's written request, unless such Party, or its trustee or receiver, elects within [\*\*] to continue to perform all of its obligations under this Agreement, or (b) after any rejection of this Agreement by or on behalf of such Party, if not previously delivered as provided under clause (a) above (any such event described in clause (a) or (b) above, and occurring while such Title 11 case is pending, being a "Delivery Event"). All rights of the Parties under this Section 5.8 and under Section 365(n) of Title 11 are in addition to and not in substitution of any and all other rights, powers, and remedies that each Party may have under this Agreement, Title 11, and any other applicable Laws. The Parties agree that they intend the foregoing rights to extend to the maximum extent permitted by Law and any provisions of applicable contracts with Third Parties, including for purposes of Title 11, (i) the right of access to any intellectual property (including all embodiments thereof) of Voyager or Neurocrine, as applicable, or any Third Party with whom Voyager or Neurocrine contracts to perform an obligation of Voyager or Neurocrine under this Agreement, and, in the case of the Third Party, that is necessary for the Development and Manufacture of Collaboration Products and (ii) the right to contract directly with any Third Party described in clause (i) in this sentence to complete the contracted work, provided however, that in each case such rights shall be subject to the confidentiality obligations contemplated by this Agreement. If a bankruptcy proceeding is commenced by or against Voyager, notwithstanding anything to the contrary in Article 10, Neurocrine may, to the maximum extent permitted by Law, take appropriate actions in connection with the filing, prosecution, maintenance and enforcement of any Voyager Licensed Patent Rights licensed to Neurocrine under this Agreement to the extent that Voyager is required or has the right to take such actions under this Agreement and to the extent that Voyager fails to take such actions following at least [\*\*] prior written notice from Neurocrine.

# ARTICLE 6 MANUFACTURING

- 6.1 <u>Manufacturing Responsibilities Prior to Transition Date</u>. Prior to the Transition Date for a Program, Voyager shall be responsible for the Manufacture of Collaboration Products from such Program, subject to Section 2.1.7 or unless otherwise agreed by the Parties in writing.
- 6.2 <u>Manufacturing After Transition Date</u>. No later than [\*\*] prior to the anticipated Transition Date for a Program, the Parties shall discuss in good faith the allocation of Manufacturing and supply responsibilities between the Parties with regard to the Collaboration Product(s) from such Program in connection with Neurocrine's and, to the extent applicable, Voyager's Development and Commercialization activities hereunder. The Parties may negotiate

in good faith either or both a clinical supply agreement and/or a commercial supply agreement for Voyager to supply Neurocrine with any Collaboration Product.

# ARTICLE 7 GENERAL PROVISIONS RELATING TO ACTIVITIES

7.1 <u>Compliance</u>. All Development, Manufacturing and Commercialization activities to be conducted by a Party under this Agreement shall be conducted in compliance with applicable Laws, including all applicable cGMP, GLP and GCP requirements.

## 7.2 <u>Regulatory Activities</u>.

#### 7.2.1 INDs and Related Communications.

- (a) Subject to the terms of any applicable Co-Co Agreement, from and after the applicable Transition Date, Neurocrine shall, as between the Parties, have the sole right to prepare, obtain and maintain all INDs, Regulatory Approval Applications (including the setting of the overall regulatory strategy therefor), other Regulatory Approvals, pricing and reimbursement approvals and other submissions and to conduct communications with the Regulatory Authorities and Governmental Authorities in the Territory for the applicable Collaboration Products. Neurocrine will be the regulatory sponsor for all Clinical Trials commenced on Collaboration Products from and after the Effective Date. Upon Neurocrine's request, Voyager shall provide reasonable assistance to Neurocrine in connection with the regulatory activities for Collaboration Products, including the preparation of the IND for the FA Program and other relevant Regulatory Filings.
- (b) With regard to the Existing Programs, subject to the terms of any applicable Co-Co Agreement, Neurocrine shall provide drafts of each such IND, Regulatory Approval Application or other material submission or communication described in Section 7.2.1(a) to Voyager for Voyager's review and comment a reasonable period of time prior to such submission of such IND, Regulatory Approval Applications or other material submission or communications to the applicable Regulatory Authority. Neurocrine shall, and shall cause its Affiliates to, reasonably incorporate any comments of Voyager into such IND, Regulatory Approval Applications and other material submissions and communications if received by Neurocrine within [\*\*] after Neurocrine has provided access to Voyager.
- (c) With regard to the Existing Programs, subject to the terms of any applicable Co-Co Agreement, Neurocrine shall provide Voyager with prior written notice, to the extent Neurocrine has advance knowledge, of any scheduled meeting, conference, or discussion (including any advisory committee meeting) with a Regulatory Authority in the Territory relating to any substantive matter with respect to any Collaboration Product in such Existing Program, within [\*\*] after Neurocrine or its Affiliate first receives notice of the scheduling of such meeting, conference, or discussion (or within such shorter period as may be necessary in order to give Voyager a reasonable opportunity to attend such meeting, conference, or discussion). Voyager shall have the right to have one (1) or, to the extent reasonable, more of its employees or agents attend and participate in all such meetings, conferences, and discussions.

- (d) For clarity, this Section 7.2.1 shall not in any way prohibit Neurocrine from complying with its reporting requirements pursuant to applicable Law, including with respect to adverse event reporting.
- 7.2.2 Ownership and Assignment of Regulatory Filings. All Regulatory Filings (including all Regulatory Approvals) and pricing and reimbursement approvals in the Territory with respect to the applicable Collaboration Products shall be owned by, and shall be the sole property and held in the name of, Neurocrine or its designated Affiliate, Sublicensee or designee. Voyager shall and hereby does assign to Neurocrine all of its right, title and interest in and to all Regulatory Filings (including INDs) relating to each Collaboration Product, and Voyager shall deliver such Regulatory Filings (and any documentation or correspondence, including conversation logs, relating to or supporting such Regulatory Filings) to Neurocrine within [\*\*] after the Effective Date. No later than [\*\*] after the Effective Date, Voyager shall submit to the FDA a letter transferring sponsorship of IND Nos. [\*\*] to Neurocrine, and Neurocrine shall submit to the FDA a letter accepting transfer of sponsorship of IND Nos. [\*\*] from Voyager. Each Party shall notify the other Party concurrently with its submission of its respective letter to the FDA, such notification to include a copy of such letter.
- Sale of Priority Review Voucher. If the FDA grants to Neurocrine a priority review voucher in connection with the approval of the BLA for a Collaboration Product (a "PRV"), Neurocrine may (a) sell the PRV to a Third Party in an arm's-length transaction (a "PRV Sale"), (b) keep the PRV for its own use or use by any of its Affiliates for any product other than a Collaboration Product (a "Neurocrine PRV Use") or (c) use the PRV for a Collaboration Product (in which event (c) no payments will be due to Voyager under this Section 7.3). In the event of a PRV Sale: (1) if the PRV was for a Collaboration Product in an Existing Program and the Co-Co Option for such Existing Program was either previously exercised or had not expired or been waived by Voyager, Neurocrine shall pay Voyager an amount equal to the [\*\*]; and (2) with respect to the PRV for any other Collaboration Product from an Existing Program or a Discovery Program, Neurocrine shall pay Voyager an amount equal to the [\*\*]. In the Event of a Neurocrine PRV Use: (1) if the PRV was for a Collaboration Product in an Existing Program and the Co-Co-Option for such Existing Program was either previously exercised or had not expired or been waived by Voyager, Neurocrine shall pay Voyager an amount equal to [\*\*]; and (2) with respect to the PRV for any other Collaboration Product from an Existing Program or a Discovery Program, Neurocrine shall pay Voyager an amount equal to the [\*\*]. All payments under this Section 7.3 shall be made within [\*\*] after the closing of the PRV Sale or the effective date of Neurocrine PRV Use, as applicable.
- 7.4 Records and Audits. Each Party shall, and shall require its Affiliates and permitted subcontractors to, maintain materially complete, current and accurate hard and electronic (as applicable) copies of records of all work conducted pursuant to its Development, Manufacturing and Commercialization activities under this Agreement, and all results, data, developments and Know-How made in conducting such activities. Such records shall accurately reflect all such work done and results achieved in sufficient detail and in good scientific manner appropriate for applicable patent and regulatory purposes. Neurocrine shall have the right to receive and retain a copy of all such records of Voyager at reasonable times, upon reasonable prior written notice to Voyager, after the applicable Transition Date with regard to all such records relating to the Development or Manufacturing activities conducted by Voyager with respect to the applicable

Collaboration Product(s). Neurocrine agrees that to the extent that an In-License Agreement applicable to a given Program requires records to be retained for a period longer than the period set forth in this Section 7.4, Neurocrine shall retain applicable records for such time period as required by the applicable In-License Agreement.

# ARTICLE 8 INITIAL FEE; MILESTONES AND ROYALTIES; PAYMENTS

#### 8.1 <u>Initial Consideration</u>.

- 8.1.1 <u>Upfront Fee</u>. In partial consideration for the rights granted to Neurocrine hereunder, Neurocrine shall pay Voyager a one-time, non-refundable, non-creditable upfront payment of One Hundred Fifteen Million Dollars (\$115,000,000) (the "<u>Initial Fee</u>") within five (5) Business Days after the Effective Date. The Initial Fee shall be allocated as set forth on <u>Schedule 8.1</u> (the "<u>Allocation Schedule</u>").
- 8.1.2 <u>Equity Purchase</u>. In partial consideration of the rights granted hereunder, Voyager shall issue and sell to Neurocrine, and Neurocrine shall purchase from Voyager, shares of Voyager common stock, par value \$0.001 per share, pursuant to the terms of the stock purchase agreement attached as Exhibit A (the "<u>Stock Purchase Agreement</u>") and executed by the Parties concurrently with this Agreement.

### 8.2 <u>Milestone Payments</u>.

- (a) Each event described in Sections 8.2.1, 8.2.2, 8.2.3 and 8.2.4 is referred to as a "Milestone Event." In partial consideration for the rights and licenses granted to Neurocrine hereunder, (i) within [\*\*] after (A) in the case of Milestone Events (a), (b) and (c) (but only if [\*\*]) under Section 8.2.2 and Milestone Event (a) under Section 8.2.3, Neurocrine's receipt of written notice from Voyager following Voyager's achievement of the applicable Milestone Event or the JSC's determination that such Milestone Event was achieved and (B) in all other cases under Sections 8.2.1, 8.2.2 and 8.2.3, the first achievement of a Milestone Event set forth below by or on behalf of Neurocrine, any of its Affiliates or any Sublicensee, and (ii) in the case of Section 8.2.4, within [\*\*] after the end of the Calendar Quarter in which achievement of the applicable Commercial Milestone first occurs, Neurocrine shall make a one-time (except as provided below), non-refundable, non-creditable milestone payment to Voyager in the amount below corresponding to such Milestone Event (each, a "Milestone Payment").
- (b) If Voyager does not timely exercise its Co-Co Option with respect to an Existing Program, then the tables in Section 8.2.1 (for Development Milestones), Section 8.2.2 (for Development Milestones), and Section 8.2.4 (for Commercial Milestones) shall apply in their entirety with respect to such Existing Program. If Voyager exercises its Co-Co Option with respect to an Existing Program, then Voyager shall be entitled to receive Milestone Payments only with respect to any Milestone Event that relates to the Territory outside the Co-Co Territory for so long as such Existing Program remains a Co-Co Program, as further provided below. If a Co-Co Agreement is terminated and the applicable Program is no longer a Co-Co Program, then the tables in Section 8.2.1 (for Development Milestones), Section 8.2.2 (for Development Milestones), and Section 8.2.4 (for Commercial Milestones) shall thereafter apply with respect to such Existing

Program in the United States, but only with respect to Milestone Events achieved after termination of the Co-Co Program.

(c) Except as expressly set forth below, each Milestone Payment shall be deemed earned as of the achievement of the corresponding Milestone Event.

## 8.2.1 Development Milestone Payments for Collaboration Products under AADC Program.

|     | Milestone Event | Milestone Payment (\$) |
|-----|-----------------|------------------------|
| (a) | [**]            | [**] (\$[**])*         |
| (b) | [**]            | [**] (\$[**])*         |
| (c) | [**]            | [**] (\$[**])*         |
| (d) | [**]            | [**] (\$[**])          |
| (e) | [**]            | [**] (\$[**])          |

<sup>\*</sup>subject to adjustment as set forth below

All Milestone Payments above may be paid only one (1) time. The Milestone Payment for Milestone Event (a), if achieved, will not be payable unless and until Voyager's Co-Co Option for the AADC Program expires unexercised or at such time as Voyager provides a signed written notice of its decision not to exercise such Co-Co Option. If the Development Milestone described in Section 8.2.1(a) is not achieved with respect to the [\*\*], then the Milestone Payment associated with Section 8.2.1(a) shall become due and payable upon commencement of a [\*\*]. In the event that Voyager exercises its Co-Co Option with respect to the AADC Program, the Milestone Payments for the Milestone Events described in Sections 8.2.1(a) through (c) will not be due. In the event that a Development Milestone described in either Sections 8.2.1(b) or (c) occurs as a result of the [\*\*], the payment of the amount of the Milestone Payment with respect to Section 8.2.1(b) shall be increased to [\*\*] Dollars (\$[\*\*]) and the payment of the amount of the Milestone Payment with respect to Section 8.2.1(c) shall be increased to [\*\*] Dollars (\$[\*\*]).

### 8.2.2 <u>Development Milestone Payments for Collaboration Products under FA Program.</u>

|     | Milestone Event | Milestone Payment (\$) |
|-----|-----------------|------------------------|
| (a) | [**]            | [**] (\$[**])          |
| (b) | [**]            | [**] (\$[**])          |
| (c) | [**]            | [**] (\$[**])*         |

|     | Milestone Event | Milestone Payment<br>(\$) |
|-----|-----------------|---------------------------|
| (d) | [**]            | [**] (\$[**])*            |
| (e) | [**]            | [**] (\$[**])             |
| (f) | [**]            | [**] (\$[**])             |
| (g) | [**]            | [**] (\$[**])             |
| (h) | [**]            | [**] (\$[**])             |

<sup>\*</sup>subject to adjustment as set forth below

The Milestone Payment described in Section 8.2.2(a) may be paid for up to two (2) Development Candidates under the FA Program. All other Milestone Payments above may be paid only one (1) time for the FA Program. In the event the Development Milestone described in Section 8.2.2(f) occurs with respect to a Collaboration Product but the Milestone Event described in Section 8.2.2(e) has not occurred and the corresponding Milestone Payment has not been paid, then the Milestone Payment associated with the Milestone Event described in Section 8.2.2(e) shall be due and payable with the payment associated with the Development Milestone described in Section 8.2.2(f). In the event that Voyager exercises its Co-Co Option with respect to the FA Program, the Milestone Payments for the Milestone Events described in Sections 8.2.2(c) through (g) shall not be due. If Voyager does not timely exercise its Co-Co Option with respect to the FA Program and the Development Milestones described in Sections 8.2.2(c) and (d) occur as a result of the same study, the Milestone Payment associated with Section 8.2.2(c) shall not be payable upon achievement of the Milestone Event in Section 8.2.2(c) and instead will become due and payable (if applicable) upon occurrence of the Development Milestone described in Section 8.2.2(e), provided that if the Milestone Event described in Section 8.2.2(e) has not occurred when the Milestone Event described Section 8.2.2(f) occurs, then the Milestone Payment associated with Section 8.2.2(c) shall become due and payable upon occurrence of the Development Milestone described in Section 8.2.2(f). If the Development Milestone described in Section 8.2.2(d) has not occurred when the Milestone Event described in Section 8.2.2(e) occurs, then the Milestone Payment associated with Section 8.2.2(d) shall become due and payable upon occurrence of the Development Milestone described in Section 8.2.2(e). In the event the Development Milestone described in Section 8.2.2(g) occurs with respect to a Collaboration Product, all prior such Development Milestones that have not occurred shall be deemed to have occurred, and any Milestone Payment(s) associated with such prior Development Milestones that have not previously been paid shall be due and payable with the Milestone Payment associated with the Milestone Event described in Section 8.2.2(g). The Milestone Payment described in Section 8.2.2(h) shall only become payable if, as of the relevant time, the Territory has expanded to include countries outside the United States with respect to the FA Program in accordance with Section 5.4.

8.2.3 Development Milestone Payments for Collaboration Products under Discovery Programs.

|     | Milestone Event | Milestone Payment<br>(\$) |
|-----|-----------------|---------------------------|
| (a) | [**]            | [**] (\$[**])             |
| (b) | [**]            | [**] (\$[**])             |
| (c) | [**]            | [**] (\$[**])             |
| (d) | [**]            | [**] (\$[**])             |
| (e) | [**]            | [**] (\$[**])             |
| (f) | [**]            | [**] (\$[**])             |
| (g) | [**]            | [**] (\$[**])             |
| (h) | [**]            | [**] (\$[**])             |
| (i) | [**]            | [**] (\$[**])             |

The Milestone Payment described in Section 8.2.3(a) may be paid for up to two (2) Development Candidates in each Discovery Program. All other Milestone Payments above may be paid only one (1) time per Discovery Program. In the event the Development Milestone described in Section 8.2.3(f) occurs with respect to a Collaboration Product but the Milestone Event described in Section 8.2.3(e) has not occurred and the corresponding Milestone Payment has not been paid, then the Milestone Payment associated with the Milestone Event described in Section 8.2.3(e) shall be due and payable with the payment associated with the Development Milestone described in Section 8.2.3(f). If the Development Milestones described in Sections 8.2.3(c) and (d) occur as a result of the same study, the Milestone Payment associated with Section 8.2.3(c) shall not be payable upon achievement of the Milestone Event in Section 8.2.3(c) and instead will become due and payable upon occurrence of the Development Milestone described in Section 8.2.3(e), provided that if the Milestone Event described in Section 8.2.3(e) has not occurred when the Milestone Event described in Section 8.2.3(f) occurs, then the Milestone Payment associated with Section 8.2.3(c) shall become due and payable upon occurrence of the Development Milestone described in Section 8.2.3(f). If the Development Milestone described in Section 8.2.3(d) has not occurred when the Milestone Event described in Section 8.2.3(e) occurs, then the Milestone Payment associated with Section 8.2.3(d) shall become due and payable upon occurrence of the Development Milestone described in Section 8.2.3(e). In the event the Development Milestone described in Section 8.2.3(g) occurs with respect to a Collaboration Product, all prior such Development Milestones that have not occurred shall be deemed to have occurred, and any Milestone Payment(s) associated with such prior Development Milestones that have not previously been paid shall be due and payable with the Milestone Payment associated with the Milestone Event described in Section 8.2.3(g).

### 8.2.4 Commercial Milestones for Collaboration Products.

|     | Milestone Event   | \$ in Millions       |
|-----|---|----------------------|
| (a) | Aggregate Territory-wide (except as provided below) Net Sales of such | [**] (\$[**])        |
|     | Collaboration Product greater than or equal to \$[**]                 |                      |
| (b) | Aggregate Territory-wide (except as provided below) Net Sales of such | [**] (\$[**])        |
|     | Collaboration Product greater than or equal to \$[**]                 |                      |
| (c) | Aggregate Territory-wide (except as provided below) Net Sales of such | [**] (\$[**])        |
|     | Collaboration Product greater than or equal to \$[**]                 |                      |
| (d) | Aggregate Territory-wide (except as provided below) Net Sales of such | [**] (\$[**])        |
|     | Collaboration Product greater than or equal to \$[**]                 |                      |
|     | Total per Collaboration Product                                       | Two Hundred and      |
|     |   | Seventy-Five Million |
|     |   | (\$275,000,000)      |

The Milestone Payments above will be payable one time for each Collaboration Product to achieve the corresponding Milestone Event (subject to the aggregate cap below). With respect to Co-Co Products, Net Sales in the Co-Co Territory will not be included in aggregate Net Sales for purposes of determining whether the Commercial Milestones above have been achieved.

The aggregate amount payable under this Section 8.2.4 will not exceed one billion one hundred million dollars (\$1,100,000,000).

8.3 <u>Royalties</u>. Subject to the adjustments under Section 8.5, Neurocrine will make royalty payments, during the applicable Royalty Terms, as set forth in this Section 8.3.

### 8.3.1 Royalties on Collaboration Products under AADC Program.

(a) <u>Annual Net Sales in the United States</u>. In further consideration for the licenses and other rights granted to Neurocrine with respect to the AADC Program, Neurocrine shall make tiered royalty payments to Voyager in respect of Annual Net Sales in the United States, on a Collaboration Product-by-Collaboration Product basis, of Collaboration Products under the AADC Program that are not Co-Co Products.

|     | Annual Net Sales in the United States of the Collaboration Product   | Tiered Royalty Rate  |
|-----|--|----------------------|
| (a) | Annual Net Sales in the United States less than [**] Dollars (\$[**])  | [**] Percent ([**]%) |
| (b) | Annual Net Sales in the United States greater than or equal to [**] Dollars (\$[**]) but less than [**] Dollars (\$[**]) | [**] Percent ([**]%) |
| (c) | Annual Net Sales in the United States greater than or equal to [**] Dollars (\$[**]) but less than [**] Dollars (\$[**]) | [**] Percent ([**]%) |
| (d) | Annual Net Sales in the United States greater than or equal to [**] Dollars (\$[**])                                     | [**] Percent ([**]%) |

(b) <u>Annual Net Sales outside of the United States</u>. In further consideration for the licenses and other rights granted to Neurocrine with respect to the AADC Program, Neurocrine shall make tiered royalty payments to Voyager in respect of Annual Net Sales in the Territory outside the United States, on a Collaboration Product-by-Collaboration Product basis, of Collaboration Products under the AADC Program.

|     | Annual Net Sales outside the United States of the Collaboration Product   | Tiered Royalty Rate  |
|-----|---|----------------------|
| (a) | Annual Net Sales outside the United States less than [**] Dollars (\$[**])  | [**] Percent ([**]%) |
| (b) | Annual Net Sales outside the United States greater than or equal to [**] Dollars (\$[**]) but less than [**] Dollars (\$[**]) | [**] Percent ([**]%) |
| (c) | Annual Net Sales outside the United States greater than or equal to [**] Dollars (\$[**]) but less than [**] Dollars (\$[**]) | [**] Percent ([**]%) |
| (d) | Annual Net Sales outside the United States greater than or equal to [**] Dollars (\$[**])                                     | [**] Percent ([**]%) |

### 8.3.2 Royalties on Collaboration Products under FA Program.

(a) <u>Annual Net Sales in the United States</u>. In further consideration of the licenses and other rights granted to Neurocrine with respect to the FA Program, Neurocrine shall make tiered royalty payments to Voyager in respect of Annual Net Sales in the United States, on a Collaboration Product-by-Collaboration Product basis, of Collaboration Products under the FA Program that are not Co-Co Products.

|     | Annual Net Sales in the United States of the Collaboration Product   | Tiered Royalty Rate  |
|-----|--|----------------------|
| (a) | Annual Net Sales in the United States less than [**] Dollars (\$[**])  | [**] Percent ([**]%) |
| (b) | Annual Net Sales in the United States greater than or equal to [**] Dollars (\$[**]) but less than [**] Dollars (\$[**]) | [**] Percent ([**]%) |
| (c) | Annual Net Sales in the United States greater than or equal to [**] Dollars (\$[**]) but less than [**] Dollars (\$[**]) | [**] Percent ([**]%) |
| (d) | Annual Net Sales in the United States greater than or equal to [**] Dollars (\$[**])                                     | [**] Percent ([**]%) |

(b) <u>Annual Net Sales outside of the United States</u>. In further consideration of the licenses and other rights granted to Neurocrine with respect to the FA

Program, Neurocrine shall make tiered royalty payments to Voyager in respect of Annual Net Sales in the Territory outside the United States, on a Collaboration Product-by-Collaboration Product basis, of Collaboration Products under the FA Program. Such royalty payments shall become payable only if the Territory expands to include countries outside the United States with respect to the FA Program.

|     | Annual Net Sales outside the United States of the Collaboration Product   | Tiered Royalty Rate  |
|-----|---|----------------------|
| (a) | Annual Net Sales outside the United States less than [**] Dollars (\$[**])  | [**] Percent ([**]%) |
| (b) | Annual Net Sales outside the United States greater than or equal to [**] Dollars (\$[**]) but less than [**] Dollars (\$[**]) | [**] Percent ([**]%) |
| (c) | Annual Net Sales outside the United States greater than or equal to [**] Dollars (\$[**])                                     | [**] Percent ([**]%) |

### 8.3.3 Royalties on Collaboration Products under Discovery Programs

(a) <u>Annual Net Sales in the United States</u>. In further consideration of the licenses and other rights granted to Neurocrine with respect to each Discovery Program, Neurocrine shall make tiered royalty payments to Voyager in respect of Annual Net Sales in the United States, on a Collaboration Product-by-Collaboration Product basis, of Collaboration Products under each Discovery Program.

|     | Annual Net Sales in the United States of the Collaboration Product   | Tiered Royalty Rate  |
|-----|--|----------------------|
| (a) | Annual Net Sales in the United States less than [**] Dollars (\$[**])  | [**] Percent ([**]%) |
| (b) | Annual Net Sales in the United States greater than or equal to [**] Dollars (\$[**]) but less than [**] Dollars (\$[**]) | [**] Percent ([**]%) |
| (c) | Annual Net Sales in the United States greater than or equal to [**] Dollars (\$[**]) but less than [**] Dollars (\$[**]) | [**] Percent ([**]%) |
| (d) | Annual Net Sales in the United States greater than or equal to $[**]$ Dollars $(\$[**])$                                 | [**] Percent ([**]%) |

(b) <u>Annual Net Sales outside of the United States</u>. In further consideration of the licenses and other rights granted to Neurocrine with respect to each Discovery Program, Neurocrine shall make tiered royalty payments to Voyager in respect of Annual Net Sales in the Territory outside the United States, on a Collaboration Product-by-Collaboration Product basis, of Collaboration Products under each Discovery Program.

|     | Annual Net Sales outside the United States of the Collaboration Product   | Tiered Royalty Rate  |
|-----|---|----------------------|
| (a) | Annual Net Sales outside the United States less than [**] Dollars (\$[**])  | [**] Percent ([**]%) |
| (b) | Annual Net Sales outside the United States greater than or equal to [**] Dollars (\$[**]) but less than [**] Dollars (\$[**]) | [**] Percent ([**]%) |
| (c) | Annual Net Sales outside the United States greater than or equal to [**] Dollars (\$[**]) but less than [**] Dollars (\$[**]) | [**] Percent ([**]%) |
| (d) | Annual Net Sales outside the United States greater than or equal to [**] Dollars (\$[**])                                     | [**] Percent ([**]%) |

- 8.3.4 <u>Calculation of Royalties</u>. Royalties on aggregate Net Sales of Collaboration Products in a Calendar Year shall be paid at the rate applicable to the portion of Net Sales within each of the Annual Net Sales tiers during such Calendar Year. For example, if, during a Calendar Year, Annual Net Sales of Collaboration Products under the AADC Program in the United States are equal to \$[\*\*], then the royalties payable by Neurocrine would be calculated by adding [\*\*], to equal total royalties of \$[\*\*].
- 8.4 <u>Royalty Period</u>. On a country-by-country and Collaboration Product-by-Collaboration Product basis, royalty payments in the Territory shall commence on the First Commercial Sale of such Collaboration Product in such country and terminate upon the latest of: (a) the expiration, invalidation or abandonment date of the last Valid Claim of the Voyager Licensed Patent Rights or Joint Patent Rights that claims the composition of matter or method of use (for an indication for which such Collaboration Product received Regulatory Approval in such country) of such Collaboration Product in such country; (b) ten (10) years from First Commercial Sale of such Collaboration Product in such country (the applicable "<u>Royalty Term</u>").

### 8.5 Royalty Adjustments.

8.5.1 <u>Valid Claim Expiration</u>. If, with respect to a Collaboration Product in any country in the Territory, at any time in the Royalty Term for such Collaboration Product and country there is no Valid Claim within the Voyager Licensed Patent Rights or the Joint Patent Rights that claims the composition of matter or method of use (for an indication for which such Collaboration Product received Regulatory Approval in such country) of such Collaboration Product in such country shall be reduced by fifty percent (50%) from the royalties otherwise due for such Collaboration Product in such country under Section 8.3. If such royalty reduction applies to any country other than the United States, it will be calculated by determining the portion of total Net Sales in the Territory outside the United States of the relevant Collaboration Product in a Calendar Quarter that is attributable to the country in which such reduction applies, and by determining the total royalties for the Territory outside the United States without reduction, and then reducing by fifty percent

(50%) the applicable portion (based on Net Sales) of the total royalties attributable to the country in which such reduction applies.

- 8.5.2 <u>Biosimilar Reduction</u>. If, in any country in the Territory during the Royalty Term in such country for a Collaboration Product, a Biosimilar Product with respect to such Collaboration Product is launched in such country, then, for any Calendar Quarter in which such Biosimilar Product(s) comprise greater than or equal to [\*\*] percent ([\*\*]%) of the total units of such Collaboration Product and Biosimilar Product(s) sold in such country (based on sales of units of such Collaboration Product and Biosimilar Product(s) as reported by IQVIA, or, if such data are not available, such other reliable data source as reasonably determined by Voyager and Neurocrine) the royalties payable for such Collaboration Product with respect to such country for such Calendar Quarter shall be reduced by fifty percent (50%) from the royalties otherwise due for such Collaboration Product in such country under Section 8.3. Such reduction shall be calculated as described in the last sentence of Section 8.5.1.
- 8.5.3 <u>Stacking</u>. If Neurocrine or any of its Affiliates determines in good faith that it is reasonably necessary to (a) obtain a license from a Third Party under one or more Valid Claims licensable by such Third Party Covering a Collaboration Product or under Know-How licensable by such Third Party in order for Neurocrine, its Affiliates and Sublicensees to Exploit such Collaboration Product in the Field in a country in the Territory and (b) make payments under such license, and Neurocrine or any of its Affiliates actually enters into any such license, then the amount of Neurocrine's royalty payments under Section 8.3 for such Collaboration Product in such country in a Calendar Quarter may be reduced by fifty percent (50%) of the royalties and other amounts actually paid by Neurocrine or any of its Affiliates to such Third Party to the extent applicable to such Collaboration Product in such country during such Calendar Quarter; provided, however, that neither Neurocrine nor any of its Affiliates shall be entitled to make reductions hereunder for any amounts payable by Neurocrine or any of its Affiliates relating to any Neurocrine IP existing as of the Effective Date.
- 8.5.4 <u>Limits on Deductions</u>. On a Collaboration Product-by-Collaboration Product basis, in no event shall the cumulative effect of the adjustments in Sections 8.5.1, 8.5.2 or 8.5.3 reduce the royalties payable to Voyager pursuant to Section 8.3 below fifty percent (50%) of the amounts that would otherwise have been payable with respect to the applicable Collaboration Product in the applicable country in the applicable Calendar Quarter, as determined pursuant to Section 8.3.4. Neurocrine may carry forward to subsequent Calendar Quarters any amounts it could not deduct as a result of the application of the preceding sentence.

### 8.6 <u>Reports; Payment of Royalty</u>.

8.6.1 <u>Reports.</u> During the Term, following the First Commercial Sale of any Collaboration Product in any country in the Territory (excluding the First Commercial Sale in the United States of a Co-Co Product for which reporting shall be addressed in the applicable Co-Co Agreement), Neurocrine shall furnish to Voyager a written report within [\*\*] after the end of each Calendar Quarter showing, on a Collaboration Product-by-Collaboration Product and country-by-country basis, the Net Sales of each Collaboration Product in each country of the Territory and the royalties payable under this Agreement. Royalties with respect to Net Sales of Collaboration Products shall be due and payable on the date such royalty report is due.

8.6.2 <u>Compliance with In-License Agreements</u>. Neurocrine and its Affiliates and Sublicensees shall provide any information reasonably requested by Voyager to enable Voyager to comply with any applicable reporting requirements under the In-License Agreements. Provided that Voyager timely notifies Neurocrine of such reporting requirement, Neurocrine shall ensure that all applicable and necessary information is received by Voyager from Neurocrine, whether generated by Neurocrine, any of its Affiliates or any Sublicensee, sufficiently in advance (no fewer than [\*\*] in advance) of the date(s) on which such information is due to the relevant Inbound Licensor under an In-License Agreement to avoid a breach of such In-License Agreement. All payments owed by Voyager under the In-License Agreements, including license fees, royalties and milestones, shall be allocated between the Parties as set forth in Section 5.2.4 and such payment shall be remitted to the applicable Inbound Licensor by Voyager. Notwithstanding anything to the contrary in this Agreement, unless otherwise agreed by the applicable counterparty, the provisions regarding currency conversion, international payments and late payments, and other relevant definitions and provisions, of the relevant In-License Agreements shall apply to calculate the payments due under the relevant In-License Agreements (but not the payments due under this Agreement).

## 8.7 <u>Accounting; Audit</u>.

- 8.7.1 Each Party (the "<u>Payor</u>") agrees to keep, and to require its Affiliates and Sublicensees to keep, full, clear and accurate records for a minimum period of [\*\*] after the relevant payment is owed pursuant to this Agreement, setting forth as applicable the sales and other disposition of Collaboration Products sold or otherwise disposed of, the Development and Commercialization activities with respect to Collaboration Products, and the Development Costs incurred therewith, in sufficient detail to enable royalties and compensation payable to, or the Development Costs payable by, the other Party (the "<u>Payee</u>") hereunder to be determined.
- 8.7.2 Neurocrine agrees, upon not less than [\*\*] prior written notice, to permit, and to require its Affiliates to permit, such books and records relating to such Collaboration Products to be examined by an independent accounting firm selected by Voyager and reasonably acceptable to Neurocrine for the purpose of verifying reports provided (or required to be provided) by Neurocrine under this Article 8 or under the Co-Co Agreements. Voyager agrees, upon not less than [\*\*] prior written notice, to permit, and to require its Affiliates to permit, such books and records relating to Development Costs and other costs under the Co-Co Agreements to be examined by an independent accounting firm selected by Voyager and reasonably acceptable to Neurocrine for the purpose of verifying reports provided (or required to be provided) by Voyager under Section 2.2.2 or under the Co-Co Agreements. Any such audit shall not be performed more frequently than [\*\*] period, shall not audit any previously audited records, and shall be conducted under appropriate confidentiality provisions, for the sole purpose of verifying the accuracy and completeness of all financial, accounting and numerical information and calculations provided under this Agreement or under the Co-Co Agreements. The independent accounting firm shall only share the results of the audit, not the underlying records, with the auditing party.
- 8.7.3 Any audit conducted by Voyager is to be made at the expense of Voyager, except if the results of the audit reveal an underpayment of royalties, milestones or other payments to Voyager under this Agreement or under the Co-Co Agreements of [\*\*] percent ([\*\*]%) or more in the audited period, in which case (a) Neurocrine shall promptly remit to Voyager the amount of

such underpayment and (b) the reasonable fees and expenses for such audit shall be paid by Neurocrine. Any audit conducted by Neurocrine is to be made at the expense of Neurocrine, except if the results of the audit reveal an overpayment of Development Costs or other payments to Voyager under this Agreement or under the Co-Co Agreements of [\*\*] percent ([\*\*]%) or more in the audited period, in which case (x) Voyager shall promptly remit to Neurocrine the amount of such overpayment and (y) the reasonable fees and expenses for such audit shall be paid by Voyager. For clarity, any audit that reveals an underpayment or overpayment, as the case may be, of less than [\*\*] percent ([\*\*]%) in the audited period, shall be made at the expense of the Party conducting the audit.

- 8.8 <u>Currency Conversion</u>. When calculating Net Sales, the amount of such sales or costs in foreign currencies shall be converted into Dollars using the standard methodologies employed by Neurocrine generally for consolidation purposes. Neurocrine shall provide reasonable documentation of the calculation and reconciliation of the conversion figures on a Collaboration Product-by-Collaboration Product and country-by-country basis as part of its report of Net Sales for the period covered under the report.
- 8.9 <u>Books and Records</u>. Any books and records to be maintained under this Agreement by a Party or its Affiliates or Sublicensees shall be maintained in accordance with Accounting Standards.
- 8.10 <u>Methods of Payments</u>. All payments due from one Party to the other Party under this Agreement shall be paid in Dollars by wire transfer to a bank in the United States designated in writing by the Payee.

#### 8.11 Taxes.

- 8.11.1 Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the activities of the Parties under this Agreement.
- 8.11.2 In the event that Neurocrine is required to withhold any tax to be paid to, or held for the benefit of, the tax or revenue authorities in any country in the Territory regarding any payment to Voyager, such amount shall be deducted from the payment to be made by Neurocrine; provided that Neurocrine shall take reasonable and lawful actions to avoid and minimize such withholding and promptly notify Voyager so that Voyager may take lawful actions to avoid and minimize such withholding. Neurocrine shall promptly furnish Voyager with copies of any tax certificate or other documentation evidencing such withholding, as necessary, to enable Voyager to support a claim, if permissible, for income tax credit in respect of any amount so withheld. Each Party shall cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty in effect from time to time. The Parties shall use commercially reasonable efforts to reduce or eliminate such withholding, including providing any reasonable documentation to reduce or eliminate such withholding.
- 8.11.3 If a withholding or deduction obligation arises as a result of any action by Neurocrine (including any assignment, sublicense, change of place of incorporation, or failure to comply with applicable Laws or filing or record retention requirements) (a "Withholding Tax

<u>Action</u>"), then the sum payable by Neurocrine (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that Voyager receives a sum equal to the sum which it would have received had no such Withholding Tax Action occurred.

8.12 <u>Late Payments</u>. Any undisputed amount owed by Neurocrine to Voyager under this Agreement that is not paid on or before the date such payment is due shall bear simple interest at a rate per annum equal to the lesser of (a) the greater of (i) the prime or equivalent rate per annum quoted by *The Wall Street Journal* on the first Business Day after such payment is due, plus [\*\*], or (ii) [\*\*] percent ([\*\*]%) per month, or (b) the highest rate permitted by applicable Law, calculated on the number of days such payments are paid after such payments are due.

# ARTICLE 9 EXCLUSIVITY

#### 9.1 <u>Exclusivity</u>.

#### 9.1.1 <u>Voyager</u>.

- (a) During the Term of this Agreement, neither Voyager nor any of its Affiliates shall, except as otherwise permitted in this Article 9, either alone or with or for any Third Party, Develop, Manufacture or Commercialize any Competitive Product or grant any Affiliate or Third Party a license or sublicense to enable any Third Party to do so.
- (b) Notwithstanding the foregoing, (i) Voyager shall have no restriction under this Section 9.1.1 with respect to the Development, Manufacture or Commercialization of Gene Therapy Products directed to any Target that was the subject of a Terminated Program and is not the subject of any other Program, provided, however, that, Voyager may not utilize any Neurocrine IP or Confidential Information of Neurocrine in such Development, Manufacture or Commercialization, and (ii) nothing in this Section 9.1.1 shall preclude Voyager from complying with its obligations to grant rights to Genzyme under and in accordance with the Genzyme Agreement (as such agreement exists as of the Effective Date) if Genzyme exercises the option granted to it thereunder.

#### 9.1.2 Neurocrine.

- (a) During the Term of this Agreement, neither Neurocrine nor any of its Affiliates shall, except as otherwise permitted in this Article 9, either alone or with or for any Third Party, Develop, Manufacture or Commercialize any Competitive Product or grant any Affiliate or Third Party a license or sublicense to do so.
- (b) Notwithstanding the foregoing, Neurocrine shall have no restriction under this Section 9.1.2 with respect to the Development, Manufacture or Commercialization of Gene Therapy Products directed to any Target that was the subject of a Terminated Program and is not the subject of any other Program; provided, however, that Neurocrine may not utilize any Voyager IP or Confidential Information of Voyager in such Development, Manufacture or Commercialization.

9.2 <u>Exception for Basic Research.</u> Notwithstanding Section 9.1, Neurocrine and Voyager shall be free during the Term, either alone or with or for an Affiliate or a Third Party, to conduct basic scientific, non-clinical and pre-clinical Development with respect to the biological mechanism of action, pharmacology, structure-activity relationship (SAR) or the like for any Gene Therapy Product; provided, however, that neither Party shall conduct any basic scientific, non-clinical and pre-clinical Development with respect to a Collaboration Product, other than under a Development Plan, Neurocrine Plan or Co-Co Agreement, without the prior written approval of the Joint R&D Working Group, and the conduct of such non-clinical and pre-clinical Development shall be subject to the supervision and oversight of the Joint R&D Working Group.

### 9.3 Acquisitions.

- 9.3.1 If, during the term of the exclusivity covenant in Section 9.1, a Party or any of its Affiliates (such Party, the "Acquisition Party.") acquires or is acquired by a Third Party (an "Acquired Affiliate") (whether such acquisition occurs by way of a purchase of assets, merger, consolidation, change of control or otherwise) that is, at the time of such acquisition, engaging in any activities that would violate Section 9.1.1 or 9.1.2, as applicable, if conducted by such Acquisition Party (such activities, an "Acquired Competing Program" and any product Developed, Commercialized or otherwise Exploited thereunder, an "Acquired Competing Product"), then the Acquisition Party or its Acquired Affiliate shall, no later than [\*\*] following the date of consummation of the relevant acquisition, notify the other Party in writing that the Acquisition Party or such Acquired Affiliate shall:
- (a) divest, whether by license or otherwise, its interest in the Acquired Competing Program to a Third Party, to the extent necessary to be in compliance with Section 9.1, with no rights in such Acquired Competing Program retained by the Acquisition Party or any of its Affiliates; or
- (b) terminate Research, Development, Manufacture and Commercialization under the Acquired Competing Program, to the extent necessary to be in compliance with Section 9.1.
- 9.3.2 If the Acquisition Party or its Acquired Affiliate notifies the other Party in writing that it intends to divest such Acquired Competing Program or terminate Development, Manufacture and Commercialization under the Acquired Competing Program as provided in Section 9.3.1(a) or 9.3.1(b), then the Acquisition Party or Acquired Affiliate, as applicable, shall effect the consummation of such divestiture within [\*\*] or effect such termination within [\*\*] after the consummation of the relevant acquisition, subject to compliance with applicable Law, and shall confirm to the other Party in writing when such divestiture or termination has been completed. The Acquisition Party shall keep the other Party reasonably informed of its and its Affiliates' efforts and progress in effecting such divestiture or termination until it is completed. Until such divestiture or termination occurs, the Acquisition Party shall keep its and its Affiliates' activities with respect to such Acquired Competing Program separate from their activities under this Agreement or any Co-Co Agreement.

9.3.3 Subject to the Acquisition Party's compliance with this Section 9.3, the activities of such Acquisition Party or its Acquired Affiliate with respect to any Competing Acquirer Program shall not be a breach of this Agreement.

#### ARTICLE 10 INTELLECTUAL PROPERTY RIGHTS

## 10.1 Ownership of Inventions; Disclosure.

- 10.1.1 Ownership. Subject to Section 10.1.2, (a) title to all Inventions made solely by employees or agents of Voyager in the course of activities conducted pursuant to this Agreement shall be owned by Voyager; (b) title to all Inventions made solely by employees or agents of Neurocrine in the course of activities conducted pursuant to this Agreement shall be owned by Neurocrine; and (c) title to all Inventions made jointly by employees or agents of Neurocrine and employees or agents of Voyager in the course of activities conducted pursuant to this Agreement (each, a "Joint Invention") shall be owned jointly by Neurocrine and Voyager. For purposes of determining ownership hereunder, inventorship of Inventions made pursuant to this Agreement shall be determined in accordance with the patent laws of the United States. Except as expressly provided in this Agreement, each Party may (subject to the licenses and exclusivity provisions of this Agreement) practice the Joint IP, but neither Party may grant licenses or otherwise encumber its ownership interest in any Joint IP without the prior written consent of the other Party.
- 10.1.2 Exceptions. Notwithstanding Section 10.1.1 and anything to the contrary set forth in this Agreement, Voyager shall exclusively own all Vectorization IP made in the course of the Collaboration, regardless of which Party or its employees or agents conceived or reduced to practice such Invention or whether such Invention was jointly developed by the Parties. Neurocrine, on behalf of itself and its Affiliates, hereby assigns, and to the extent such present assignment is not possible, agrees to assign, to Voyager all of Neurocrine's right, title and interest in and to such Vectorization IP, and all intellectual property rights therein, and, thereafter, such Vectorization IP and any intellectual property rights therein shall not be considered Neurocrine IP or Joint IP, but shall be considered Voyager IP, to the extent applicable.

#### 10.1.3 Disclosure of Inventions.

- (a) During the Term, the Parties shall promptly disclose to each other any Inventions relating to any Collaboration Candidate, Development Candidate or Collaboration Product.
- (b) During the Term, Neurocrine shall promptly disclose to Voyager any Vectorization Know-How made solely by Neurocrine or jointly by the Parties.
- 10.1.4 <u>Background IP</u>. Each Party shall retain ownership of intellectual property rights, including Patent Rights and Know-How, existing as of the Effective Date, and nothing in this Agreement shall assign any ownership to the other Party with respect to such intellectual property rights.

#### 10.2 Patent Prosecution and Maintenance.

#### 10.2.1 Voyager Licensed Platform Patent Rights.

- (a) Subject to the terms of any applicable In-License Agreement and Co-Co Agreement:
- (i) Subject to the remainder of this Section 10.2.1(a), Voyager shall have the sole right, at its sole cost and cost and expense, for Prosecuting and Maintaining the Vectorization Patent Rights and for conducting and defending any Defense Proceeding relating thereto.
- (ii) Subject to Section 10.2.2, Voyager shall have the first right, at its sole cost and expense, for Prosecuting and Maintaining the Voyager Licensed Platform Patent Rights and for conducting and defending any opposition, reexamination request, nullity action, interference, or other post-grant proceeding involving an attack upon the validity, title or enforceability thereof relating thereto, and for initiating any interference, including in each case any appeals therefrom (each, a "Defense Proceeding") (except that in connection with any actions subject to Section 10.3, the Party with responsibility for such action pursuant to Section 10.3 shall have responsibility for any related Defense Proceedings). Upon request by Neurocrine, the Parties shall coordinate and use reasonable efforts, in connection with Voyager's Prosecution and Maintenance of the Voyager Licensed Platform Patent Rights, to enable Neurocrine to file patent applications, including divisionals, continuations or other patent applications for Voyager Target-Specific Patent Rights.
- (iii) Voyager shall keep Neurocrine fully informed with respect to (A) the issuance of a Voyager Licensed Platform Patent Right being Prosecuted and Maintained by Voyager pursuant to this Section 10.2.1(a), and (B) the abandonment of any Voyager Licensed Platform Patent Right.
- (iv) Without limiting the foregoing, Voyager shall (A) provide Neurocrine with copies of the text of the applications for any Voyager Licensed Platform Patent Right as soon as practicable but at least [\*\*] before filing, except for urgent filings, in which case Voyager shall provide copies as soon as practicable before, simultaneously with or immediately after filing; (B) provide Neurocrine with a copy of each submission made to and material or substantive document received from a patent authority, court or other tribunal regarding any Voyager Licensed Platform Patent Right reasonably promptly after making such filing or receiving such document, including a copy of each application as filed together with notice of its filing date and application number; (C) keep Neurocrine advised of the status of all substantive communications, actual and prospective filings or submissions regarding any Voyager Licensed Platform Patent Right, and give Neurocrine copies of any such communications, filings and submissions proposed to be sent to any patent authority or judicial body; and (D) consider in good faith and reasonably incorporate Neurocrine's comments on such communications, filings and submissions for any Voyager Licensed Platform Patent Right (including particular countries in which Neurocrine desires Voyager to file a particular Voyager Licensed Platform Patent Right, provided, however, that Neurocrine shall reimburse Voyager for all expenses incurred in Prosecuting and Maintaining Patent Rights in countries requested by Neurocrine in which a

company similarly situated to Voyager may not file patent applications in accordance with commercially reasonable business practices), unless incorporating such comments would reasonably be expected to have a material adverse effect on the scope of any Voyager Licensed Platform Patent Right that covers products being developed or commercialized by Voyager that are not Collaboration Products. Neurocrine's rights pursuant to this Section 10.2.1(a)(iv) shall terminate with respect to Voyager Licensed Platform Patent Rights that are relevant to one Program only at such time as such Program is terminated pursuant to the terms of this Agreement.

(b) Voyager shall notify Neurocrine as to any decision to abandon, to cease Prosecution and Maintenance of, or not to continue to pay the expenses of Prosecution and Maintenance of, any Voyager Licensed Platform Patent Right in any country in which it was filed. Voyager will provide such notices at least [\*\*] prior to any filing or payment due date, or any other due date that requires action, in connection with such Voyager Licensed Platform Patent Right. Thereafter, Neurocrine may, upon written notice to Voyager, in Voyager's name and at Neurocrine's sole cost and expense, control the Prosecution and Maintenance of such Voyager Licensed Platform Patent Right, and Neurocrine shall keep Voyager informed of the status of such Voyager Licensed Platform Patent Right in accordance with Sections 10.2.1(a)(iii) and (iv), *mutatis mutandis*.

# 10.2.2 Voyager Target-Specific Patent Rights.

- (a) Subject to the terms of any applicable In-License Agreement and Co-Co Agreement:
- Prosecuting and Maintaining the Voyager Target-Specific Patent Rights and for conducting any Defense Proceeding relating thereto (except that in connection with any counterclaims brought in actions subject to Section 10.3, the Party with responsibility for such action pursuant to Section 10.3 shall have responsibility for such Defense Proceedings); provided, however, that with regard to patent applications within Voyager Target-Specific Patent Rights that were filed prior to the Effective Date and patent applications claiming priority thereto, Voyager shall continue to Prosecute and Maintain, at Neurocrine's expense, such patent applications until [\*\*], or earlier as the Parties agree in writing; and provided further that the provisions of Section 10.2.1(a)(iv) shall apply to Voyager's Prosecution and Maintenance of such patent applications within the Voyager Target-Specific Rights.
- (ii) Neurocrine shall keep Voyager fully informed with respect to (A) the issuance of a Voyager Target-Specific Patent Right being Prosecuted and Maintained by Neurocrine pursuant to this Section 10.2.2(a), and (B) the abandonment of any Voyager Target-Specific Patent Right Prosecuted and Maintained by Neurocrine pursuant to this Section 10.2.2(a); provided, however, that if Voyager continues to Prosecute and Maintain Voyager Target-Specific Patent Rights pursuant to Section 10.2.2(a)(i), Voyager shall not be permitted to abandon such Patent Rights without Neurocrine's written consent.
- (iii) Without limiting the foregoing, Neurocrine shall (A) provide Voyager with copies of the text of the applications for any Voyager Target-Specific Patent Right it Prosecutes or Maintains as soon as practicable but at least [\*\*] before filing, except for urgent

filings, in which case Neurocrine shall provide copies as soon as practicable before, simultaneously with or immediately after filing; (B) provide Voyager with a copy of each submission made to and material or substantive document received from a patent authority, court or other tribunal regarding any Voyager Target-Specific Patent Right reasonably promptly after making such filing or receiving such document, including a copy of each application as filed together with notice of its filing date and application number; (C) keep Voyager advised of the status of all substantive communications, actual and prospective filings or submissions regarding any Voyager Target-Specific Patent Right, and give Voyager copies of any such communications, filings and submissions proposed to be sent to any patent authority or judicial body; and (D) consider in good faith Voyager's comments on such communications, filings and submissions for any such Voyager Target-Specific Patent Right and shall reasonably incorporate such comments unless their incorporation would reasonably be expected to have a material adverse effect on the scope of any Voyager Target-Specific Patent Right.

- (b) Neurocrine shall notify Voyager as to any decision to abandon, to cease Prosecution and Maintenance of, or not to continue to pay the expenses of Prosecution and Maintenance of, any Voyager Target-Specific Patent Right in any country in which it was filed. Neurocrine will provide such notices at least [\*\*] prior to any filing or payment due date, or any other due date that requires action, in connection with such Voyager Target-Specific Patent Right. Thereafter, Voyager may, upon written notice to Neurocrine, in Voyager's name and at Voyager's sole cost and expense, control the Prosecution and Maintenance of such Voyager Target-Specific Patent Right, and Neurocrine will have the rights thereto as set forth in Sections 10.2.1(a)(i) and (ii) with respect to such Voyager Target-Specific Patent Right.
- 10.2.3 <u>Neurocrine Patent Rights</u>. Neurocrine shall be responsible, at its sole cost and expense, and shall have the exclusive right, but not the obligation, for Prosecuting and Maintaining the Neurocrine Patent Rights and for conducting Defense Proceedings relating thereto.

# 10.2.4 Joint Patent Rights.

- (a) Subject to the terms of any applicable Co-Co Agreement:
- (i) Subject to Section 10.2.4(b), Neurocrine shall have the first right, at its sole cost and expense, for Prosecuting and Maintaining in both Parties' names the Joint Patent Rights specifically excluding any Vectorization Patent Rights Covering Vectorization Know-How that was jointly developed by the Parties and assigned to Voyager pursuant to Section 10.1.2). Voyager shall execute any powers of attorney necessary for Neurocrine's counsel to conduct such activities.
- (ii) Neurocrine shall keep Voyager fully informed with respect to (A) the issuance of any Joint Patent Right being Prosecuted and Maintained by Neurocrine pursuant to this Section 10.2.4(a), and (B) the abandonment of any Joint Patent Right being Prosecuted and Maintained by Neurocrine pursuant to this Section 10.2.4(a).
- (iii) Without limiting the foregoing, Neurocrine shall (A) provide Voyager with copies of the text of the applications for any such Joint Patent Right as soon as

practicable but at least [\*\*] before filing, except for urgent filings, in which case Neurocrine shall provide copies as soon as practicable before, simultaneously with or immediately after filing; (B) provide Voyager with a copy of each submission made to and material or substantive document received from a patent authority, court or other tribunal regarding any such Joint Patent Right reasonably promptly after making such filing or receiving such material document, including a copy of each application as filed together with notice of its filing date and application number; (C) keep Voyager advised of the status of all substantive communications, actual and prospective filings or submissions regarding any such Joint Patent Right, and shall give Voyager copies of any such communications, filings and submissions proposed to be sent to any patent authority or judicial body; and (D) consider in good faith Voyager's comments on such communications, filings and submissions for any such Joint Patent Right.

- (b) Neurocrine shall notify Voyager as to any decision to abandon, to cease Prosecution and Maintenance of, or not to continue to pay the expenses of Prosecution and Maintenance of, any such Joint Patent Right in any country in which it was filed. Neurocrine shall provide such notices at least [\*\*] prior to any filing or payment due date, or any other due date that requires action, in connection with such Joint Patent Right. Thereafter, Voyager may, upon written notice to Neurocrine, in both Parties' names and at Voyager's sole cost and expense, control the Prosecution and Maintenance of such Joint Patent Right, and Voyager shall keep Neurocrine reasonably informed of the status of such Joint Patent Right in accordance with Sections 10.2.4(a)(ii) and (iii), *mutatis mutandis*.
- 10.2.5 The Parties shall undertake reasonable efforts and cooperate to ensure to the fullest extent practicable and not prejudicial that Joint Patent Rights are Prosecuted and Maintained in a manner that separates the claims pertaining to one Program and the Collaboration Products arising therefrom, on the one hand, from other Programs and the Collaboration Products arising therefrom, on the other hand, into distinct patent applications and ultimately separate issued patents.
- 10.2.6 <u>Cooperation</u>. Each Party shall reasonably cooperate with and assist the other Party in connection with the activities of such Party under Section 10.2 upon the reasonable request of the other Party, including by making scientists and scientific records reasonably available and the execution of all such documents and instruments and the performance of such acts as may be reasonably necessary in order to permit the other Party to continue any Prosecution or Maintenance of the applicable Patent Rights.
- 10.2.7 <u>Patent Term Extension</u>. Notwithstanding anything to the contrary in Section 10.2.1, 10.2.2 or 10.2.4, the JSC shall discuss all decisions regarding patent term extensions in the Territory, including in the United States with respect to extensions pursuant to 35 U.S.C. § 156 *et. seq.* and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable, for Voyager Licensed Patent Rights and the Joint Patent Rights, in each case including whether or not to so apply and which Party shall so apply; provided that Neurocrine shall have the right to make all decisions with respect to any such extension of a Voyager Patent Right or Joint Patent Right Covering any Collaboration Product; provided that Neurocrine shall not have the right to extent any Voyager Licensed Platform Patent Right that Voyager intends to extend with respect to a different product for which there is no other Patent

Right reasonably available to extend. Each Party shall provide prompt and reasonable assistance, as requested by the other Party, including by taking such action as is required under any applicable Law to obtain such extension or supplementary protection certificate.

- 10.3 <u>Enforcement and Defense</u>. Subject to the terms of any applicable In-License Agreement and any applicable Co-Co Agreement:
- 10.3.1 <u>Notice</u>. Each Party shall promptly notify the other of any knowledge it acquires of any (a) actual or potential infringement by a Third Party of any Voyager Patent Right, Neurocrine Patent Right or Joint Patent Right that is or would be competitive with a Collaboration Product or (b) submission to a Party or a Regulatory Authority of an application for a product (including an application under Section 351(k) of the PHSA) that references a Product ("Competitive Infringement").

#### 10.3.2 Actions.

- (a) If any Neurocrine Patent Right is infringed by a Third Party in any country in the Territory, then Neurocrine shall have the sole right, but not the obligation, to institute and control any action or proceeding with respect to such infringement of such Patent Right, by counsel of its own choice.
- (b) If any Vectorization Patent Right that is not a Voyager Patent Right is infringed by a Third Party in any country in the Territory, then Voyager shall have the sole right, but not the obligation, to institute and control any action or proceeding with respect to such infringement of such Patent Right, by counsel of its own choice. If, in any such proceeding brought by Voyager, Neurocrine is required to join for standing purposes or in order for Voyager to commence or continue such proceeding, then Neurocrine shall join such proceeding, at Voyager's expense, and shall be represented in such proceeding by counsel of Voyager's choice at Voyager's expense, unless Neurocrine elects to be represented by counsel of its own chose at Neurocrine's expense.
- (c) Voyager shall have the primary right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to Competitive Infringement of any Voyager Licensed Platform Patent Right, by counsel of its own choice, provided that Voyager shall not unreasonably refuse to accept input from Neurocrine with respect to such proceeding. If in any such proceeding brought by Voyager, Neurocrine is required to join for standing purposes or in order for Voyager to commence or continue any such proceeding, then Neurocrine shall join such proceeding, at Voyager's expense, and shall be represented in such proceeding by counsel of Neurocrine's choice at Neurocrine's expense. If Voyager does not bring an infringement action pursuant to this Section 10.3.2(c) within [\*\*] after receipt of notice of the existence of an infringement (or in cases where there is a relevant statutory period during which an infringement action must be commenced or in which any material rights may be lost that would expire prior to the expiration of such [\*\*] period and of which Neurocrine has notified Voyager promptly after it becomes aware, [\*\*] prior to the expiration of such relevant statutory period), Voyager and Neurocrine shall meet and discuss Voyager's reasons for not initiating a lawsuit or otherwise making or prosecuting a claim. If following such discussions Neurocrine desires to initiate a lawsuit or otherwise make or prosecute a claim with respect to the Competitive

Infringement and so notifies Voyager in writing, then upon receiving Voyager's prior written consent, which consent shall not be unreasonably withheld, Neurocrine may institute, prosecute, and control such action; provided that, if, under the terms of an applicable In-License Agreement, Voyager has an applicable enforcement right that it cannot delegate to Neurocrine then, at Neurocrine's request and expense, Voyager shall exercise such rights in such infringement action as directed by Neurocrine. If in any such proceeding Voyager is required to join for standing purposes or in order for Neurocrine (or an Inbound Licensor) to commence or continue any such proceeding, then Voyager shall join such proceeding, at Neurocrine's expense, and shall be represented in such proceeding by counsel of Voyager's choice at Voyager's expense.

Neurocrine shall have the primary right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to Competitive Infringement of any Voyager Target-Specific Patent Right or Joint Patent Right, by counsel of its own choice, provided that Neurocrine shall not unreasonably refuse to accept input from Voyager with respect to such proceeding. If in any such proceeding brought by Neurocrine, Voyager is required to join for standing purposes or in order for Neurocrine to commence or continue any such proceeding, then Voyager shall join such proceeding, at Neurocrine's expense, and shall be represented in such proceeding by counsel of Voyager's choice at Voyager's expense. The exercise by Neurocrine of the right to bring an infringement action shall be subject to and consistent with the terms of all applicable In-License Agreements; provided that, if, under the terms of an applicable In-License Agreement, Voyager has an applicable enforcement right that it cannot delegate to Neurocrine then, at Neurocrine's request and expense, Voyager shall exercise such rights in such infringement action as directed by Neurocrine. If Neurocrine does not bring an infringement action pursuant to this Section 10.3.2(d) within [\*\*] after receipt of notice of the existence of an infringement (or in cases where there is a relevant statutory period during which an infringement action must be commenced or in which any material rights may be lost that would expire prior to the expiration of such [\*\*] period and of which Voyager has notified Neurocrine promptly after it becomes aware, [\*\*] prior to the expiration of such relevant statutory period), Voyager and Neurocrine shall meet and discuss Neurocrine's reasons for not initiating a lawsuit or otherwise making or prosecuting a claim. If following such discussions Voyager desires to initiate a lawsuit or otherwise make or prosecute a claim with respect to the Competitive Infringement and so notifies Neurocrine in writing, then upon receiving Neurocrine's prior written consent, which consent shall not be unreasonably withheld, Voyager may institute, prosecute, and control such action. If in any such proceeding Neurocrine is required to join for standing purposes or in order for Voyager (or an Inbound Licensor) to commence or continue any such proceeding, then Neurocrine shall join such proceeding, at Voyager's expense, and shall be represented in such proceeding by counsel of Neurocrine's choice at Neurocrine's expense. The Party initiating the suit shall have the sole and exclusive right to elect counsel for any suit initiated by it pursuant to Section 10.3.2(a), (c) or (d); provided that, with respect to a Voyager Target-Specific Patent Right or Joint Patent Right, such counsel is reasonably acceptable to the other Party.

(e) Each Party agrees to cooperate fully in any action under this Section 10.3.2 that is controlled by the other Party, including executing legal papers and cooperating in the prosecution as may be reasonably requested by the controlling Party, all at the controlling Party's expense.

- Unless otherwise agreed by the Parties in writing, and subject to the terms of the Co-(f) Co Agreements, the amount of any recovery from a proceeding brought under this Section 10.3.2 shall first be applied to the Out-of-Pocket Cost of such action incurred by the Party prosecuting the applicable action, and any remaining recovery amount shall be applied to the Out-of-Pocket Cost of such action incurred by the other Party (if any), and then, of the remaining amount, (i) any recovery for a proceeding brought by Neurocrine with respect to a Voyager Target-Specific Patent Right, Voyager Licensed Platform Patent Right or Joint Patent Right or a proceeding brought by Voyager with respect to a Voyager Licensed Platform Patent Right shall be retained by Neurocrine, but shall be deemed Net Sales of the applicable Collaboration Product in the applicable country and subject to royalty payments under Section 8.3 or, with respect to Co-Co Products, shared between the Parties at the Co-Co Rate, (ii) any recovery for a proceeding brought by Voyager with respect to a Voyager Target-Specific Patent Right shall be allocated [\*\*] percent ([\*\*]%) to Voyager and [\*\*] percent ([\*\*]%) to Neurocrine and (iii) any recovery for a proceeding brought with respect to a Neurocrine Patent Right shall be retained by Neurocrine. If, in connection with a proceeding brought under this Section 10.3.2 with respect to a Voyager Target-Specific Patent Right, an Inbound Licensor is entitled to a portion of any recovery that is greater than the portion of the recovery payable, after costs, to Voyager, the Parties will meet and agree in good faith on an alternative sharing of such recovery to that set forth in the immediately preceding sentence that takes into account the amounts payable to the applicable Inbound Licensor and results in an equitable allocation of the remaining amounts to Neurocrine and Voyager after payment of such amounts to the applicable Inbound Licensor.
- 10.3.3 <u>Defense</u>. With respect to any defense or declaratory judgment actions relating to, or other attack upon, validity or enforceability of a Voyager Patent Right, Neurocrine Patent Right or Joint Patent Right that is not a Defense Proceeding, the Party with responsibility for the Prosecution and Maintenance of such Patent Right shall have the first right, but not the obligation, to assume the defense thereof at its sole cost and expense, except that if such action is in connection with a Competitive Infringement, Section 10.3.2 will apply to such action (as if it were enforcement against a Competitive Infringement).

## 10.4 <u>Infringement Claimed by Third Parties</u>.

- 10.4.1 If a Third Party commences, or threatens to commence, any proceeding against a Party alleging infringement of such Third Party's intellectual property by the Exploitation by a Party, its Affiliates, subcontractors or Sublicensees of any Collaboration Candidate or any Collaboration Product, the Party against whom such proceeding is threatened or commenced shall give prompt notice to the other Party.
- 10.4.2 Unless the Party against whom such proceeding is filed seeks indemnification for a claim covered pursuant to Article 13, such Party shall, as between the Parties, have the sole right to control the defense and settlement of any such proceeding under Section 10.4.1 at its own cost.
- 10.5 <u>Marking</u>. Neurocrine and its Affiliates and Sublicensees shall mark each Collaboration Product in such a manner to conform with the patent laws and practice of any country in which such Collaboration Product is Manufactured or sold or to which such

Collaboration Product is shipped to ensure maximum enforceability of Patent Rights in such country.

10.6 <u>Trademarks</u>. Except for Collaboration Products arising from the AADC Program if Voyager exercises its Co-Co Option for such Program, Neurocrine shall have the right to brand Collaboration Products in the Territory using Neurocrine-related trademarks and any other trademarks and trade names it determines appropriate, which may vary by country or within a country ("Neurocrine Product Marks"). Neurocrine shall own all rights in the Neurocrine Product Marks and, as between the Parties, shall have the sole right to register, maintain, enforce and defend the Neurocrine Product Marks, at its sole expense, provided that Neurocrine will provide Voyager appropriate licenses to the Neurocrine Product Marks under any applicable Co-Co Agreement to undertake activities assigned to Voyager thereunder so requiring such licenses. If Voyager exercises its Co-Co Option for the AADC Program, branding of Co-Co Products arising from the AADC Program shall be governed by the applicable provisions of the applicable Co-Co Agreement and subject to final review and approval of the JSC.

#### ARTICLE 11 CONFIDENTIALITY

- 11.1 <u>Confidentiality; Exceptions</u>. Except to the extent expressly authorized by this Agreement, or as otherwise agreed in writing, the Parties agree that the receiving Party (the "<u>Receiving Party</u>") (a) shall keep confidential and shall not publish or otherwise disclose and (b) shall not use for any purpose other than as provided for in this Agreement (which purpose includes exercising its rights and performing its obligations under this Agreement), in each case (a) and (b) any Know-How or other confidential and proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) that is disclosed to it by the other Party (the "<u>Disclosing Party</u>"), including trade secrets, Know-How, inventions or discoveries, proprietary information, formulae, processes, techniques and information relating to the Disclosing Party's past, present or future marketing, financial, or Exploitation activities of any product or potential product or useful technology of the Disclosing Party or the pricing thereof (collectively, "<u>Confidential Information</u>" of the Disclosing Party), except that "Confidential Information" shall exclude information to the extent that it can be established by the Receiving Party that such information:
- 11.1.1 was in the lawful knowledge and possession of the Receiving Party prior to the time it was first disclosed to the Receiving Party by the Disclosing Party, or was otherwise developed independently by the Receiving Party without reference to any of the Disclosing Party's Confidential Information, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the Receiving Party;
- 11.1.2 was generally available to the public or otherwise part of the public domain at the time of its first disclosure to the Receiving Party by the Disclosing Party;
- 11.1.3 became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party by the Disclosing Party and other than through any act or omission of the Receiving Party in breach of this Agreement or the Existing Confidentiality Agreement; or

11.1.4 was lawfully disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others.

For the avoidance of doubt, any information disclosed by a Party to the other Party prior to the Execution Date pursuant to the Confidential Disclosure Agreement between Voyager and Neurocrine dated August 28, 2018 (as amended from time to time, the "Existing Confidentiality Agreement"), that was considered Confidential Information (as defined in the Existing Confidentiality Agreement) of a Party shall be Confidential Information of such Party hereunder, subject to the provisions of Sections 11.1.1, 11.1.2, 11.1.3 and 11.1.4. Notwithstanding the foregoing, any Inventions within the Vectorization Know-How shall be considered the Confidential Information of Voyager, with Voyager considered the Disclosing Party and Neurocrine considered the Receiving Party, and Neurocrine may not rely on Section 11.1.1 with respect to any such Inventions developed by Neurocrine under this Agreement and assigned to Voyager.

Authorized Disclosure. Except as expressly provided otherwise in this Agreement, a Receiving Party may disclose Confidential Information of the Disclosing Party as follows: (a) to the extent required to those of its employees, agents and representatives who reasonably need to know such Confidential Information in order to advise or assist the Receiving Party in connection with the performance of its obligations or exercise of its rights granted or reserved in this Agreement and under appropriate written (or legal or ethical such as in the case of attorneys) confidentiality and non-use obligations no less protective of the Disclosing Party than those set forth in this Agreement; (b) as required by applicable Law; provided, however, that if a Receiving Party is required by Law to make any such disclosure of a Disclosing Party's Confidential Information it will, except where impracticable, give reasonable advance notice to the Disclosing Party of such disclosure requirement, limit disclosure to only the Confidential Information requested to be disclosed and, if requested by the Disclosing Party, cooperate with the Disclosing Party to secure confidential treatment of such Confidential Information required to be disclosed; (c) in communication with existing or bona fide prospective investors, lenders, professional advisors, acquirers, merger partners, subcontractors, licensees or Inbound Licensors on a need to know basis, in each case under appropriate written (or legal or ethical such as in the case of attorneys) confidentiality and non-use obligations substantially equivalent to those of this Agreement, except that the term of such obligations may be shorter, and with respect to any disclosure to an Inbound Licensor under an Existing In-License Agreement, Neurocrine acknowledges that the relevant Inbound Licensor is obligated to retain any information provided to it in confidence only as required pursuant to the terms of the applicable Existing In-License Agreement; (d) to the extent mutually agreed to in writing by the Parties; (e) to a patent authority in connection with Prosecution and Maintenance, Defense Proceedings and enforcement of Patent Rights in accordance with Article 10; and (f) in the case of Neurocrine as Receiving Party, in Regulatory Filings for Collaboration Products and, in each case under appropriate written confidentiality and non-use obligations substantially equivalent to those of this Agreement, to Third Party contractors in connection with its Development, Manufacture and Commercialization of Collaboration Products. The confidentiality and non-use obligations set forth under this Agreement shall survive the termination or expiration of this Agreement for a period of [\*\*].

11.3 Press Release; Disclosure of Agreement.

11.3.1 On or promptly after the Effective Date, the Parties shall jointly issue a public announcement of the execution of this Agreement. Subject to Sections 11.3.2, 11.3.3 and 11.4, neither Party may issue any subsequent press release or other public disclosure regarding this Agreement or its terms or the Parties' activities hereunder, or any results or data arising hereunder, except (a) with the other Party's prior written consent, (b) for any disclosure that is reasonably necessary to comply with applicable securities exchange listing requirements or other applicable Laws, provided that the Party making such disclosure provides the other Party a copy of the proposed disclosure as soon as reasonably practicable and reasonably considers any comments thereto provided by the other Party within [\*\*] after the receipt of such proposed disclosure or such shorter period required to comply with applicable Laws, (c) in the case of Voyager, to announce the exercise of the Co-Co Option, provided that Voyager first provides Neurocrine a copy of the proposed disclosure and reasonably considers any timely comments thereto provided by Neurocrine, or (d) in the case of Neurocrine, disclosure of any information relating to the Development, Manufacture or Commercialization of any Collaboration Product that does not include Confidential Information of Voyager, provided that Neurocrine first provides Voyager a copy of the proposed disclosure and reasonably considers any timely comments thereto provided by Voyager. Notwithstanding the foregoing, to the extent information regarding this Agreement has already been publicly disclosed, each Party (other than a Party that had caused such information to become publicly disclosed in breach of this Article 11, if applicable) may subsequently disclose the same information to the public without the consent of the other Party, as long as it remains accurate at the time of subsequent disclosure.

11.3.2 Notwithstanding Section 11.3.1, each Party shall be permitted to disclose the existence and terms of this Agreement to the extent required to comply with applicable Laws or legal process, including the rules or regulations of the U.S. Securities and Exchange Commission, or similar agency in any country other than the United States, or of any stock exchange, including Nasdaq. Notwithstanding the foregoing, before disclosing this Agreement or any of the terms hereof, the Parties will coordinate in advance with each other in connection with the redaction of certain provisions of this Agreement with respect to any filings with the U.S. Securities and Exchange Commission or similar agency in any country other than the United States, or of any stock exchange, including Nasdaq, on which securities issued by a Party or a Party's Affiliate are traded (the "Redacted Version"), and each Party will use commercially reasonable efforts to seek confidential treatment for such terms as may be reasonably requested by the other Party; provided that the Parties will use commercially reasonable efforts to file redacted versions with any governing bodies that are consistent with the Redacted Version.

11.3.3 Each Party shall be permitted to disclose the terms of this Agreement, in each case under appropriate confidentiality obligations substantially equivalent to those of this Agreement (except that the term of the obligations may be shorter as consistent with the applicable Party's ordinary business practices with regard to the protection of its confidential information), to any existing or bona fide prospective investors, lenders, professional advisors, acquirers, merger partners, licensees or Inbound Licensors, except that, with respect to any disclosure to an Inbound Licensor under an Existing In-License Agreement, Neurocrine acknowledges that the relevant Inbound Licensor is obligated to retain any information provided to it in confidence only as required pursuant to the terms of the applicable Existing In-License Agreement.

- <u>Publications</u>. The Parties recognize that it may be useful or required to publish or publicly disclose the results of Exploitation activities conducted hereunder, and each Party (and its Affiliates and Sublicensees) shall be free to publish or publicly disclose such results, including on its clinical trials registry or on a governmentsponsored database such as www.clinicaltrials.gov, subject to the prior review by the other Party for patentability and protection of its Confidential Information as described in this Section 11.4; provided that any publication by Voyager of any data or results obtained under activities conducted under the subject matter of this Agreement shall be subject to approval by the JSC. The Party that desires to publish such results shall provide the other Party with a copy of such proposed abstract, manuscript, or presentation no less than [\*\*] in the case of abstracts) prior to its intended submission for publication. The reviewing Party shall respond in writing promptly and in no event later than [\*\*] in the case of abstracts) after receipt of the proposed material, with one or more of the following: (a) comments on the proposed material, which the publishing Party shall consider in good faith, (b) a specific statement of concern, based upon the need to seek patent protection or to block publication if the reviewing Party determines that the proposed disclosure contains or describes intellectual property that should be maintained as a trade secret to protect a Collaboration Product or any Exploitation activities conducted under this Agreement, and/or (c) an identification of the reviewing Party's Confidential Information that is contained in the material reviewed. In the event of concern over patent protection or whether maintaining a trade secret would be a priority, the publishing Party agrees not to submit such publication or to make such presentation that contains such information until the reviewing Party is given a reasonable period of time, and in no event more than [\*\*], unless otherwise agreed by the Parties, to seek patent protection for any material in such publication or presentation which it believes is patentable or to resolve any other issues; provided, however, that the publishing Party shall abandon such proposed publication or presentation if the reviewing Party reasonably determines in good faith that maintaining such information as a trade secret is a commercially reasonable priority. Any Confidential Information of the reviewing Party shall, if requested by the reviewing Party, be removed. Furthermore, with respect to any proposed abstracts, manuscripts or summaries of presentations by Clinical Trial investigators, such materials shall be subject to review under this Section 11.4 to the extent that Neurocrine or Voyager (as the case may be) has the right to do so. Voyager shall not grant any other Third Party any rights to publish results generated under this Agreement without approval by an appropriate Committee.
- 11.5 <u>Remedies</u>. Each Party shall be entitled to seek, in addition to any other right or remedy it may have, at Law or in equity, a temporary injunction, without the posting of any bond or other security, enjoining or restraining the other Party from any violation or threatened violation of this Article 11.
- 11.6 [\*\*] <u>Agreement</u>. Pursuant to Section 14.8 of the [\*\*] Agreement, Neurocrine agrees that it shall not make any form of representation or statement which would constitute an express or implied endorsement by [\*\*] of any Licensed Products (as defined in the [\*\*] Agreement), and that it shall not authorize others to do so, without first having obtained written approval from [\*\*], except as may be required by governmental law, rule or regulation.

#### ARTICLE 12 REPRESENTATIONS AND WARRANTIES

- 12.1 <u>Representations and Warranties of Both Parties</u>. Each Party hereby represents and warrants to the other Party, as of the Execution Date and as of the Effective Date, that:
- 12.1.1 such Party is duly organized, validly existing and in good standing under the Laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;
- 12.1.2 such Party has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;
- 12.1.3 this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof;
- 12.1.4 the execution, delivery and performance of this Agreement by such Party do not conflict with or result in a breach of any agreement or any provision thereof, or any instrument or understanding, oral or written, to which it is a party or by which it is bound, or any provision of the organization documents of such Party, nor violate any Laws of any court, governmental body or administrative or other agency having jurisdiction over such Party; and
- 12.1.5 no government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any applicable Laws currently in effect, is or will be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement and such other agreements, except as may be required to obtain clearance of this Agreement under the HSR Act, to conduct Clinical Trials, to Manufacture Collaboration Products, or to seek or obtain Regulatory Approvals.
- 12.2 <u>Representations, Warranties and Covenants, as applicable, of Voyager</u>. Voyager hereby represents, warrants, and covenants to Neurocrine, as of the Execution Date and, except as set forth below, with respect to each Discovery Program, as of the date the JSC approves the applicable Discovery Target (subject to any disclosures in the Schedule of Exceptions attached hereto as Exhibit C, which disclosures shall be deemed to be exceptions to such representations and warranties) that:
- 12.2.1 Voyager has the right to grant all rights and licenses it purports to grant to Neurocrine under this Agreement;
- 12.2.2 Voyager has not granted, and will not during the Term grant, any right or license to any Third Party that would conflict with the rights or licenses granted to Neurocrine hereunder;
- $12.2.3 \quad \text{Exhibit B sets forth a true and complete list, as of the Execution Date, of all Voyager} \\ \text{Licensed Patent Rights, indicating the assignee(s) of each such Patent Right; and Voyager} \\$

is the sole and exclusive owner of, or otherwise Controls via an exclusive license, the Voyager Licensed Patent Rights, free and clear of any claims, liens, charges or encumbrances other than licenses granted by Voyager that do not conflict with the licenses granted to Neurocrine under this Agreement;

- 12.2.4 The inventions claimed by the Voyager Licensed Patent Rights (a) were not conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof and (b) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(e) and (c) are not otherwise subject to 35 U.S.C. §§ 200-212, as amended, as well as any regulations promulgated thereunder;
- 12.2.5 No claim or litigation has been brought or threatened in writing against Voyager or, to its Knowledge, any Third Party by any Person alleging that the Voyager IP or Vectorization Technology is infringing or, if practiced or commercialized, will infringe the rights of any Third Party, or that the development of the Voyager IP or Vectorization Technology infringed or misappropriated the intellectual property rights of any Third Party, and to Voyager's Knowledge there is no basis for any such claim;
- 12.2.6 To Voyager's Knowledge, the conduct of the Development Plans have not, do not and will not infringe any Patent Rights or misappropriate any materials, Know-How or other intellectual property of any Third Party;
- 12.2.7 There are no judgments, orders, decrees or settlements against or owed by Voyager or any of its Affiliates, and, there is no written claim, written demand, suit, proceeding, arbitration, and to Voyager's Knowledge, other claim, demand, inquiry, investigation or other legal action of any nature, civil, criminal, regulatory or otherwise, pending or, to the Knowledge of Voyager, threatened against Voyager or any of its Affiliates, in each case relating to the Voyager IP, the Programs and Collaboration Products or the transactions contemplated by this Agreement;
- 12.2.8 To Voyager's Knowledge, no Person is infringing or threatening to infringe, or misappropriating or threatening to misappropriate, the Voyager IP, and no Person has challenged or threatened to challenge the inventorship, ownership, Voyager's right to use, scope, validity or enforceability of, or Voyager's or any Inbound Licensor's rights in or to, any Voyager Licensed Patent Rights (including through the institution or threat of institution of interference, derivation, post-grant review, opposition, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous Governmental Authority);
- 12.2.9 To Voyager's Knowledge, the Voyager Licensed Patent Rights are valid and enforceable, or in the case of pending patent applications, will be valid and enforceable upon issuance, the inventorship of each Voyager Patent Right is properly identified on each patent and patent application, and Voyager has complied (and, to its Knowledge, its Inbound Licensors have complied) with, all applicable Laws and duties of candor with respect to the filing, prosecution and maintenance of the Voyager Licensed Patent Rights. Voyager has paid, with respect to all Voyager Licensed Patent Rights to which Voyager has prosecution and maintenance rights, and, to Voyager's Knowledge, its Inbound Licensors have paid all maintenance and annuity fees with respect to the Voyager Licensed Patent Rights due as of the Execution Date;

- 12.2.10 All of its employees, officers, and consultants have executed agreements or have existing obligations under applicable Laws requiring assignment to Voyager of all inventions made during the course of and as the result of their association with Voyager and obligating the individual to maintain as confidential Voyager's Confidential Information as well as confidential information of other Persons (including Neurocrine and its Affiliates) which such individual may receive, in each case to the extent required to support Voyager's obligations under this Agreement;
- 12.2.11 (i) Neither Voyager nor, to Voyager's Knowledge, any Third Party, is in breach of any In-License Agreement in any material respect and, to Voyager's Knowledge, each In-License Voyager Agreement is in full force and effect, and neither Voyager nor any of its Affiliates has received any written notice of breach of any In-License Agreements; (ii) there are no agreements between Voyager (or any of its Affiliates), on the one hand, and a Third Party, on the other hand, pursuant to which Voyager or any of its Affiliates has Control of any Voyager IP as of the Execution Date other than those listed on Schedule 1.37, (iii) none of the Existing In-License Agreements includes any obligations that restrict or conflict with the practice of the licenses granted by Neurocrine hereunder; and (iv) true, correct and complete copies of each Existing In-License Agreement have been provided to Neurocrine.
- 12.2.12 Except for any contract granting only a non-exclusive license to (a) a Third Party to provide services or products to Voyager in a fee-for-service arrangement that does not convey to any Third Party or allow any Third Party to retain any rights in any Voyager Licensed Patent Rights or Voyager Know-How or (b) Inbound Licensors for non-commercial research and educational purposes, there are no agreements pursuant to which Voyager or any of its Affiliates has granted any right or license to practice any Voyager Licensed Patent Rights or Voyager Know-How that would be inconsistent or in conflict with the rights granted pursuant to this Agreement;
- 12.2.13 Voyager has taken reasonable precautions to preserve the confidentiality of the Voyager Know-How, including requiring each Person having access to the Voyager Know-How to be subject to confidentiality, non-use and non-disclosure obligations protecting the Voyager Know-How as the confidential, proprietary materials and information of Voyager;
- 12.2.14 Voyager has made available to Neurocrine (a) all Regulatory Filings relating to Collaboration Candidates, (b) all information in Voyager's or its Affiliates' Control related to the safety or efficacy of any Collaboration Candidate or Collaboration Product and (c) all other information in Voyager's Control requested by Neurocrine.
- 12.2.15 Voyager and its Affiliates have generated, prepared, maintained and retained all Regulatory Filings for Collaboration Candidates and Collaboration Products in accordance with GLP, GCP and all other applicable Laws, and all such information is complete and accurate;
- 12.2.16 Voyager and its Affiliates have conducted, and its and their respective contractors and consultants have conducted, all Development of Collaboration Candidates and Collaboration Products in accordance with GLP, GCP and all other applicable Laws;

- 12.2.17 Neither Voyager nor any of its Affiliates, nor, to Voyager's Knowledge, any of its or their respective officers, employees or agents, has (a) committed an act, (b) made a statement or (c) failed to act or make a statement that, in each case (a), (b) and (c), (A) would be or create an untrue statement of material fact or fraudulent statement to the FDA or any other Governmental Authority with respect to the Exploitation of Collaboration Candidates and Collaboration Products or (B) could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory;
- 12.2.18 Since November 10, 2015, Voyager and its Affiliates have conducted and will conduct their business in compliance with the Foreign Corrupt Practices Act of 1977 and any other applicable anti-corruption Laws. Voyager covenants as follows:
- (a) Voyager and its and its Affiliates' employees and contractors shall not, in connection with the performance of their respective obligations under this Agreement, directly or indirectly through Third Parties, unlawfully pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a Public Official or Entity or other person for the purpose of corruptly obtaining or retaining business for or with, or directing business to, any person, including, without limitation, either Party, and Voyager represents and warrants that as of the Execution Date, Voyager, and to its Knowledge, its and its Affiliates' employees and contractors, have not directly or indirectly promised, offered or provided any unlawful corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a Public Official or Entity or any other person in connection with the performance of Voyager's obligations under this Agreement, and Voyager covenants that it and its Affiliates' employees and contractors shall not, directly or indirectly, engage in any of the foregoing.
- (b) Voyager and its Affiliates, and their respective employees and contractors, in connection with the performance of their respective obligations under this Agreement, shall not cause Neurocrine or its respective Affiliates, employees or agents to be in violation of the FCPA or any other applicable Law.
- (c) Voyager shall without unreasonable delay notify Neurocrine if Voyager has any credible information or reasonable suspicion that there may be a violation of the FCPA or any other applicable Law in connection with the performance of this Agreement or the Development, Manufacture or Commercialization of any Collaboration Candidate or Collaboration Product.
- (d) In connection with the performance of its obligations under this Agreement, Voyager shall comply and shall cause its and its Affiliates' employees and contractors to comply with Voyager's own anti-corruption and anti-bribery policy, a copy of which will be provided to Neurocrine within [\*\*] of the Effective Date.
- (e) Neurocrine will have the right, upon reasonable prior written notice and during Voyager's regular business hours, to engage an independent Third Party to audit

Voyager's books and records in the event that a suspected violation of any of the representations, warranties or covenants in this Section 12.2.18 needs to be investigated.

- (f) In the event that Voyager has violated or been reasonably suspected of violating any of the representations, warranties or covenants in this Section 12.2.18, Voyager will cause its or its Affiliates' personnel or others working under its direction or control to submit to periodic training that Voyager will provide on anti-corruption law compliance.
- (g) Voyager will, at Neurocrine's request, annually certify to Neurocrine in writing Voyager's compliance, in connection with the performance of Voyager's obligations under this Agreement, with the representations, warranties or covenants in this Section 12.2.18.
- (h) Neurocrine shall have the right to suspend or terminate this Agreement in its entirety where there is a credible finding, after a reasonable investigation, that Voyager, in connection with performance of its obligations under this Agreement, has violated the FCPA; and
- 12.2.19 Voyager (a) will promptly notify Neurocrine of any lawsuits, claims, administrative actions, regulatory inquiries or investigations, or other proceedings asserted or commenced against Voyager or its Affiliates or their respective employees or agents involving in any material way the ability of Voyager to deliver the rights, licenses and sublicenses granted herein; and (b) will promptly notify Neurocrine in writing of any facts or circumstances that come to Voyager's attention and that cause, or are reasonably expected to cause, any of the representations and warranties contained in Section 12.1 or 12.2 to be untrue in any material respect at any time during the Term.

# 12.3 <u>Mutual Covenants</u>. Each Party hereby covenants to the other Party that:

- 12.3.1 All individuals who are employees or independent contractors of such Party or any of its Affiliates working under this Agreement are and will be under written obligation to assign or, in the case of independent contractors, assign or exclusively license, all right, title and interest in and to all Inventions and other Know-How, and all intellectual property rights therein, developed under this Agreement to such Party or its Affiliate as the sole owner or exclusive licensee thereof;
- 12.3.2 Such Party will not employ, or use any contractor or consultant that employs or uses, any Person (a) that is debarred by the FDA (or subject to a similar sanction of EMA or any other Governmental Authority) or (b) to such Party's Knowledge, that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMA or any other Governmental Authority), in each of clauses (a) and (b) in the conduct of its activities under this Agreement;
- 12.3.3 In performing its obligations or exercising its rights under this Agreement, such Party, its Affiliates, and, with respect to Neurocrine, its Sublicensees, shall comply with all applicable Law, including all anti-corruption Laws; and

- 12.3.4 Such Party will not grant any license relating to the Voyager IP (if such Party is Voyager) or the Neurocrine IP (if such Party is Neurocrine) that would conflict with the rights or licenses granted or to be granted to the other Party hereunder.
- 12.4 <u>Disclaimer</u>. Except as otherwise expressly set forth in this Agreement, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY THAT ANY PATENTS ARE VALID OR ENFORCEABLE, AND EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.

## ARTICLE 13 INDEMNIFICATION; INSURANCE

- 13.1 <u>Indemnification by Neurocrine</u>. Subject to Section 13.3 and the terms of the Co-Co Agreement, Neurocrine shall indemnify, hold harmless and defend:
- 13.1.1 Voyager and its Affiliates, and its or their respective directors, officers, employees, agents and representatives, from and against any and all liabilities, damages, losses, costs and expenses, including the reasonable fees of attorneys and other professional advisors (collectively, "Losses"), to the extent arising out of or resulting from any Third Party suits, claims, actions, proceedings or demands ("Third Party Claims") to the extent resulting from:
- (a) The gross negligence, recklessness or intentional misconduct of Neurocrine or any of its Affiliates, or its or their respective directors, officers, employees, agents or representatives, in connection with performance by or on behalf of Neurocrine of Neurocrine's obligations or exercise of Neurocrine's rights under this Agreement;
- (b) any breach of this Agreement, including any representation or warranty or covenant, by Neurocrine; or
- the Exploitation of Collaboration Candidates and Collaboration Products conducted by or on behalf of Neurocrine, any of its Affiliates or any Sublicensee hereunder (excluding Development or Manufacturing carried out by Voyager hereunder), including (a) any product liability, personal injury, property damage or other damage, and (b) infringement of any Patent Rights or other intellectual property rights of any Third Party, except to the extent related to any Vectorization Technology licensed to Neurocrine hereunder; <u>provided</u>, <u>however</u>, <u>that</u>, Losses arising from Exploitation of any Collaboration Product under any Co-Co Agreement shall be shared as Development Costs or profit or loss, as applicable, in accordance with the term of such Co-Co Agreement;

except, in each case ((a)-(c)), to the extent arising from the gross negligence, recklessness or intentional misconduct of Voyager or any of its Affiliates or its or their respective directors, officers, employees, agents or representatives or Voyager's breach of this Agreement, including any representation, warranty or covenant.

- 13.1.2 [\*\*], its trustees, officers, agents and employees (the "[\*\*] <u>Indemnitees</u>"), as set forth in Section 9.3 of the [\*\*] Agreement, if the Patent Rights under the [\*\*] Agreement become sublicensed to Neurocrine hereunder.
- 13.2 <u>Indemnification by Voyager</u>. Subject to Section 13.3 and the terms of the Co-Co Agreements, Voyager shall indemnify, hold harmless and defend, Neurocrine and its Affiliates, and its or their respective directors, officers, employees and agents, from and against any and all Losses, to the extent arising out of or resulting from any Third Party Claims to the extent resulting from:
- 13.2.1 the gross negligence, recklessness or intentional misconduct of Voyager or any of its Affiliates or subcontractors, or its or their respective directors, officers, employees, agents or representatives, in connection with performance by or on behalf of Voyager of Voyager's obligations or exercise of Voyager's rights under this Agreement;
- 13.2.2 any breach of this Agreement, including any representation or warranty or covenant, by Voyager;
- 13.2.3 the Exploitation of Collaboration Candidates and Collaboration Products conducted by or on behalf of Voyager or any of its Affiliates, or any of their respective licensees (excluding Development, Manufacturing or Commercialization carried out by Neurocrine hereunder), outside of the Territory or before the Effective Date or after termination of this Agreement, and including (a) any product liability, personal injury, property damage or other damage and (b) infringement of any Patent Rights or other intellectual property rights of any Third Party; provided, however, that, Losses arising from Exploitation of any Collaboration Product under any Co-Co Agreement shall be shared as Development Costs or profit or loss, as applicable, in accordance with the term of such Co-Co Agreement; or
- 13.2.4 the infringement of any Patent Rights or other intellectual property rights of any Third Party by the Exploitation of any Collaboration Product conducted by or on behalf of Neurocrine or its Affiliates or any Sublicensees, to the extent related to any Vectorization Technology licensed to Neurocrine by Voyager hereunder;
- except, in each case (13.2.1 13.2.4), to the extent arising from the gross negligence, recklessness or intentional misconduct of Neurocrine or any of its Affiliates or its or their respective directors, officers, employees, agents or representatives or Neurocrine's breach of this Agreement, including any representation, warranty or covenant.
- 13.3 <u>Procedure</u>. A Person entitled to indemnification under this Article 13 (an "<u>Indemnified Party</u>") shall give prompt written notification to the Person from whom indemnification is sought (the "<u>Indemnifying Party</u>") of the commencement of any Third Party Claim for which indemnification may be sought or, if earlier, upon the assertion of any such Third Party Claim (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Third Party Claim as provided in this Section 13.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice). Within [\*\*] after delivery of such notification, the Indemnifying Party may, upon written notice

thereof to the Indemnified Party, assume control of the defense of such Third Party Claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense and, without limiting the Indemnifying Party's indemnification obligations, the Indemnifying Party shall reimburse the Indemnified Party for all reasonable costs and expenses, including attorney fees, incurred by the Indemnified Party in defending itself within [\*\*] after receipt of any reasonably detailed invoice and supporting documentation therefor from the Indemnified Party. The Party not controlling such defense may participate therein at its own expense; provided that, if the Indemnifying Party assumes control of such defense and the Indemnified Party in good faith concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such Third Party Claim, the Indemnifying Party shall be responsible for the reasonable fees and expenses of counsel to the Indemnified Party in connection therewith. The Party controlling such defense shall keep the other Party advised of the status of such Third Party Claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto. The Indemnified Party shall not agree to any settlement of such Third Party Claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, delayed or conditioned. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, which shall not be unreasonably withheld, delayed or conditioned, agree to any settlement of such Third Party Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto, that imposes any liability or obligation on the Indemnified Party or that acknowledges fault by the Indemnified Party.

## 13.4 <u>Insurance</u>. Subject to the terms of any applicable Co-Co Agreement:

- 13.4.1 <u>Voyager's Insurance Obligations</u>. Voyager shall maintain, at its cost, insurance against liability and other risks associated with its activities and obligations under this Agreement, including its Clinical Trials and its indemnification obligations hereunder, in such amounts, subject to such deductibles and on such terms as are reasonable for a company such as Voyager for the activities to be conducted by it under this Agreement. Voyager shall furnish to Neurocrine evidence of such insurance upon request. If the Patent Rights under the [\*\*] Agreement become sublicensed to Neurocrine hereunder, Neurocrine shall name the [\*\*] Indemnitees as additional insureds, pursuant to Section 13.1 of the [\*\*] Agreement.
- 13.4.2 <u>Neurocrine's Insurance Obligations</u>. Neurocrine shall maintain, at its cost, insurance against liability and other risks associated with its and its Affiliates' and any Sublicensees' activities and obligations under this Agreement, including Clinical Trials, the Exploitation of Collaboration Products and Neurocrine's indemnification obligations hereunder, in such amounts and on such terms as are reasonable and customary for a company such as Neurocrine for the activities to be conducted by it under this Agreement. Neurocrine shall furnish to Voyager evidence of such insurance upon request.
- 13.5 <u>Limitation of Liability</u>. EXCEPT FOR A BREACH OF ARTICLE 9 OR ARTICLE 11 OR FOR CLAIMS OF A THIRD PARTY THAT ARE SUBJECT TO INDEMNIFICATION UNDER THIS ARTICLE 13, NEITHER VOYAGER NOR NEUROCRINE, NOR ANY OF THEIR RESPECTIVE AFFILIATES, LICENSORS, LICENSEES OR SUBLICENSEES, WILL BE LIABLE TO THE OTHER PARTY, ITS

AFFILIATES OR SUBLICENSEES FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES, OR LOST PROFITS, ROYALTIES, DATA OR PROCUREMENT OF SUBSTITUTE GOODS, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY OR CONTRIBUTION, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE.

# ARTICLE 14 TERM AND TERMINATION

- 14.1 <u>Term</u>. This Agreement shall commence as of the Effective Date and, unless terminated earlier, this Agreement shall continue in full force and effect until the later of (a) the expiration of the last to expire Royalty Term with respect to all Collaboration Products in all countries in the Territory or (b) the last expiration or termination of all Co-Co Agreements (the "<u>Term</u>").
- 14.2 <u>Termination by Neurocrine</u>. Neurocrine may terminate this Agreement in its entirety or on a Program-by-Program and/or country-by-country basis by providing written notice of termination to Voyager, which notice specifies the scope of the termination and includes an effective date of termination at least (a) one hundred eighty (180) days after the date of the notice if such notice is provided prior to First Commercial Sale of any Collaboration Product to which the termination applies or (b) one (1) year after the date of the notice is provided after First Commercial Sale of any Collaboration Product to which the termination applies.

#### 14.3 <u>Termination for Breach</u>.

- 14.3.1 This Agreement may be terminated (a) on a Program-by-Program basis, at any time upon written notice by either Party if the other Party is in material breach of this Agreement with respect to such Program or (b) in its entirety, at any time upon written notice by either Party if the other Party is in material breach of this Agreement with respect to all Programs, or if such material breach does not relate specifically to any Program, in either case ((a) or (b)) except if the breaching Party has cured such breach within [\*\*] in the case of a payment breach ([\*\*] in the case of the Initial Fee), or within [\*\*] in the case of all other breaches, after the non-breaching Party has provided written notice to the breaching Party of such breach; provided that if the breach is curable but is not capable of cure within such [\*\*] period, then the cure period will be extended for so long as the breaching Party is diligently implementing a cure plan reasonably designed to cure such breach, provided that, such cure period does not exceed [\*\*] in total.
- 14.3.2 Without limiting Section 14.3.1, if the applicable material breach is a material breach by Neurocrine of its obligations under Section 4.2.2 to use Commercially Reasonable Efforts with respect to a Program in one or more, but not all, of the Major Market Countries, then Voyager will not have the right to terminate this Agreement with respect to such Program in all countries but instead may terminate this Agreement with respect to such Program only in the Major Market Country(ies) in which there was an uncured material breach by Neurocrine with respect to its obligation to use Commercially Reasonable Efforts.

- 14.3.3 If the Parties reasonably and in good faith disagree as to whether there has been a material breach, the Party that seeks to dispute that there has been a material breach shall contest the allegation in accordance with Section 15.2 during the applicable cure period. The cure period for any allegation made in good faith as to a material breach under this Agreement will, subject to Sections 14.3.1 and 15.3, including the suspension of such cure period set forth therein, run from the date that written notice of breach was first provided to the breaching Party by the non-breaching Party.
- 14.4 <u>Termination for Failure to Make Equity Purchase</u>. If Neurocrine fails to purchase from Voyager shares of Voyager common stock pursuant to the terms and within the timeframe specified in the Stock Purchase Agreement (subject to any cure provisions therein), then Voyager shall have the right to terminate this Agreement in its entirety upon written notice to Neurocrine.
- <u>Termination for Patent Challenge</u>. If, during the Term, Neurocrine (a) commences or participates in any action or proceeding (including any patent opposition or re-examination proceeding), or otherwise asserts any claim, challenging or denying the validity or enforceability of any claim of Voyager Licensed Patent Rights, except in the normal course of patent prosecution, or (b) actively assists any other Person in bringing or prosecuting any action or proceeding (including any patent opposition or reexamination proceeding) challenging or denying the validity or enforceability of any claim of Voyager Licensed Patent Rights (each of (a) and (b), a "Patent <u>Challenge</u>"), then, to the extent permitted by applicable Laws, Voyager shall have the right, exercisable within sixty (60) days following receipt of notice regarding such Patent Challenge, in its sole discretion, to terminate this Agreement with respect to such Voyager Patent Right(s), such termination to be effective ninety (90) days following such notice (or such longer period as Voyager may designate in such notice) unless Neurocrine withdraws or causes to be withdrawn all such challenge(s) (or in the case of ex-parte proceedings, multi-party proceedings, or other Patent Challenges that Neurocrine does not have the power to unilaterally withdraw or cause to be withdrawn, Neurocrine ceases actively assisting any other party to such Patent Challenge and, to the extent Neurocrine is a party to such Patent Challenge, it withdraws from such Patent Challenge) within such ninety (90)-day period. The foregoing sentence shall not apply (i) with respect to any Voyager Licensed Patent Rights that Voyager first asserts against Neurocrine or any of its Affiliates where the Patent Challenge is made in defense of such assertion, or (ii) with respect to any Patent Challenge commenced by a Third Party that after the Effective Date acquires or is acquired by Neurocrine or its Affiliates or its or their business or assets, whether by stock purchase, merger, asset purchase or otherwise, but only with respect to Patent Challenges commenced prior to the closing of such acquisition. The following will not be considered a Patent Challenge: (A) responding to compulsory discovery, subpoenas or other requests for information in a judicial or arbitration proceeding or (B) complying with any applicable Law or court order.
- 14.6 <u>Effects of Termination Other than by Neurocrine for Voyager Breach</u>. Without limiting any other legal or equitable remedies that either Party may have, if this Agreement is terminated (in whole or in part) for any reason except by Neurocrine pursuant to Section 14.3 above, then the following shall apply, provided that if termination of this Agreement is limited to a particular country(ies) or Program(s) then the following shall apply only with respect to such country(ies) or Program(s):
  - 14.6.1 the license grants to Neurocrine in Section 5.1 shall terminate immediately;

- 14.6.2 Neurocrine shall, and hereby does, effective upon such termination, grant to Voyager a royalty-bearing, sublicenseable (through multiple tiers) license under the Neurocrine IP that has been used with or incorporated into Collaboration Products in such Program as of the effective date of termination to Exploit Collaboration Products in such Program in the terminated country(ies), which license will be non-exclusive or exclusive as requested by Voyager; the Parties shall negotiate in good faith commercially reasonable royalties payable by Voyager to Neurocrine on sales of such Collaboration Products, which shall reflect the value of, and Neurocrine's investment in the development of, such Collaboration Products and the exclusivity of the license, and the terms related to such royalty payments.
- 14.6.3 if Voyager so requests, and to the extent permitted under the relevant agreement at the time of termination, Neurocrine shall transfer to Voyager any agreements between Neurocrine or any of its Affiliates, on the one hand, and any Affiliate or Third Party, on the other hand, to the extent relating to the Exploitation of any Collaboration Product in the terminated Program(s) and country(ies) to which Neurocrine or any of its Affiliates or any Sublicensees is a party, subject to any required consents of such Third Party, which Neurocrine shall use commercially reasonable efforts to obtain promptly (but shall not be obligated to pay any additional consideration to such Third Party);
- 14.6.4 if the date of expiration or termination of the Agreement is after any Transition Event, then, with respect to any Collaboration Product that is the subject of a terminated Program:
- (a) Neurocrine shall provide to Voyager a fair and accurate description of the status of the Exploitation of any Collaboration Product in such Program in the Field in the terminated country(ies) through the effective date of termination or expiration;
- (b) Neurocrine shall as promptly as practicable transfer to Voyager or Voyager's designee (i) possession and ownership of all Regulatory Filings (including any supporting documentation or data therefor), Regulatory Approvals and pricing and reimbursement approvals relating to the Exploitation of such Collaboration Products in the terminated Program(s) and country(ies), (ii) copies of all non-clinical and clinical data relating to any of such Collaboration Products, and all adverse event or other safety data in the possession or Control of Neurocrine, any of its Affiliates or any Sublicensee related to such Collaboration Products; (ii) if this Agreement is terminated in its entirety, all records and materials containing Confidential Information of Voyager. To the extent required to effect the transfer of any Regulatory Filing or Regulatory Approvals in any terminated country(ies), Neurocrine shall appoint, and cause its Affiliates and use Commercially Reasonable Efforts to cause its Sublicensees to appoint, Voyager as the agent for Neurocrine, its Affiliates and, as applicable, the Sublicensees for all matters relating to such Collaboration Products involving Regulatory Authorities in such terminated country(ies) until all Regulatory Approvals and other Regulatory Filings have been transferred to Voyager or its designee;
- (c) if the effective date of termination or expiration is after the First Commercial Sale of a Collaboration Product in any country in the Territory, then Neurocrine shall appoint Voyager or its designee as the exclusive distributor of the Collaboration Product in the Territory and grant Voyager the right to appoint sub-distributors, until such time as all Regulatory

Approvals and pricing and reimbursement approvals in the Territory have been transferred to Voyager or its designee;

- (d) if Neurocrine or any of its Affiliates is Manufacturing such Collaboration Product, then, at Voyager's option, Neurocrine shall supply such Collaboration Product to Voyager in the Territory at Neurocrine's fully burdened manufacturing cost plus [\*\*]percent ([\*\*]%) thereof (except that such percentage above cost shall not apply if Voyager terminated this Agreement pursuant to Section 14.3 above), until the earlier of (A) such time as all Regulatory Approvals and pricing and reimbursement approvals in the Territory have been transferred to Voyager or its designee, Voyager has obtained all necessary Manufacturing approvals and Voyager has procured or developed its own source of the Collaboration Product supply for the Territory or (B) [\*\*] following the effective date of such termination or expiration;
- (e) Neurocrine shall promptly transfer and assign to Voyager all of Neurocrine's and its Affiliates' and shall use Commercially Reasonable Efforts to cause its Sublicensees to transfer and assign any Sublicensee's rights, title and interests in and to all Neurocrine Product Marks used in the Commercialization of such Collaboration Products (but not any house marks of such Person or any trademark containing the word "Neurocrine" owned by Neurocrine or any of its Affiliates or, as applicable, any Sublicensee); and
- (f) Neurocrine shall, upon Voyager's written request, transfer to Voyager any inventory of such Collaboration Products owned or controlled by Neurocrine or any of its Affiliates and shall use Commercially Reasonable Efforts to cause any Sublicensee to transfer any such inventory of such Collaboration Products owned or controlled by such Sublicensee as of the termination date at the actual price paid by Neurocrine, such Affiliate or, as applicable, such Sublicensee for such supply.
- 14.6.5 Neurocrine shall provide any other assistance reasonably requested by Voyager for the purpose of allowing Voyager or its designee to proceed expeditiously with the Exploitation of Collaboration Products in the Field in the Territory over a [\*\*] period following termination, and Voyager shall pay Neurocrine's FTE Costs and Out-of-Pocket Costs to conduct such assistance (except in the event Voyager terminated this Agreement pursuant to Section 14.3 above);
- 14.6.6 Neurocrine shall, and shall cause its Affiliates and use Commercially Reasonable Efforts to cause its Sublicensees to, execute all documents as may be reasonably requested by Voyager in order to give effect to the foregoing clauses; and
- 14.6.7 If this Agreement is terminated in its entirety, Voyager shall return to Neurocrine or destroy, and certify such destruction in writing any Confidential Information of Neurocrine, except for any such Confidential Information that Voyager has the right to use pursuant to the terms of this Agreement.
- 14.7 <u>Effects of Termination by Neurocrine for Voyager Breach</u>. If Neurocrine terminates this Agreement with respect to one or more Programs pursuant to Section 14.3, then all rights and obligations under this Agreement with respect to such terminated Programs will terminate, except as expressly provided in Section 14.9, and if such termination is of this

Agreement in its entirety, Voyager shall return to Neurocrine or destroy, and certify such destruction in writing, any Confidential Information of Neurocrine. If Neurocrine has the right to terminate this Agreement with respect to one or more Programs for Voyager's material breach pursuant to Section 14.3, then in lieu of termination, and in addition to the remedies provided in Section 2.1.5, Neurocrine shall have the right to keep this Agreement in effect and to elect the following upon written notice to Voyager:

- 14.7.1 If a Co-Co Agreement is then in effect with respect to the terminated Program(s), then such Co-Co Agreement(s) will terminate, and Voyager will no longer have the right to co-develop and co-commercialize the applicable Collaboration Products with Neurocrine; and
- 14.7.2 Subject to the applicable terms of any In-License Agreement, Neurocrine shall no longer have any obligations with respect to diligence or to use Commercially Reasonable Efforts with respect to any Collaboration Products resulting from the applicable Programs.

#### 14.8 HSR Filing; Termination Upon HSR Denial.

- 14.8.1 Except for the Parties' obligations under Article 11, Article 12 and this Section 14.8, which shall be effective as of the Execution Date, this Agreement shall not become effective until the Effective Date.
- 14.8.2 Each Party will use reasonable efforts to do, or cause to be done, all things necessary, proper and advisable to, as promptly as practicable, take all actions necessary to obtain expiration or termination of all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act, including filing with the U.S. Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice, any HSR Filing required of it under the HSR Act with respect to the transactions contemplated hereby within ten (10) Business Days after the Execution Date (or such later time as may be agreed to in writing by the Parties). The Parties shall cooperate with one another to the extent necessary in the preparation of any such HSR Filing and during the review by the U.S. Federal Trade Commission and/or the Antitrust Division of the U.S. Department of Justice. Each Party shall be responsible for its own costs, expenses, and filing fees associated with any HSR Filing; provided, however, that Neurocrine shall be solely responsible for any fees (other than penalties that may be incurred as a result of actions or omissions on the part of Voyager) required to be paid in connection with making any such HSR Filing. If the Parties make an HSR Filing hereunder, then this Agreement shall terminate (a) at the election of either Party, immediately upon notice to the other Party, if the U.S. Federal Trade Commission or the U.S. Department of Justice seeks a preliminary injunction under the Antitrust Laws against Neurocrine and Voyager to enjoin the transactions contemplated by this Agreement; or (b) at the election of either Party, immediately upon notice to the other Party, in the event that the HSR Clearance Date shall not have occurred on or prior to one hundred eighty (180) days after the effective date of the HSR Filing. In the event of such termination, this Agreement shall be of no further force and effect.

14.9 <u>Accrued Rights; Surviving Provisions of the Agreement.</u>

- 14.9.1 Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination or expiration, including any payment obligations hereunder , and any and all damages or remedies arising from any breach hereunder. Such termination or expiration shall not relieve any Party from obligations which are expressly indicated to survive expiration or termination of this Agreement.
- 14.9.2 The provisions of Articles 10, 11, 13, and 15 and Sections 2.2.2, 2.3, 2.4, the last sentence of 5.1 (only for those licenses that have become irrevocable prior to termination), 8.7, 8.8, 8.9, 8.10, 8.11, 8.12, 12.4, 14.6, 14.7, 14.9, shall survive the termination of this Agreement in its entirety or expiration of this Agreement for any reason, in accordance with their respective terms and conditions, and for the duration stated, and where no duration is stated, shall survive indefinitely.

#### ARTICLE 15 MISCELLANEOUS

- 15.1 <u>Governing Law.</u> This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed in accordance with the Laws of the State of New York without reference to conflicts of laws principles; provided that with respect to matters involving the enforcement of intellectual property rights, the Laws of the applicable country shall apply. The provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement or any subject matter hereof.
- Dispute Resolution. Except for the disputes at the JSC, which matters shall be resolved as provided in Section 3.6, in the event of any dispute arising out of or in connection with this Agreement ("Dispute"), either Party shall refer such Dispute in writing to the Parties' respective Executive Officers, and such Executive Officers shall attempt in good faith to resolve such Dispute. If the Dispute is not resolved within [\*\*] after it has been referred to the Executive Officers, the Dispute shall be finally settled through binding arbitration pursuant to Section 15.3. Any disputes concerning the propriety of the commencement of arbitration shall be finally settled by the arbitral tribunal.

## 15.3 Arbitration Request.

- 15.3.1 <u>No Arbitration of Patent Issues</u>. Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patents Covering the Manufacture, use, importation, offer for sale or sale of Collaboration Products shall be submitted to a court of competent jurisdiction in the country in which such Patents were granted or arose.
- 15.3.2 <u>Arbitration Procedure</u>. Any Disputes that have not been amicably resolved pursuant to Section 15.2 within the [\*\*] time period specified therein shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce (the "<u>ICC</u>") before a tribunal comprised of three arbitrators. Each Party shall nominate one arbitrator and within [\*\*] of the second arbitrator's appointment, the two party-nominated arbitrators shall nominate the third arbitrator, who shall serve as president of the tribunal. The arbitrators shall have experience in pharmaceutical licensing disputes. An arbitrator shall be deemed to meet this qualification unless a Party objects within [\*\*] after the arbitrator is nominated. The seat, or legal place, or will be

New York City, New York, United States. The language of the arbitration shall be English. The Parties shall mutually agree on the rules to govern discovery and the rules of evidence for the arbitration within [\*\*] after the commencement of the arbitration. If the Parties fail to timely agree to such rules, the United States Federal Rules of Civil Procedure will govern discovery and the United States Federal Rules of Evidence will govern evidence for the arbitration. Subject to Section 13.5, the arbitrators shall be authorized to award compensatory damages, but shall not be authorized to award punitive, special, consequential, or any other similar form of damages, or to reform, modify, or materially change this Agreement. The arbitrators shall also be authorized to grant temporary, preliminary or permanent equitable remedies or relief, including an injunction or order for specific performance. The award of the arbitrators shall be the sole and exclusive remedy of the Parties, except for those remedies that are set forth in this Agreement or which apply to a Party by operation of the applicable provisions of this Agreement, and the Parties hereby expressly agree to waive the right to appeal from the decisions of the arbitrator, and there shall be no appeal to any court or other authority (government or private) from the decision of the arbitrator. Judgment on the award rendered by the arbitrators may be entered in any court of competent jurisdiction.

- 15.3.3 <u>Costs</u>. During the pendency of the arbitration each Party shall bear its own attorneys' fees, costs, and expenses of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators and the ICC administrative expenses; <u>provided</u>, <u>however</u>, that the arbitrators, in their final award, shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party its costs and expenses of arbitration, including its reasonable attorneys' fees, the fees and costs of the arbitrators and ICC, and other costs and expenses (including, for example, expert witness fees and expenses, transcripts, photocopy charges and travel expenses), as determined by the arbitrators.
- 15.3.4 <u>Preliminary Injunctions</u>. Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order, preliminary injunction or other interim relief from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the award of the arbitrators on the ultimate merits of any dispute.
- 15.3.5 <u>Confidentiality</u>. The Parties agree that the arbitration shall be kept confidential. The existence and contents of the arbitration, any non-public information provided in the arbitration, and any submissions, orders or awards made in the arbitration shall be deemed Confidential Information of each of the Parties and subject to Article 11, except that a Party may disclose such information to the arbitrators, the ICC, its counsel, experts, witnesses and any other person to the extent required for the conduct of the arbitration, or as required by applicable Law, to protect or pursue a legal right, or to enforce or challenge an awards in *bona fide* legal
- 15.3.6 <u>Suspension of Cure Period</u>. From the date the Secretariat of the International Court of Arbitration receives the request for arbitration and until such time as the Dispute has been finally settled, the running of the time periods as to which Party must cure a breach of this Agreement shall be suspended as to any breach that has been referred to arbitration.
- 15.3.7 <u>Consolidation</u>. In order to facilitate the comprehensive resolution of related disputes, and upon request of any Party to the arbitration proceeding, the International Court of

Arbitration may consolidate the arbitration proceeding with any other arbitration relating to this Agreement to a Co-Co Agreement

15.4 <u>Assignment</u>. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that either Party may, without the other Party's written consent, assign this Agreement and its rights and obligations hereunder in whole or in part to (a) an Affiliate; or (b) the Acquirer in the context of a Change of Control. Any purported assignment in violation of this Section 15.4 shall be void.

# 15.5 Change of Control.

- 15.5.1 Voyager shall notify Neurocrine in writing within [\*\*] after entering into any agreement providing for or intended to result in any Change of Control of Voyager, identifying the parties to such agreement.
- 15.5.2 Following the effectiveness of such Change of Control: (a) Neurocrine shall have the right to disband the JSC and to require Voyager to adopt reasonable procedures, to be agreed upon in writing with Neurocrine, to limit the dissemination of Neurocrine's Confidential Information to only those personnel having a need to know such Confidential Information in order for Voyager to perform its obligations or to exercise its rights under this Agreement, (b) all unexercised Co-Co Options will terminate, (c) Co-Co-Agreements will terminate to the extent provided in Section 4.1.4(b), and (d) if the Acquirer is Developing or Commercializing a branded product that directly competes with a product being Developed or Commercialized by Neurocrine, Neurocrine will have the rights set forth in Section 2.1.5 (as if Voyager had materially breached its Development obligations and failed to cure such breach).
- 15.5.3 Voyager covenants that, following a Change of Control of Voyager, (a) there will be no material change in the level or nature of efforts or resources expended by Voyager with respect to, or the qualifications and experience of the personnel assigned to (including with respect to the allocation of their time to), any Program and (b) each employee of Voyager or its Affiliates who worked on any Program during the [\*\*] period immediately prior to the Change of Control or who would reasonably be expected to work on any Program thereafter will continue to work on such Program for so long as s/he remains an employee of Voyager or any of its Affiliates.
- 15.6 <u>Performance by Affiliates and Sublicensees</u>. Each Party hereby acknowledges and agrees that it shall be responsible for the full and timely performance as and when due under, and observance of all applicable covenants, terms, conditions and agreements set forth in this Agreement by its Affiliate(s), licensees and Sublicensees.
- 15.7 <u>Force Majeure</u>. No Party shall be held liable or responsible to the other Party nor be deemed to be in default under, or in breach of any provision of, this Agreement for failure or delay in fulfilling or performing any obligation (other than a payment obligation) of this Agreement when such failure or delay is due to force majeure. For purposes of this Agreement, force majeure is defined as any cause beyond the reasonable control of the affected Party and without the fault or negligence of such Party, which may include acts of God; material changes in

Law; war; civil commotion; destruction of production facilities or materials by fire, flood, earthquake, explosion or storm; labor disturbances; epidemic; and failure of public utilities or common carriers. In such event the Party affected by such force majeure shall immediately notify the other Party of such inability and of the period for which such inability is expected to continue. The Party giving such notice shall thereupon be excused from such of its obligations under this Agreement as it is thereby disabled from performing for so long as it is so disabled for up to a maximum of ninety (90) days, after which time the Parties shall promptly meet to discuss in good faith how to best proceed in a manner that maintains and abides by the Agreement. To the extent possible, each Party shall use reasonable efforts to minimize the duration of any force majeure.

15.8 <u>Notices</u>. Any notice or request required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), or reputable overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

If to Voyager,

addressed to: Voyager Therapeutics, Inc.

75 Sidney Street

Cambridge, MA 02139

Attention: Chief Executive Officer

Telephone: 857-259-5340 Facsimile: 617-621-2971

with a copy to: Wilmer Cutler Pickering Hale and Dorr LLP

7 World Trade Center 250 Greenwich Street New York, NY 10007

Attention: Brian A. Johnson, Esq.

Telephone: 212-937-7206 Facsimile: 212-230-8888

If to Neurocrine,

addressed to: Neurocrine Biosciences, Inc.

12780 El Camino Real San Diego, CA 92130

Attention: Chief Legal Officer Telephone: 858-617-7714 Facsimile: 858-777-3488

with a copy to: Cooley LLP

4401 Eastgate Mall San Diego, CA 92121

Attention: Jason L. Kent, Esq.

Telephone: 858-550-6044 Facsimile: 858 550 6420

or to such other address for such Party as it shall have specified by like notice to the other Party, <u>provided that</u> notices of a change of address shall be effective only upon receipt thereof. If delivered personally or by facsimile transmission, the date of delivery shall be deemed to be the date on which such notice or request was given. If sent by overnight express courier service, the date of delivery shall be deemed to be the next Business Day after such notice or request was deposited with such service. If sent by certified mail, the date of delivery shall be deemed to be the third (3rd) Business Day after such notice or request was deposited with the U.S. Postal Service.

- 15.9 <u>Export Clause</u>. Each Party acknowledges that the Laws of the United States restrict the export and re-export of commodities and technical data of United States origin. Each Party agrees that it will not export or re-export restricted commodities or the technical data of the other Party in any form without the appropriate United States and foreign government licenses.
- 15.10 <u>Waiver</u>. Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term except to the extent set forth in writing.
- 15.11 <u>Severability</u>. If any provision hereof should be invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.
- 15.12 Entire Agreement. This Agreement, together with the Schedules hereto, sets forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties and supersede and terminate all prior agreements and understanding between the Parties. In particular, and without limitation, this Agreement supersedes and replaces the Existing Confidentiality Agreement and any and all term sheets relating to the transactions contemplated by this Agreement and exchanged between the Parties prior to the Effective Date. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.
- 15.13 <u>Independent Contractors</u>. Nothing herein shall be construed to create any relationship of employer and employee, agent and principal, partnership or joint venture between

the Parties. Each Party is an independent contractor. Neither Party shall assume, either directly or indirectly, any liability of or for the other Party. Neither Party shall have the authority to bind or obligate the other Party and neither Party shall represent that it has such authority.

- 15.14 <u>CREATE Act</u>. It is the intention of the Parties that this Agreement is a "joint research agreement" as that phrase is defined in Section 35 U.S.C. 100(h). Notwithstanding anything to the contrary in this Agreement, each Party will have the right to invoke the America Invents Act Joint Research Agreement exception codified at 35 U.S.C. § 102(c) (the "<u>JRA Exception</u>") when exercising its rights under this Agreement, but only with prior written consent of the other Party in its sole discretion. In the event that a Party intends to invoke the JRA Exception, once agreed to by the other Party if required by the preceding sentence, it will notify the other Party and the other Party will cooperate and coordinate its activities with such Party with respect to any filings or other activities in support thereof.
- Headings; Construction; Interpretation. Headings and any table of contents used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. The terms of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of Law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause or Schedule shall be deemed to be a reference to any Article, Section, subsection, paragraph, clause or Schedule, of or to, as the case may be, this Agreement. Except where the context otherwise requires, (a) any definition of or reference to any agreement, instrument or other document refers to such agreement, instrument other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any Law refers to such Law including all rules and regulations thereunder and any successor Law, in each case as from time to time enacted, repealed or amended, (c) the words "herein," "hereof" and "hereunder," and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof, (d) the words "include," "includes," and "including" shall be deemed to be followed by the phrase "but not limited to," "without limitation" or words of similar import, (e) the word "or" is used in the inclusive sense (and/or), (f) words in the singular or plural form include the plural and singular form, respectively, (g) references to any gender refer to each other gender, (h) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement, and (i) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein shall be interpreted in a correlative manner.
- 15.16 <u>Further Actions</u>. Each Party shall execute, acknowledge and deliver such further instruments, and do all such other acts, as may be necessary or appropriate in order to carry out the expressly stated purposes and the clear intent of this Agreement.

- 15.17 <u>Parties in Interest</u>. All of the terms and provisions of this Agreement shall be binding upon, and shall inure to the benefit of and be enforceable by the parties hereto and their respective successors, heirs, administrators and permitted assigns.
- 15.18 <u>Counterparts</u>. This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies from separate computers or printers. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

[Signature page to follow]

IN WITNESS WHEREOF, and intending to be legally bound hereby, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Execution Date.

# Voyager Therapeutics, Inc.

By: /s G. Andre Turenne

Name: G. Andre Turenne

Title: President and Chief Executive Officer

# Neurocrine Biosciences, Inc.

By: /s/ Kevin Gorman

Name: Kevin Gorman

Title: CEO

(Signature Page to Collaboration and License Agreement)

# Schedule 1.37

# **EXISTING IN-LICENSE AGREEMENTS**

| [**] Agreement    |
|-------------------|
| Genzyme Agreement |
| [**] Agreement    |
|                   |

# Schedule 1.68

# KNOWLEDGE INDIVIDUALS

Neurocrine: [\*\*].

#### **Schedule 5.2.1**

#### SPECIFIC OBLIGATIONS UNDER THE [\*\*] AGREEMENT

(Sections references are with respect to the [\*\*] Agreement)

#### STATUTORY AND [\*\*] REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

- Prior to the **First Commercial Sale**, the **Licensee** agrees to provide the [\*\*], upon the [\*\*]'s written request, with reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** solely for the [\*\*]'s research use to the extent that providing **Licensed Products** or materials to the [\*\*] will not adversely effect the development of **Licensed Products** or the practice of the **Licensed Process**.
- 5.2 The **Licensee** agrees that products used or sold in the United States embodying **Licensed Products** or produced through use of **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from the [\*\*].

#### RECORD KEEPING

8.1 The **Licensee** agrees to keep accurate and correct records of **Licensed Products** made, used, sold, or imported and **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due the [\*\*]. These records shall be retained for at least [\*\*] following a given reporting period and shall be available during normal business hours for inspection, at the expense of the [\*\*], by an accountant or other designated auditor selected by the [\*\*] for the sole purpose of verifying reports and royalty payments hereunder. The accountant or auditor shall only disclose to the [\*\*] information relating to the accuracy of reports and royalty payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of [\*\*] percent ([\*\*]%) for any [\*\*] period, then the **Licensee** shall reimburse the [\*\*] for the cost of the inspection at the time the **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.8. All royalty payments required under this Paragraph shall be due within [\*\*] of the date the [\*\*] provides the **Licensee** notice of the payment due.

#### **PERFORMANCE**

- 10.1 The **Licensee** shall use its reasonable commercial efforts to bring the **Licensed Products** and **Licensed Processes** to **Practical Application**. "Reasonable commercial efforts" for the purposes of this provision shall include best efforts to adhere to the **Commercial Development Plan** in Appendix F and performance of the **Benchmarks** in Appendix E. The efforts of a **Sublicensee** shall be considered the efforts of the **Licensee**.
- 10.2 The **Licensee** agrees, after its **First Commercial Sale**, to make reasonable quantities of **Licensed Products** or materials produced through the use of **Licensed Processes** available to patient assistance programs.

- 12.5 The **Licensee** shall indemnify and hold the [\*\*], its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or properly damage in connection with or arising out of:
  - (a) the use by or on behalf of the **Licensee**, its **Sublicensees**, its directors, employees, or third parties of any **Licensed Patent Rights**; or
  - (b) the design, manufacture, distribution, or use of any Licensed Products, Licensed Processes or Supplied Materials by the Licensee, or other products or processes developed in connection with or arising out of the Licensed Patent Rights.
- 13.7 The [\*\*] reserves the right according to 35 <u>U.S.C., §209(d)(3)</u> to terminate or modify this **Agreement** if it is determined that the action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the **Licensee**.
- 13.8 Within [\*\*] of receipt of 'written notice of the [\*\*]'s unilateral decision to modify or terminate this **Agreement**, the **Licensee** may, consistent with the provisions of 37 CFR §404.11, appeal the decision by written submission to the designated the [\*\*] official. The decision of the designated [\*\*] official shall be the final agency decision. The **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.
- 13.9 Within [\*\*] of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by the **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expense, due to the [\*\*] shall become immediately due and payable upon termination or expiration. If terminated under this Article 13, **Sublicensees** may elect to convert their sublicenses to direct licenses with the [\*\*] pursuant to Paragraph 4.3. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, the **Licensee** shall return all **Licensed Products** or other materials included within the Licensed Patent Rights to the [\*\*] or provide the [\*\*] with written certification of the destruction thereof. The **Licensee** may not be granted additional the [\*\*] licenses if the final reporting requirement is not fulfilled.

# **Schedule 5.2.4(a)**

# CERTAIN INTELLECTUAL PROPERTY

Intellectual property described in a communication from counsel to Voyager to counsel to Neurocrine dated the Execution Date.

# Schedule 8.1

# ALLOCATION SCHEDULE

| \$115,000,000 allocated as follows: |                                  |  |  |  |  |
|-------------------------------------|----------------------------------|--|--|--|--|
|                                     | \$[**] to the AADC Program       |  |  |  |  |
|                                     | \$[**] to the FA Program         |  |  |  |  |
|                                     | \$[**] to each Discovery Program |  |  |  |  |
|                                     |                                  |  |  |  |  |
|                                     |                                  |  |  |  |  |

# Exhibit A

# STOCK PURCHASE AGREEMENT

# STOCK PURCHASE AGREEMENT

By and Between

NEUROCRINE BIOSCIENCES, INC.

**AND** 

VOYAGER THERAPEUTICS, INC.

Dated as of January 28, 2019

# TABLE OF CONTENTS

|    |   | Page |
|----|---|------|
| 1. | Definitions.  | 1    |
|    | 1.1 Defined Terms   | 1    |
|    | 1.2 Additional Defined Terms  | 4    |
| 2. | Purchase and Sale of Common Stock.                                    | 5    |
|    | 2.1 General   | 5    |
|    | 2.2 Calculation   | 5    |
| 3. | Closing Date; Deliveries.   | 5    |
|    | 3.1 Closing Date  | 5    |
|    | 3.2 Deliveries  | 5    |
| 4. | Representations and Warranties of the Company                         | 6    |
|    | 4.1 Organization, Good Standing and Qualification                     | 6    |
|    | 4.2 Capitalization and Voting Rights                                  | 6    |
|    | 4.3 Subsidiaries  | 7    |
|    | 4.4 Authorization   | 7    |
|    | 4.5 No Defaults   | 8    |
|    | 4.6 No Conflicts  | 8    |
|    | 4.7 No Governmental Authority or Third Party Consents                 | 8    |
|    | 4.8 Valid Issuance of Shares  | 9    |
|    | 4.9 Litigation  | 9    |
|    | 4.10 Licenses and Other Rights; Compliance with Laws                  | 9    |
|    | 4.11 Company SEC Documents; Financial Statements; Nasdaq Stock Market | 9    |
|    | 4.12 Absence of Certain Changes                                       | 11   |
|    | 4.13 Offering   | 12   |
|    | 4.14 No Integration   | 12   |
|    | 4.15 Brokers' or Finders' Fees  | 12   |
|    | 4.16 Investment Company   | 12   |
|    | 4.17 No General Solicitation  | 12   |
|    | 4.18 Foreign Corrupt Practices  | 12   |
|    | 4.19 Regulation M Compliance  | 12   |
|    | 4.20 Office of Foreign Assets Control.                                | 13   |
|    | 4.21 Development Matters  | 13   |
|    |   |      |

|    | 4.22 Intellectual Property  | 13 |
|----|---|----|
|    | 4.23 Real and Personal Property                                   | 14 |
|    | 4.24 Labor and Employment   | 15 |
|    | 4.25 ERISA Matters  | 15 |
|    | 4.26 Environmental Matters  | 16 |
|    | 4.27 Taxes  | 16 |
|    | 4.28 Insurance  | 16 |
| 5. | Representations and Warranties of the Investor                    | 17 |
|    | 5.1 Organization; Good Standing                                   | 17 |
|    | 5.2 Authorization   | 17 |
|    | 5.3 No Conflicts  | 17 |
|    | 5.4 No Governmental Authority or Third Party Consents             | 18 |
|    | 5.5 Purchase Entirely for Own Account                             | 18 |
|    | 5.6 Disclosure of Information                                     | 18 |
|    | 5.7 Investment Experience and Accredited Investor Status          | 18 |
|    | 5.8 Acquiring Person  | 18 |
|    | 5.9 Restricted Securities   | 18 |
|    | 5.10 Legends  | 19 |
|    | 5.11 Financial Assurances   | 19 |
|    | 5.12 SEC Reports  | 19 |
| 6. | Investor's Conditions to Closing                                  | 19 |
|    | 6.1 Representations and Warranties                                | 19 |
|    | 6.2 Representations and Warranties in the Collaboration Agreement | 20 |
|    | 6.3 Covenants   | 20 |
|    | 6.4 Investor Agreement  | 20 |
|    | 6.5 Collaboration Agreement                                       | 20 |
|    | 6.6 No Material Adverse Effect                                    | 20 |
|    | 6.7 Listing   | 20 |
| 7. | Company's Conditions to Closing                                   | 20 |
|    | 7.1 Representations and Warranties                                | 20 |
|    | 7.2 Covenants   | 20 |
|    | 7.3 Investor Agreement  | 20 |
|    | 7.4 Collaboration Agreement                                       | 21 |

| 8.  | Mutual Conditions to Closing                          | 21 |
|-----|---|----|
|     | 8.1 HSR Act Qualification                             | 21 |
|     | 8.2 Absence of Litigation                             | 21 |
|     | 8.3 No Prohibition                                    | 21 |
| 9.  | Termination   | 21 |
|     | 9.1 Ability to Terminate                              | 21 |
|     | 9.2 Effect of Termination                             | 22 |
| 10. | Additional Covenants and Agreements                   | 22 |
|     | 10.1 Market Listing                                   | 22 |
|     | 10.2 Notification under the HSR Act                   | 22 |
|     | 10.3 Assistance and Cooperation                       | 23 |
|     | 10.4 Legend Removal                                   | 23 |
|     | 10.5 Conduct of Business                              | 24 |
| 11. | Miscellaneous   | 24 |
|     | 11.1 Governing Law; Submission to Jurisdiction        | 24 |
|     | 11.2 Waiver.  | 24 |
|     | 11.3 Notices  | 25 |
|     | 11.4 Entire Agreement                                 | 25 |
|     | 11.5 Headings; Nouns and Pronouns; Section References | 25 |
|     | 11.6 Severability                                     | 25 |
|     | 11.7 Assignment                                       | 25 |
|     | 11.8 Parties in Interest                              | 26 |
|     | 11.9 Counterparts                                     | 26 |
|     | 11.10 Third Party Beneficiaries                       | 26 |
|     | 11.11 No Strict Construction                          | 26 |
|     | 11.12 Survival of Warranties                          | 26 |
|     | 11.13 Remedies  | 26 |
|     | 11.14 Expenses  | 26 |
|     | 11.15 No Publicity                                    | 26 |

Exhibit A – Notices

#### STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (this "**Agreement**"), dated as of January 28, 2019 (the "**Signing Date**"), by and between Neurocrine Biosciences, Inc. (the "**Investor**"), a Delaware corporation with its principal place of business at 12780 El Camino Real, San Diego, CA 92130, and Voyager Therapeutics, Inc. (the "**Company**"), a Delaware corporation, with its principal place of business at 75 Sidney Street, Cambridge, MA 02139.

WHEREAS, pursuant to the terms and subject to the conditions set forth in this Agreement, the Company desires to issue and sell to the Investor, and the Investor desires to subscribe for and purchase from the Company, certain shares of common stock, par value \$0.001 per share, of the Company (the "Common Stock"); and

WHEREAS, simultaneously with the execution of this Agreement, the Company and the Investor are entering into the Collaboration Agreement and the Investor Agreement.

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for good and valuable consideration, the adequacy and sufficiency of which are hereby acknowledged, the Investor and the Company agree as follows:

### 1. <u>Definitions</u>.

1.1 <u>Defined Terms</u>. When used in this Agreement, the following terms shall have the respective meanings specified therefor below:

"2014 Stock Option and Grant Plan" shall mean the Company's 2014 Stock Option and Grant Plan, as amended to date and as the same may be amended and/or restated from time to time.

"2015 Employee Stock Purchase Plan" shall mean the Company's 2015 Employee Stock Purchase Plan, as amended to date and as the same may be amended and/or restated from time to time.

"2015 Stock Option and Incentive Plan" shall mean the Company's 2015 Stock Option and Incentive Plan, as amended to date and as the same may be amended and/or restated from time to time.

"Affiliate" shall mean, with respect to any Person, another Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if such Person (ii) owns, directly or indirectly, beneficially or legally, more than fifty percent (50%) of the outstanding voting securities or capital stock of such other Person, or has other comparable ownership interest with respect to any Person other than a corporation; or (ii) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of such other Person. For the purposes of this Agreement, in no

event shall the Investor or any of its Affiliates be deemed Affiliates of the Company or any of its Affiliates, nor shall the Company or any of its Affiliates be deemed Affiliates of the Investor or any of its Affiliates.

- "Aggregate Purchase Price" shall mean \$50,000,000.00.
- "Agreement" shall have the meaning set forth in the Preamble, including all Exhibits attached hereto.
- "Board" shall mean the Board of Directors of the Company.
- "Business Day" shall mean a day on which banking institutions in Boston, Massachusetts, United States and San Diego, California, United States are open for business, excluding any Saturday or Sunday.
  - "Closing Conditions" shall mean the conditions to Closing set forth in Sections 6, 7, and 8 hereof.
- "Collaboration Agreement" shall mean the Collaboration and License Agreement, of even date herewith, between the Investor and the Company.
  - "Company Financial Advisors" shall mean Guggenheim Securities, LLC and Chestnut Securities, Inc.
  - "DOJ" shall mean the U.S. Department of Justice.
  - "Effect" shall have the meaning set forth in the definition of "Material Adverse Effect."
- **"Exchange Act"** shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.
  - "FTC" shall mean the U.S. Federal Trade Commission.
  - "GAAP" shall mean generally accepted accounting principles in the United States.
- "Governmental Authority" shall mean any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority or functions of any nature pertaining to government.
- "HSR Act" shall mean the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended from time to time.
- "HSR Clearance" shall mean the expiration or termination of all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act.

"HSR Filing" shall mean the filings by the Company and Investor with the FTC and the Antitrust Division of the DOJ of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in the Transaction Agreements and the Collaboration Agreement, together with all required documentary attachments thereto.

"**Investor Agreement**" shall mean that certain Investor Agreement, of even date herewith, between the Investor and the Company.

"LAS" shall mean the Nasdaq Notification Form: Listing of Additional Shares.

"Law" shall mean any law, statute, rule, regulation, order, judgment or ordinance having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision.

"Material Adverse Effect" shall mean any change, event or occurrence (each, an "Effect") that, individually or when taken together with all other Effects that have occurred prior to the date of determination of the occurrence of the Material Adverse Event, has had a material adverse effect on the business, properties, management, financial position, stockholders' equity or results of operations of the Company and its subsidiaries taken as a whole or on the performance by the Company of its obligations under the Transaction Agreements, except to the extent that any such Effect results from or arises out of: (A) changes in conditions in the United States or global economy or capital or financial markets generally, including changes in interest or exchange rates, (B) changes in general legal, regulatory, political, economic or business conditions or changes in generally accepted accounting principles in the United States or interpretations thereof, (C) acts of war, sabotage or terrorism, or any escalation or worsening of any such acts of war, sabotage or terrorism, (D) earthquakes, hurricanes, floods or other natural disasters, (E) the announcement of the Transaction Agreements, the Collaboration Agreement or the Transaction, (F) any change in the Company's stock price or trading volume or any failure to meet internal projections or forecasts or published revenue or earnings projections of industry analysts (provided that the underlying events giving rise to any such change shall not be excluded) or (G) any breach, violation or nonperformance by the Investor or any of its Affiliates under the Collaboration Agreement, provided, however, that the Effects excluded in clauses (A), (B), (C) and (D) shall only be excluded to the extent such Effects are not disproportionately adverse on the Company and its subsidiaries as compared to other companies operating in the Company's industry.

"Per-Share Purchase Price" shall mean \$11.9625.

"**Person**" shall mean any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Governmental Authority or other entity, as well as any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the Exchange Act.

"Rule 144" shall mean Rule 144 promulgated under the Securities Act.

"Sales Agreement" shall mean that certain Sales Agreement, by and between the Company and Cowen and Company, LLC, dated as of December 1, 2016.

"SEC" shall mean the U.S. Securities and Exchange Commission.

"Securities Act" shall mean the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"**Termination Date**" shall mean the date that is one hundred and eighty (180) days after the effective date of the HSR Filing.

"**Third Party**" shall mean any Person other than the Investor, the Company or any Affiliate of the Investor or the Company.

"**Transaction**" shall mean the issuance and sale of the Shares by the Company, and the purchase of the Shares by the Investor, in accordance with the terms hereof.

"Transaction Agreements" shall mean this Agreement and the Investor Agreement.

"Transfer Agent" shall mean the Company's transfer agent.

1.2 <u>Additional Defined Terms</u>. In addition to the terms defined in Section 1.1 hereof, the following terms shall have the respective meanings assigned thereto in the sections indicated below:

| <u>Defined Term</u>   | <u>Section</u>  |
|-----------------------|-----------------|
| Closing               | Section 3.1     |
| Closing Date          | Section 3.1     |
| Common Stock          | Preamble        |
| Company               | Preamble        |
| Company SEC Documents | Section 4.11(a) |
| Investor              | Preamble        |
| Modified Clause       | Section 11.6    |
| Shares                | Section 2.1     |
| Signing Date          | Preamble        |

#### 2. <u>Purchase and Sale of Common Stock.</u>

- 2.1 <u>General</u>. Subject to the terms and conditions of this Agreement, at the Closing, the Company shall issue and sell to the Investor and the Investor shall purchase from the Company, a number of shares of Common Stock (the "**Shares**") calculated pursuant to Section 2.2 hereof.
- 2.2 <u>Calculation</u>. The number of Shares shall be 4,179,728, which is calculated by dividing the Aggregate Purchase Price by the Per-Share Purchase Price, rounded down to the nearest whole share.

### 3. <u>Closing Date; Deliveries</u>.

3.1 <u>Closing Date</u>. The closing of the purchase and sale of the Shares hereunder (the "**Closing**") shall take place remotely via the exchange of documents and signatures at 9:00 a.m. New York City time on the second (2nd) Business Day following the satisfaction or waiver of all of the Closing Conditions (other than those conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction at such time of such conditions), or at such other time, date, and location as the parties may agree. The date the Closing occurs is hereinafter referred to as the "**Closing Date**."

#### 3.2 Deliveries.

- Deliveries by the Company. At the Closing, the Company shall deliver, or (a) cause to be delivered, to the Investor the Shares, registered in the name of the Investor, and the Company shall instruct its transfer agent to register such issuance at the time of such issuance. The Company shall also deliver at the Closing: (i) a certificate in form and substance reasonably satisfactory to the Investor and duly executed on behalf of the Company by an authorized executive officer of the Company, certifying that the conditions to Closing set forth in Sections 6 and 8.2 hereof have been fulfilled and (ii) a certificate of the secretary or assistant secretary of the Company dated as of the Closing Date certifying (A) that attached thereto is a true and complete copy of the Amended and Restated By-laws of the Company as in effect at the time of the actions by the Board referred to in clause (B) below and on the Closing Date; (B) that attached thereto is a true and complete copy of all resolutions adopted by the Board authorizing the execution, delivery and performance of the Transaction Agreements and the Transaction and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby and thereby as of the Closing Date; (C) that attached thereto is a true and complete copy of the Company's Fifth Amended and Restated Certificate of Incorporation as in effect at the time of the actions by the Board referred to in clause (B) above and on the Closing Date; and (D) as to the incumbency and specimen signature of any officer of the Company executing a Transaction Agreement on behalf of the Company.
- (b) <u>Deliveries by the Investor</u>. At the Closing, the Investor shall deliver, or cause to be delivered, to the Company the Aggregate Purchase Price by wire transfer of immediately available United States funds to an account designated by

the Company. The Company shall notify the Investor in writing of the wiring instructions for such account not less than two (2) Business Days before the Closing Date. The Investor shall also deliver, or cause to be delivered, at the Closing: (i) a certificate in form and substance reasonably satisfactory to the Company duly executed by an authorized executive officer of the Investor certifying that the conditions to Closing set forth in Section 7 hereof have been fulfilled and (ii) a certificate of the secretary or assistant secretary of the Investor dated as of the Closing Date certifying as to the incumbency and specimen signature of any officer executing a Transaction Agreement on behalf of the Investor.

4. <u>Representations and Warranties of the Company</u>. The Company hereby represents and warrants to the Investor that:

### 4.1 <u>Organization, Good Standing and Qualification</u>.

- (a) The Company has been duly organized and is validly existing and in good standing under the laws of its jurisdiction of organization, is duly qualified to do business and is in good standing in each jurisdiction in which its ownership or lease of property or the conduct of its businesses requires such qualification, and has all power and authority necessary to own or hold its properties and to conduct the businesses in which it is engaged, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, have a Material Adverse Effect.
- (b) The Company has all requisite corporate power and corporate authority to enter into the Transaction Agreements and the Collaboration Agreement, to issue and sell the Shares and to perform its obligations under and to carry out the other transactions contemplated by the Transaction Agreements and the Collaboration Agreement.

### 4.2 <u>Capitalization and Voting Rights</u>.

(a) As of the Signing Date, the authorized capital of the Company consists of: (i) 120,000,000 shares of Common Stock of which, (A) 32,601,748 shares are issued and outstanding, (B) 4,886,021 shares are issuable upon the exercise of outstanding stock options or upon the settlement of outstanding equity awards issued pursuant to the 2014 Stock Option and Grant Plan or the 2015 Stock Option and Incentive Plan, (C) 2,259,224 shares are reserved for future issuance pursuant to the 2015 Stock Option and Incentive Plan, and (D) 1,289,093 shares are reserved for future issuance pursuant to the 2015 Employee Stock Purchase Plan, as amended to date and as the same may be amended and/or restated from time to time, and (ii) 5,000,000 shares of preferred stock, par value \$0.001 per share, of which no shares are issued and outstanding. The Company is also party to the Sales Agreement pursuant to which the Company may issue and sell shares of its Common Stock having an aggregate offering price of up to \$75,000,000 through Cowen and Company, LLC, from time to time, in "at-the-market" offerings or certain negotiated transactions. All of the issued and outstanding shares of Common Stock have been duly authorized and validly issued and

are fully paid and non-assessable, were issued in compliance with federal and state securities Laws, and are not subject to any pre-emptive rights.

- (b) Except as described or referred to in Section 4.2(a) above and as provided in the Investor Agreement, as of the Signing Date, there are no outstanding rights (including, without limitation, pre-emptive rights), warrants or options to acquire, or instruments convertible into or exchangeable for, any shares of capital stock or other equity interest in the Company, or any contract, commitment, agreement, understanding or arrangement of any kind relating to the issuance of any capital stock of the Company, any such convertible or exchangeable securities or any such rights, warrants or options.
- (c) Except as disclosed in the Company SEC Documents, no Person has any right to cause the Company to effect the registration under the Securities Act of any securities of the Company.
- (d) The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the SEC is contemplating terminating such registration.
- 4.3 <u>Subsidiaries</u>. As of the Signing Date, the Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Schedule 1 hereto. All the outstanding shares of capital stock or other equity interests of each subsidiary owned, directly or indirectly, by the Company have been duly authorized and validly issued, are fully paid and non-assessable (except, in the case of any foreign subsidiary, for directors' qualifying shares) and are owned directly or indirectly by the Company, free and clear of any lien, charge, encumbrance, security interest, restriction on voting or transfer or any other claim of any third party.

#### 4.4 Authorization.

- (a) The Company has full right, power and authority to execute and deliver the Transaction Agreements and the Collaboration Agreement and to perform its obligations hereunder and thereunder; and all action required to be taken for the due and proper authorization, execution and delivery by it of each of the Transaction Agreements and the Collaboration Agreement and the consummation by it of the transactions contemplated thereby has been duly and validly taken.
- (b) The Transaction Agreements and the Collaboration Agreement have been duly executed and delivered by the Company and, upon the due execution and delivery of the Transaction Agreements and the Collaboration Agreement by the Investor, will constitute valid and legally binding obligations of the Company, enforceable against the Company in accordance with their respective terms, except, with respect to the Investor Agreement and the Collaboration Agreement, as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or

similar laws affecting creditors' rights generally or by equitable principles relating to enforceability (collectively, the "Enforceability Exceptions").

- (c) No stop order or suspension of trading of the Common Stock has been imposed by the Nasdaq Stock Market, the SEC or any other Governmental Authority and remains in effect.
- 4.5 No Defaults. The Company is not (i) in violation of its charter or by-laws or similar organizational documents; (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company is a party, by which the Company is bound or to which any of the property or assets of the Company is subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority having jurisdiction over the Company or any of its subsidiaries, except, in the case of clauses (ii) and (iii) above, for any such default or violation that would not, individually or in the aggregate, have a Material Adverse Effect.
- Agreements and the Collaboration Agreement, the issuance and sale of the Shares and the consummation of the transactions contemplated by the Transaction Agreements and the Collaboration Agreement will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company is a party, by which the Company is bound or to which any of the property or assets of the Company is subject, (ii) result in any violation of the provisions of the charter or by-laws or similar organizational documents of the Company or (iii) result in the violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority having jurisdiction over the Company or any of its subsidiaries, except, in the case of clauses (i) and (iii) above, for any such conflict, breach, violation or default that would not, individually or in the aggregate, have a Material Adverse Effect.
- 4.7 <u>No Governmental Authority or Third Party Consents</u>. No consent, approval, authorization, order, license, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Company of each of the Transaction Agreements or the Collaboration Agreement or the issuance and sale of the Shares, except (i) such filings as may be required to be made with the SEC and with any state blue sky or securities regulatory authority, which filings shall be made in a timely manner in accordance with all applicable Laws, (ii) as required pursuant to the HSR Act and (iii) with respect to the Shares, the filing with the Nasdaq Stock Market of, and the absence of unresolved issues with respect to, an LAS and, if required, a Nasdaq Shares Outstanding Change Form.

- 4.8 <u>Valid Issuance of Shares</u>. When issued, sold and delivered at the Closing in accordance with the terms hereof for the Aggregate Purchase Price, the Shares shall be duly authorized, validly issued, fully paid and nonassessable, free from any liens, encumbrances or restrictions on transfer, including pre-emptive rights, rights of first refusal or other similar rights, other than as arising pursuant to the Transaction Agreements, as a result of any action by the Investor or under federal or state securities Laws.
- 4.9 <u>Litigation</u>. There are no legal, governmental or regulatory investigations, actions, suits or proceedings pending to which the Company is a party or to which any property of the Company is subject that, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect; and no such investigations, actions, suits or proceedings are, to the knowledge of the Company, threatened or contemplated by any governmental or regulatory authority or others.
- 4.10 <u>Licenses and Other Rights; Compliance with Laws</u>. The Company and its subsidiaries possess or are in the process of obtaining all licenses, certificates, permits and other authorizations issued by, and have made all declarations and filings with, the appropriate federal, state, local or foreign governmental or regulatory authorities that are necessary for the ownership or lease of their respective properties or the conduct of their respective businesses as described in the Company SEC Documents, except where the failure to possess or make the same would not, individually or in the aggregate, have a Material Adverse Effect; and except as described in the Company SEC Documents, neither the Company nor any of its subsidiaries has received notice of any revocation or modification of any such license, certificate, permit or authorization or has any reason to believe that any such license, certificate, permit or authorization will not be renewed. The Company and its subsidiaries are, and at all times since January 1, 2017, have been, in compliance with all statutes, rules and regulations applicable to the ownership, packaging, processing, use, distribution, import, or export of any product manufactured or distributed by the Company or its subsidiaries, except where such noncompliance would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

#### 4.11 Company SEC Documents; Financial Statements; Nasdag Stock Market.

(a) Since January 1, 2017, the Company has timely filed all required reports, schedules, forms, statements and other documents (including exhibits and all other information incorporated therein) required to be filed by it under the Securities Act and the Exchange Act, and any required amendments to any of the foregoing, with the SEC (the "Company SEC Documents"). As of their respective filing dates, each of the Company SEC Documents complied in all material respects with the requirements of the Securities Act, the Exchange Act, and the rules and regulations of the SEC promulgated thereunder applicable to such Company SEC Documents, and no Company SEC Documents when filed, declared effective or mailed, as applicable, contained any untrue statement of a material fact or omitted to state a material fact

required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

- (b) As of the Signing Date, there are no outstanding or unresolved comments in comment letters received from the SEC or its staff.
- (c) The financial statements of the Company included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and in its quarterly reports on Form 10-Q for the quarterly periods ended March 31, 2018; June 30, 2018; and September 30, 2018 present fairly the financial position of the Company and its consolidated subsidiaries as of the dates indicated and the results of their operations and the changes in their cash flows for the periods specified; such financial statements have been prepared in conformity with GAAP applied on a consistent basis throughout the periods covered thereby, except as otherwise disclosed therein and, in the case of unaudited, interim financial statements, subject to normal year-end audit adjustments and the exclusion of certain footnotes, and any supporting schedules included in the Company SEC Documents present fairly the information required to be stated therein.
- (d) The Common Stock is listed on the Nasdaq Stock Market, and the Company has taken no action designed to, or which is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the Nasdaq Stock Market. The Company has not received any notification that, and has no knowledge that, the SEC or the Nasdaq Stock Market is contemplating terminating such listing or registration.
- The Company and its subsidiaries have established systems of "internal (e) control over financial reporting" (as defined in Rule 13a-15(f) of the Exchange Act) that have been designed by, or under the supervision of, their respective principal executive and principal financial officers, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including, but not limited to, internal accounting control sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences and (v) interactive data in eXtensible Business Reporting Language included in the Company SEC Documents fairly presents the information called for in all material respects and is prepared in accordance with the SEC's rules and guidelines applicable thereto. Except as disclosed in the Company SEC Documents, there are no material weaknesses in the Company's internal controls. The Company's auditors and the Audit Committee of the Board have been advised of: (i) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which have adversely affected or are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial

information; and (ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

- (f) The Company maintains disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) that comply with the requirements of the Exchange Act; such disclosure controls and procedures have been designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to the Company's management to allow timely decisions regarding disclosures. The Company has conducted evaluations of the effectiveness of its disclosure controls as required by Rule 13a-15 of the Exchange Act.
- (g) There is and has been no material failure on the part of the Company or, to the knowledge of the Company, any of the Company's directors or officers, in their capacities as such, to comply with any applicable provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith, including Section 402 related to loans and Sections 302 and 906 related to certifications.

### 4.12 <u>Absence of Certain Changes</u>.

Except as disclosed in the Company SEC Documents, since September 30, 2018, (i) there has not been any material change in the capital stock (other than (x) the issuance of shares of Common Stock upon exercise of stock options, the settlement of equity awards and the exercise of warrants described as outstanding in, and the grant of options and awards under existing equity incentive plans described in, the Company SEC Documents and (y) the issuance of shares of Common Stock, options and equity awards granted to new employees of the Company as inducement awards pursuant to Nasdaq Listing Rule 5635(c)(4)), short-term debt or long-term debt of the Company or any of its subsidiaries, or any dividend or distribution of any kind declared, set aside for payment, paid or made by the Company on any class of capital stock, or any material adverse change, or any development that would reasonably be expected to result in a material adverse change, in or affecting the business, properties, management, financial position, stockholders' equity, results of operations of the Company and its subsidiaries taken as a whole; (ii) neither the Company nor any of its subsidiaries has entered into any transaction or agreement (whether or not in the ordinary course of business) that is material to the Company and its subsidiaries taken as a whole or incurred any liability or obligation, direct or contingent, that is material to the Company and its subsidiaries taken as a whole; and (iii) neither the Company nor any of its subsidiaries has sustained any loss or interference with its business that is material to the Company and its subsidiaries taken as a whole and that is either from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor disturbance or dispute or any action, order or decree of any court or arbitrator or governmental or regulatory authority.

- 4.13 <u>Offering</u>. Subject to the accuracy of the Investor's representations set forth in Sections 5.5, 5.6, 5.7, 5.9, and 5.10 hereof, the offer, sale and issuance of the Shares to be issued in conformity with the terms of this Agreement constitute transactions which are exempt from the registration requirements of the Securities Act and from all applicable state registration or qualification requirements. Neither the Company nor any Person acting on its behalf will take any action that would cause the loss of such exemption.
- 4.14 <u>No Integration</u>. The Company has not, directly or through any agent, sold, offered for sale, solicited offers to buy or otherwise negotiated in respect of, any security (as defined in the Securities Act), that is or will be integrated with the sale of the Shares in a manner that would require registration of the Shares under the Securities Act.
- 4.15 <u>Brokers' or Finders' Fees</u>. Except with respect to the Company Financial Advisors, neither the Company nor any of its subsidiaries is a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against the Company or any of its subsidiaries for a brokerage commission, finder's fee or like payment in connection with the transactions contemplated by the Transaction Agreements and the Collaboration Agreement.
- 4.16 <u>Investment Company</u>. The Company is not and, immediately after giving effect to the offering and sale of the Shares and the application of the proceeds thereof, will not be required to register as an "investment company" or an entity "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940, as amended, and the rules and regulations of the SEC thereunder.
- 4.17 <u>No General Solicitation</u>. Neither the Company nor any person acting on behalf of the Company has offered or sold any of the Shares by any form of general solicitation or general advertising. The Company has offered the Shares for sale only to the Investor.
- 4.18 Foreign Corrupt Practices. Neither the Company nor, to the knowledge of the Company, any agent or other person acting on behalf of the Company, has: (i) directly or indirectly used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company (or made by any person acting on its behalf of which the Company is aware) which is in violation of law or (iv) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977, as amended, or any applicable non-U.S. anti-bribery Law.
- 4.19 <u>Regulation M Compliance</u>. The Company has not taken, directly or indirectly, any action designed to or that would reasonably be expected to cause or result in stabilization or manipulation of the price of the Common Stock to facilitate the sale or resale of the Shares.

4.20 <u>Office of Foreign Assets Control</u>. Neither the Company nor, to the Company's knowledge, any director, officer, agent, employee or Affiliate of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

#### 4.21 <u>Development Matters</u>.

- (a) All preclinical and clinical studies conducted by or on behalf of the Company to support approval for commercialization of the Company's products have been conducted by the Company, or to the Company's knowledge by third parties, in compliance with all applicable federal, state or foreign laws, rules, orders and regulations, except for such failure or failures to be in compliance which would not reasonably be expected to have, singly or in the aggregate, a Material Adverse Effect.
- The studies, tests and preclinical or clinical trials conducted by or on behalf of the Company that are described in the Company SEC Documents (the "Company Studies and Trials") were and, if still pending, are being, conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to, where applicable, accepted professional scientific standards; the descriptions of the results of the Company Studies and Trials contained in the Company SEC Documents are accurate in all material respects; the Company has no knowledge of any other studies or trials not described in the Company SEC Documents, the results of which are inconsistent with or call in question the results described or referred to in the Company SEC Documents; and the Company has not received any notices or correspondence from the United States Food and Drug Administration (the "FDA") or any foreign, state or local governmental authority exercising comparable authority requiring the termination, suspension or material modification of any Company Studies and Trials that termination, suspension or material modification would reasonably be expected to have a Material Adverse Effect and, to the Company's knowledge, there are no reasonable grounds for the same. The Company has obtained (or caused to be obtained) informed consent by or on behalf of each human subject who participated in the Company Studies and Trials. To the Company's knowledge, none of the Company Studies and Trials involved any investigator who has been disqualified as a clinical investigator or has been found by the FDA to have engaged in scientific misconduct. To the Company's knowledge, the manufacturing facilities and operations of its suppliers are operated in compliance in all material respects with all applicable statutes, rules, regulations and policies of the FDA and comparable governmental authorities outside of the United States to which the Company is subject.
- 4.22 <u>Intellectual Property</u>. The Company owns, possesses, or can acquire on reasonable terms the right to use all (i) patents, patent applications, trademarks, trademark registrations, service marks, service mark registrations, Internet domain name registrations, copyrights, copyright registrations, licenses and trade secret rights (collectively, "**Intellectual Property Rights**") and (ii) inventions, software, works of authorships, trademarks, service marks, trade names, databases, formulae, know how, Internet domain names and other intellectual property (including trade secrets and other unpatented and/or unpatentable proprietary confidential information, systems, or

procedures) (collectively, "Intellectual Property Assets") necessary to conduct its business as currently conducted, and as proposed to be conducted and described in the SEC Documents. The Company has not received any opinion from its legal counsel concluding that any activities of its business infringes, misappropriates, or otherwise violates, valid and enforceable Intellectual Property Rights of any other person, and has not received written notice of any challenge, which is to its knowledge still pending, by any other person to the rights of the Company with respect to any Intellectual Property Rights or Intellectual Property Assets owned or used by the Company. To the Company's knowledge, the Company's business as now conducted does not give rise to any infringement of, any misappropriation of, or other violation of, any valid and enforceable Intellectual Property Rights of any other person. All licenses for the use of the Intellectual Property Rights described in the SEC Documents are valid, binding upon, and enforceable by or against the Company, and to the Company's knowledge, by or against the parties thereto in accordance with their terms. The Company has complied in all material respects with, and is not in breach of, nor has it received any asserted or threatened claim of breach of any intellectual property licenses for the use of the Intellectual Property Rights, and the Company has no knowledge of any breach or anticipated breach by any other person of any such intellectual property licenses. No claim has been made or is pending against the Company alleging the infringement by the Company of any patent, trademark, service mark, trade name, copyright, trade secret, license in or other intellectual property right or franchise right of any person. The Company has taken reasonable steps to protect, maintain and safeguard its Intellectual Property Rights, including the execution of appropriate nondisclosure and confidentiality agreements. The consummation of the transactions contemplated by this Agreement will not result in the loss or impairment of or payment of any additional amounts with respect to, nor require the consent of any other person in respect of, the Company's right to own, use, or hold for use any of the Intellectual Property Rights as owned, used or held for use in the conduct of the business as currently conducted. The Company has at all times complied in all material respects with all applicable laws relating to privacy, data protection, and the collection and use of personal information collected, used, or held for use by the Company in the conduct of the Company's business. No claims have been asserted or threatened against the Company alleging a violation of any person's privacy or personal information or data rights and the consummation of the transactions contemplated hereby will not breach or otherwise cause any violation of any law related to privacy, data protection, or the collection and use of personal information collected, used, or held for use by the Company in the conduct of the Company's business. The Company takes reasonable measures to ensure that such information is protected against unauthorized access, use, modification or other misuse. The Company has taken all necessary actions to secure and record its ownership of all works of authorship and inventions made by its employees, consultants and contractors with an obligation of assignment during the time they were employed by or under contract with the Company and which relate to the Company's business. All founders and key employees have signed confidentiality and invention assignment agreements with the Company.

4.23 <u>Real and Personal Property</u>. The Company has good and marketable title in fee simple (in the case of real property) to, or has valid and marketable

rights to lease or otherwise use, all items of real or personal property, which are material to the business of the Company taken as a whole, in each case free and clear of all liens, encumbrances, security interests, claims and defects that do not, singularly or in the aggregate, materially affect the value of such property and do not interfere with the use made and proposed to be made of such property by the Company; and all of the leases and subleases material to the business of the Company, and under which the Company holds properties described in the SEC Documents, are in full force and effect and the Company has not received any notice of any material claim of any sort that has been asserted by anyone adverse to the rights of the Company under any of the leases or subleases mentioned above, or affecting or questioning the rights of the Company to the continued possession of the leased or subleased premises under any such lease or sublease.

- 4.24 <u>Labor and Employment</u>. There is (a) no unfair labor practice complaint pending against the Company, nor to the Company's knowledge, threatened against it, before the National Labor Relations Board, any state or local labor relations board or any foreign labor relations board, and no significant grievance or significant arbitration proceeding arising out of or under any collective bargaining agreement is so pending against the Company, or, to the Company's knowledge, threatened against it and (b) no labor disturbance by or dispute with, employees of the Company exists or, to the Company's knowledge, is contemplated or threatened, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its principal suppliers, manufacturers, customers or contractors, that would reasonably be expected, singularly or in the aggregate, to have a Material Adverse Effect. The Company is not aware that any key employee or significant group of employees of the Company plans to terminate employment with the Company.
- 4.25 ERISA Matters. No "prohibited transaction" (as defined in Section 406 of the Employee Retirement Income Security Act of 1974, as amended, including the regulations and published interpretations thereunder ("ERISA"), or Section 4975 of the Internal Revenue Code of 1986, as amended from time to time (the "Code")) or "accumulated funding deficiency" (as defined in Section 302 of ERISA) or any of the events set forth in Section 4043(b) of ERISA (other than events with respect to which the thirty (30)-day notice requirement under Section 4043 of ERISA has been waived) has occurred or could reasonably be expected to occur with respect to any employee benefit plan of the Company which would, singularly or in the aggregate, reasonably be expected to have a Material Adverse Effect. Each employee benefit plan of the Company is in compliance in all material respects with applicable law, including ERISA and the Code. The Company has not incurred and would not reasonably be expected to incur liability under Title IV of ERISA with respect to the termination of, or withdrawal from, any pension plan (as defined in ERISA). Each pension plan for which the Company would have any liability that is intended to be qualified under Section 401(a) of the Code is so qualified, and nothing has occurred, whether by action or by failure to act, which would, singularly or in the aggregate, reasonably be expected to cause the loss of such qualification.

- 4.26 <u>Environmental Matters</u>. The Company is in compliance in all material respects with all foreign, federal, state and local rules, laws and regulations relating to the use, treatment, storage and disposal of hazardous or toxic substances or waste and protection of health and safety or the environment which are applicable to its businesses (the "**Environmental Laws**"). There has been no storage, generation, transportation, handling, treatment, disposal, discharge, emission, or other release of any kind of toxic or other wastes or other hazardous substances by, due to, or caused by the Company (or, to the Company's knowledge, any other entity for whose acts or omissions the Company is or may otherwise be liable) upon any of the property now or previously owned or leased by the Company, or upon any other property, in violation of any law, statute, ordinance, rule, regulation, order, judgment, decree or permit or which would, under any law, statute, ordinance, rule (including rule of common law), regulation, order, judgment, decree or permit, give rise to any liability; and there has been no disposal, discharge, emission or other release of any kind on to such property or into the environment surrounding such property of any toxic or other wastes or other hazardous substances.
- 4.27 Taxes. The Company (i) has timely filed all necessary federal, state, local and foreign tax returns (or timely filed extensions with respect to such returns), and all such returns were true, complete and correct, (ii) has paid all federal, state, local and foreign taxes, assessments, governmental or other charges due and payable for which it is liable, including, without limitation, all sales and use taxes and all taxes which the Company is obligated to withhold from amounts owing to employees, creditors and third parties, and (iii) does not have any tax deficiency or claims outstanding or assessed or, to its knowledge, proposed against it, except those, in each of the cases described in clauses (i), (ii) and (iii) above, that would not, singularly or in the aggregate, reasonably be expected to have a Material Adverse Effect. The Company has not engaged in any transaction which is a corporate tax shelter or which could be characterized as such by the Internal Revenue Service or any other taxing authority. The accruals and reserves on the books and records of the Company in respect of tax liabilities for any taxable period not yet finally determined are adequate to meet any assessments and related liabilities for any such period, and since January 1, 2017, the Company has not incurred any liability for taxes other than in the ordinary course.
- 4.28 <u>Insurance</u>. The Company carries or is covered by, insurance in such amounts and covering such risks as is adequate for the conduct of its business and the value of its properties and as is customary for companies engaged in similar businesses, at a similar stage of development, in similar industries. The Company has no reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not reasonably be expected to have a Material Adverse Effect. All policies of insurance owned by the Company are, to the Company's knowledge, in full force and effect and the Company is in compliance in all material respects with the terms of such policies. The Company has not received written notice from any insurer, agent of such insurer or the broker of the Company that any material capital improvements or any other material expenditures (other than premium

payments) are required or necessary to be made in order to continue such insurance. Except for customary deductibles, the Company does not insure risk of loss through any captive insurance, risk retention group, reciprocal group or by means of any fund or pool of assets specifically set aside for contingent liabilities other than as described in the SEC Documents.

- 5. <u>Representations and Warranties of the Investor</u>. The Investor hereby represents and warrants to the Company that:
  - 5.1 <u>Organization; Good Standing</u>. The Investor is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. The Investor has all requisite corporate power and corporate authority to enter into the Transaction Agreements, to purchase the Shares and to perform its obligations under and to carry out the other transactions contemplated by the Transaction Agreements.

#### 5.2 <u>Authorization</u>.

- (a) The Investor has full right, power and authority to execute and deliver the Transaction Agreements and the Collaboration Agreement and to perform its obligations hereunder and thereunder; and all action required to be taken for the due and proper authorization, execution and delivery by it of each of the Transaction Agreements and the Collaboration Agreement and the consummation by it of the transactions contemplated thereby has been duly and validly taken.
- (b) The Transaction Agreements and the Collaboration Agreement have been duly executed and delivered by the Investor and, upon the due execution and delivery of the Transaction Agreements and the Collaboration Agreement by the Company, will constitute valid and legally binding obligations of the Investor, enforceable against the Investor in accordance with their respective terms, except with respect to the Enforceability Exceptions.
- Agreements and the Collaboration Agreement, the subscription for and purchase of the Shares and the consummation of the transactions contemplated by the Transaction Agreements and the Collaboration Agreement will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Investor pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Investor is a party, by which the Investor is bound or to which any of the property or assets of the Investor is subject, (ii) result in any violation of the provisions of the charter or by-laws or similar organizational documents of the Investor or (iii) result in the violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority having jurisdiction over the Investor or any of its subsidiaries, except, in the case of clauses (i) and (iii) above, for any such conflict, breach, violation or default that would not, individually or in the aggregate, have a material adverse effect on

the Investor's ability to perform its obligations or consummate the Transaction in accordance with the terms of this Agreement.

- 5.4 <u>No Governmental Authority or Third Party Consents</u>. No consent, approval, authorization, order, license, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Investor of each of the Transaction Agreements or the Collaboration Agreement or with the subscription for and purchase of the Shares, except as required pursuant to the HSR Act.
- 5.5 Purchase Entirely for Own Account. The Investor acknowledges that the Shares shall be acquired for investment for the Investor's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and the Investor has no present intention of selling, granting any participation or otherwise distributing the Shares. The Investor can bear the economic risk of an investment in the Shares indefinitely and a total loss with respect to such investment. The Investor does not have and will not have as of the Closing any contract, undertaking, agreement, arrangement or understanding with any Person to sell, transfer or grant participation to a Person any of the Shares.
- 5.6 <u>Disclosure of Information</u>. The Investor has received or has had full access to all the information from the Company and its management that the Investor considers necessary or appropriate for deciding whether to purchase the Shares hereunder. The Investor further represents that it has had an opportunity to ask questions and receive answers from the Company regarding the Company, its financial condition, results of operations and prospects and the terms and conditions of the offering of the Shares sufficient to enable it to evaluate its investment.
- 5.7 <u>Investment Experience and Accredited Investor Status</u>. The Investor is an "accredited investor" (as defined in Regulation D under the Securities Act). The Investor has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares to be purchased hereunder.
- 5.8 <u>Acquiring Person</u>. As of the Signing Date, neither the Investor nor any of its Affiliates beneficially owns, and immediately prior to the Closing, neither the Investor nor any of its Affiliates will beneficially own (in each case, as determined pursuant to Rule 13d-3 under the Exchange Act without regard for the number of days in which a Person has the right to acquire such beneficial ownership, and without regard to Investor's rights under this Agreement), any securities of the Company, except for securities that may be beneficially owned by employee benefit plans of either the Investor or any of its Affiliates.
- 5.9 Restricted Securities. The Investor understands that the Shares, when issued, shall be "restricted securities" under the federal securities Laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such Laws the Shares may be resold without registration under

the Securities Act only in certain limited circumstances. The Investor represents that it is familiar with Rule 144, as presently in effect.

- 5.10 <u>Legends</u>. The Investor understands that any certificates representing the Shares shall bear the following legends:
- (a) "THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF A REGISTRATION STATEMENT IN EFFECT WITH RESPECT TO THE SECURITIES UNDER THE SECURITIES ACT OR AN OPINION OF COUNSEL (WHICH COUNSEL SHALL BE REASONABLY SATISFACTORY TO THE COMPANY) THAT SUCH REGISTRATION IS NOT REQUIRED OR UNLESS SOLD PURSUANT TO RULE 144 OF THE SECURITIES ACT.";
- (b) "THE SECURITIES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO AND SHALL BE TRANSFERABLE ONLY UPON THE TERMS AND CONDITIONS OF AN INVESTOR AGREEMENT DATED AS OF JANUARY 28, 2019, BY AND BETWEEN VOYAGER THERAPEUTICS, INC. AND NEUROCRINE BIOSCIENCES, INC., A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF VOYAGER THERAPEUTICS, INC."; and
- (c) any legend required by applicable state securities Laws or the other Transaction Agreements.
- 5.11 <u>Financial Assurances</u>. As of the Signing Date, the Investor has, and as of the Closing Date, the Investor will have, access to cash in an amount sufficient to pay to the Company the Aggregate Purchase Price.
  - 5.12 <u>SEC Reports</u>. The Investor has reviewed the Company SEC Documents.
- 6. <u>Investor's Conditions to Closing</u>. The Investor's obligation to purchase the Shares at the Closing is subject to the fulfillment as of the Closing of the following conditions (unless waived in writing by the Investor):
  - Representations and Warranties. The representations and warranties made by the Company in Section 4 hereof shall be true and correct as of the Signing Date and as of the Closing Date as though made on and as of such Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date; provided, however, that for purposes of this Section 6.1, all such representations and warranties of the Company (other than Sections 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, and 4.11 hereof) shall be deemed to be true and correct for purposes of this Section 6.1 unless the failure or failures of such representations and warranties to be so true and correct, without regard to any "material," "materiality" or "Material Adverse Effect" qualifiers set forth therein, constitute a Material Adverse Effect.

- 6.2 Representations and Warranties in the Collaboration Agreement. The representations and warranties made by the Company in Section 12.2 of the Collaboration Agreement shall be true and correct as of the Closing Date as though made on and as of such Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date; provided, however, that for purposes of this Section 6.2, all such representations and warranties of the Company shall be deemed to be true and correct for purposes of this Section 6.2 unless the failure or failures of such representations and warranties to be so true and correct, without regard to any "material" or "materiality" qualifiers set forth therein, individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect.
- 6.3 <u>Covenants</u>. All covenants and agreements contained in this Agreement to be performed or complied with by the Company on or prior to the Closing Date shall have been performed or complied with in all material respects.
- 6.4 <u>Investor Agreement</u>. The Investor Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect.
- 6.5 <u>Collaboration Agreement</u>. The Collaboration Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect as of the Closing Date.
- 6.6 <u>No Material Adverse Effect</u>. From and after the Signing Date until the Closing Date, there shall have occurred no event that has caused a Material Adverse Effect.
- 6.7 <u>Listing</u>. The Shares shall be eligible and approved for listing on the Nasdaq Stock Market.
- 7. <u>Company's Conditions to Closing</u>. The Company's obligation to issue and sell the Shares at the Closing is subject to the fulfillment as of the Closing of the following conditions (unless waived in writing by the Company):
  - 7.1 <u>Representations and Warranties</u>. The representations and warranties made by the Investor in Section 5 hereof shall be true and correct as of the Signing Date and as of the Closing Date as though made on and as of such Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date.
  - 7.2 <u>Covenants</u>. All covenants and agreements contained in this Agreement to be performed or complied with by the Investor on or prior to the Closing Date shall have been performed or complied with in all material respects.
  - 7.3 <u>Investor Agreement</u>. The Investor Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect.

- 7.4 <u>Collaboration Agreement</u>. The Collaboration Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect.
- 8. <u>Mutual Conditions to Closing</u>. The obligations of the Investor and the Company to consummate the Closing are subject to the fulfillment as of the Closing Date of the following conditions:
  - 8.1 <u>HSR Act Qualification</u>. Any required HSR Clearances shall have been obtained.
  - 8.2 Absence of Litigation. There shall be no action, suit, proceeding or investigation by a Governmental Authority pending or currently threatened in writing against the Company or the Investor (i) that questions (A) the validity of any Transaction Agreement or (B) the right of the Company or the Investor to enter into any Transaction Agreement or to consummate the transactions contemplated hereby or thereby or (ii) which, if determined adversely, would impose substantial monetary damages on the Company or the Investor as a result of the consummation of the transactions contemplated by any Transaction Agreement.
  - 8.3 <u>No Prohibition</u>. No provision of any applicable Law and no judgment, injunction (preliminary or permanent), order or decree that prohibits, makes illegal or enjoins the consummation of the Transaction shall be in effect.

### 9. <u>Termination</u>.

- 9.1 <u>Ability to Terminate</u>. This Agreement may be terminated at any time prior to the Closing by:
  - (a) mutual written consent of the Company and the Investor;
- (b) either the Company or the Investor, upon written notice to the other, if any of the mutual conditions to the Closing set forth in Section 8 hereof shall have become incapable of fulfillment by the Termination Date and shall not have been waived in writing by the other party within ten business days after receiving receipt of written notice of an intention to terminate pursuant to this clause (b); provided, however, that the right to terminate this Agreement under this Section 9.1(b) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been the cause of, or resulted in, the failure to consummate the transactions contemplated hereby prior to the Termination Date;
- (c) the Company, upon written notice to the Investor, so long as the Company is not then in breach of its representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 6.1, 6.2, 6.3, 6.4 or 6.5 hereof, as applicable, could not be satisfied by the Termination Date, (i) upon a material breach of any covenant or agreement on the part of the Investor set forth in this Agreement, or (ii) if any representation or warranty of the Investor shall have

been or become untrue, in each case such that any of the conditions set forth in Section 7.1, 7.2, 7.3 or 7.4 hereof, as applicable, could not be satisfied by the Termination Date;

- (d) the Investor, upon written notice to the Company, so long as the Investor is not then in breach of its representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 7.1, 7.2, 7.3, or 7.4 hereof, as applicable, could not be satisfied by the Termination Date, (i) upon a material breach of any covenant or agreement on the part of the Company set forth in this Agreement, or (ii) if any representation or warranty of the Company shall have been or become untrue, in each case such that any of the conditions set forth in Section 6.1, 6.2, 6.3, 6.4 or 6.5 hereof, as applicable, could not be satisfied by the Termination Date.
- 9.2 <u>Effect of Termination</u>. In the event of the termination of this Agreement pursuant to Section 9.1 hereof, (i) this Agreement (except for this Section 9.2 and Section 11 hereof (other than Section 11.12), and any definitions set forth in this Agreement and used in such sections) shall forthwith become void and have no effect, without any liability on the part of any party hereto or its Affiliates, and (ii) all filings, applications and other submissions made pursuant to this Agreement, to the extent practicable, shall be withdrawn from the agency or other Person to which they were made or appropriately amended to reflect the termination of the transactions contemplated hereby; <u>provided</u>, <u>however</u>, that nothing contained in this Section 9.2 shall relieve any party from liability for fraud or any intentional or willful breach of this Agreement.

#### 10. Additional Covenants and Agreements.

- 10.1 <u>Market Listing</u>. From the Signing Date through the Closing Date, Company shall use all commercially reasonable efforts to (i) maintain the listing and trading of the Common Stock on the Nasdaq Stock Market and (ii) effect the listing of the Shares on the Nasdaq Stock Market, including submitting the LAS to the Nasdaq Stock Market no later than fifteen (15) calendar days prior to the Closing Date.
- 10.2 Notification under the HSR Act. Each party will use reasonable efforts to do, or cause to be done, all things necessary, proper and advisable to, as promptly as practicable, take all actions necessary to make the filings required of such party or its Affiliates under the HSR Act, including filing with the FTC and Antitrust Division of the DOJ within ten (10) Business Days of the Signing Date (or such later time as may be agreed to in writing by the parties). The parties shall cooperate with one another to the extent necessary in the preparation of any such HSR Filing and during the review by the FTC and/or the Antitrust Division of the DOJ. Each party shall be responsible for its own costs, expenses, and filing fees associated with any HSR Filing; provided, however, that the Investor shall be solely responsible for any fees (other than penalties that may be incurred as a result of actions or omissions on the part of the Company) required to be paid to any Governmental Agency in connection with making any such HSR Filing. This Agreement shall terminate at the election of either party, immediately upon notice to the other party, if the FTC or the DOJ seeks a preliminary injunction (or its equivalent) in connection therewith against the Investor and the

Company to enjoin the transactions contemplated hereby and thereby. In the event of such termination, this Agreement shall be of no further force and effect.

10.3 <u>Assistance and Cooperation</u>. Prior to the Closing, upon the terms and subject to the conditions set forth in this Agreement, each of the parties agrees to use all reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, and to assist and cooperate with the other party in doing, all things necessary, proper or advisable to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated by this Agreement, including using all reasonable efforts to accomplish the following: (i) taking all reasonable acts necessary to cause the conditions precedent set forth in Sections 6, 7 and 8 hereof to be satisfied (including, in the case of the Company, promptly notifying the Investor of any notice from the Nasdaq Stock Market with respect to the LAS); (ii) taking all reasonable actions necessary to obtain all necessary actions or non-actions, waivers, consents, approvals, orders and authorizations from Governmental Authorities and the making of all necessary registrations, declarations and filings (including registrations, declarations and filings with Governmental Authorities, if any); (iii) taking all reasonable actions necessary to obtain all necessary consents, approvals or waivers from Third Parties; and (iv) except as otherwise provided for in Section 10.2 hereof, defending any suits, claims, actions, investigations or proceedings, whether judicial or administrative, challenging this Agreement or the consummation of the transactions contemplated hereby, including seeking to have any stay or temporary restraining order entered by any court or other Governmental Authority vacated or reversed.

#### 10.4 <u>Legend Removal</u>.

- (a) Certificates evidencing the Shares shall not contain the legend set forth in Section 5.10(a) hereof: (i) following a sale of such Shares pursuant to a registration statement covering the resale of such Shares, while such registration statement is effective under the Securities Act, (ii) following any sale of such Shares pursuant to Rule 144, (iii) if such Shares are eligible for sale under Rule 144, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such Shares and without volume or manner-of-sale restrictions under Rule 144 or (iv) if such legend is not required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the SEC).
- (b) Certificates evidencing the Shares shall not contain the legend set forth in Section 5.10(b) hereof following: (i) a sale of such Shares pursuant to a registration statement covering the resale of such Shares, while such registration statement is effective under the Securities Act, (ii) any sale of such Shares pursuant to Rule 144 or (iii) the expiration of the Standstill Term (as defined in the Investor Agreement), the Lock-Up Term (as defined in the Investor Agreement) and the Voting Agreement Term (as defined in the Investor Agreement); provided that any transfer described in clause (i) or (ii) above shall have been in compliance with all applicable provisions of the Investor Agreement.

- (c) The Company agrees that at such time as any legend set forth in Section 5.10 hereof is no longer required under this Section 10.4, the Company will, no later than three (3) Business Days following the delivery by the Investor to the Company or notice by the Investor to the Company of delivery by the Investor to the Transfer Agent of a certificate representing Shares issued with such legend (together with any legal opinion required by the Transfer Agent), deliver or cause to be delivered to the Investor a certificate representing such Shares that is free from such legend, or, in the event that such shares are uncertificated, remove any such legend in the Company's stock records. The Company may not make any notation on its records or give instructions to the Transfer Agent that enlarge the restrictions on transfer set forth in Section 5.10 hereof.
- 10.5 <u>Conduct of Business</u>. During the period from the Signing Date until the Closing, except as consented to in writing by the Investor, the Company shall not (i) declare, set aside or pay any dividend or make any other distribution or payment (whether in cash, stock or property or any combination thereof) in respect of its capital stock, or establish a record date for any of the foregoing, or (ii) make any other actual, constructive or deemed distribution in respect of any shares of its capital stock or otherwise make any payments to stockholders in their capacity as such, except pursuant to repurchases of equity pursuant to the terms of its equity compensation plans.

#### 11. Miscellaneous.

- 11.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of Delaware, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Any action brought, arising out of, or relating to this Agreement shall be brought in the Court of Chancery of the State of Delaware. Each party hereby irrevocably submits to the exclusive jurisdiction of said Court in respect of any claim relating to the validity, interpretation and enforcement of this Agreement, and hereby waives, and agrees not to assert, as a defense in any action, suit or proceeding in which any such claim is made that it is not subject thereto or that such action, suit or proceeding may not be brought or is not maintainable in such courts, or that the venue thereof may not be appropriate or that this agreement may not be enforced in or by such courts. The parties hereby consent to and grant the Court of Chancery of the State of Delaware jurisdiction over such parties and over the subject matter of any such claim and agree that mailing of process or other papers in connection with any such action, suit or proceeding in the manner provided in Section 11.3 hereof or in such other manner as may be permitted by law, shall be valid and sufficient thereof.
- 11.2 <u>Waiver</u>. Neither party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either party to assert a right hereunder or to insist upon compliance with any term of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term except to the extent set forth in writing.

- 11.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth on Exhibit A attached hereto and shall be (i) delivered personally; (ii) sent by certified mail (return receipt requested), postage prepaid; or (iii) sent via a reputable nationwide overnight express courier service (signature required). Any such notice, instruction or communication shall be deemed to have been delivered (A) upon receipt if delivered by hand; (B) three (3) Business Days after it is sent by certified mail, return receipt requested, postage prepaid; or (C) one (1) Business Day after it is sent via a reputable nationwide overnight courier service. Either party may change its address by giving notice to the other party in the manner provided above; provided that notices of a change of address shall be effective only upon receipt thereof.
- Agreement, in each case together with the schedules and exhibits thereto, set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the parties and supersede and terminate all prior agreements and understanding between the parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the parties other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the parties unless reduced to writing and signed by the respective authorized officers of the parties.
- 11.5 <u>Headings; Nouns and Pronouns; Section References</u>. Headings and any table of contents used in this Agreement are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.
- 11.6 <u>Severability</u>. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("**Modified Clause**"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; <u>provided</u> that the parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.
- 11.7 <u>Assignment</u>. Except for an assignment of this Agreement or any rights hereunder by the Investor to an Affiliate, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either the Investor or the Company without (i) the prior written consent of Company in the case of any assignment by the

Investor or (ii) the prior written consent of the Investor in the case of an assignment by the Company.

- 11.8 <u>Parties in Interest</u>. All of the terms and provisions of this Agreement shall be binding upon, and shall inure to the benefit of and be enforceable by the parties hereto and their respective successors, heirs, administrators and permitted assigns.
- 11.9 <u>Counterparts</u>. This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies from separate computers or printers. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.
- 11.10 <u>Third Party Beneficiaries</u>. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any party hereto.
- 11.11 <u>No Strict Construction</u>. This Agreement has been prepared jointly and will not be construed against either party.
- 11.12 <u>Survival of Warranties</u>. The representations and warranties of the Company and the Investor contained in this Agreement shall survive the Closing and the delivery of the Shares.
- 11.13 <u>Remedies</u>. The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or Law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.
- 11.14 <u>Expenses</u>. Each party shall pay its own fees and expenses in connection with the preparation, negotiation, execution and delivery of the Transaction Agreements.
- 11.15 <u>No Publicity</u>. The parties hereto agree that the provisions of Section 11.3 of the Collaboration Agreement shall be applicable to the parties to this Agreement with respect to any public disclosures regarding the proposed transactions contemplated by the Transaction Agreements and the Collaboration Agreement or regarding the parties hereto or their Affiliates (it being understood that the provisions of Section 11.3 of the Collaboration Agreement shall be read to apply to disclosures of information relating to this Agreement and the transactions contemplated hereby).

(Signature Page Follows)

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

# NEUROCRINE BIOSCIENCES, INC.

By:/s/ Kevin Gorman

Name: Kevin Gorman

Title: CEO

### VOYAGER THERAPEUTICS, INC.

By:/s/ G. Andre Turenne

Name: G. Andre Turenne

Title: President and Chief Executive Officer

(Signature Page to Stock Purchase Agreement)

# SCHEDULE 1

# LIST OF SUBSIDIARIES

1. Voyager Securities Corporation, a Massachusetts corporation

#### **EXHIBIT A**

## **NOTICES**

## If to the Investor:

Neurocrine Biosciences, Inc. 12780 El Camino Real San Diego, CA 92130 Attention: General Counsel

## with a copy to:

Cooley LLP 4401 Eastgate Mall San Diego, CA 92121 Attention: Jason L. Kent, Esq.

## If to the Company:

Voyager Therapeutics, Inc. 75 Sidney Street Cambridge, MA 02139 Attention: Chief Executive Officer

## with a copy to:

Wilmer Cutler Pickering Hale and Dorr LLP 7 World Trade Center 250 Greenwich Street New York, NY 10007 Attention: Brian A. Johnson, Esq.

# Exhibit B VOYAGER LICENSED PATENT RIGHTS

## **Exhibit B**

| Voyager Ref | Status | Application No. | Filing            | Assignment  | Named Inventors | Application Title |
|-------------|--------|-----------------|-------------------|-------------|-----------------|-------------------|
|             |        | Publication No. | Date/             | Recordation |                 |                   |
|             |        | Patent No.      | Pub Date/         | Date;       |                 |                   |
|             |        |                 | <b>Issue Date</b> | Reel/Frame  |                 |                   |
| [**]        | [**]   | [**]            | [**]              | [**]        | [**]            | [**]              |

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 11 pages were omitted. [\*\*]

#### \*Status Key

**Abandoned**: Application has been abandoned; **Allowed**: Application has been allowed by the Patent/Trademark Office; **Completed**: Follow on case filed by 12-month US/FF conversion deadline; **Expired**: Application and/or Patent has expired; **Granted**: Application has been granted as a Patent; **Nat'l Phase**: PCT has entered National Phase countries; **Pending**: Application filed but not yet published; **Published**: Application has been published by the Patent Office; **Registered**: Application has registered by the Trademark Office; **Refused**: EPO's Decision not to grant a patent because it does not fulfill the necessary requirements; **Withdrawn**: Application has been withdrawn from publication and has lapsed

# Exhibit C

# SCHEDULE OF EXCEPTIONS

None.

## **EXECUTION VERSION**

STOCK PURCHASE AGREEMENT

By and Between

NEUROCRINE BIOSCIENCES, INC.

AND

VOYAGER THERAPEUTICS, INC.

Dated as of January 28, 2019

## TABLE OF CONTENTS

|    |       |  | Page |
|----|-------|--|------|
| 1. | Defii | nitions.   | 1    |
|    |       | Defined Terms  | 1    |
|    | 1.2   | Additional Defined Terms   | 4    |
| 2. | Purcl | hase and Sale of Common Stock.                                   | 5    |
|    |       | General  | 5    |
|    | 2.2   | Calculation  | 5    |
| 3. | Closi | ing Date; Deliveries.  | 5    |
|    |       | Closing Date   | 5    |
|    | 3.2   | Deliveries   | 5    |
| 4. | Repr  | resentations and Warranties of the Company                       | 6    |
|    | 4.1   | Organization, Good Standing and Qualification                    | 6    |
|    | 4.2   | Capitalization and Voting Rights                                 | 6    |
|    | 4.3   | Subsidiaries   | 7    |
|    | 4.4   | Authorization  | 7    |
|    | 4.5   | No Defaults  | 8    |
|    | 4.6   | No Conflicts   | 8    |
|    | 4.7   | No Governmental Authority or Third Party Consents                | 8    |
|    | 4.8   | Valid Issuance of Shares   | 9    |
|    | 4.9   | Litigation   | 9    |
|    | 4.10  | Licenses and Other Rights; Compliance with Laws                  | 9    |
|    | 4.11  | Company SEC Documents; Financial Statements; Nasdaq Stock Market | 9    |
|    | 4.12  | Absence of Certain Changes                                       | 11   |
|    | 4.13  | Offering   | 12   |
|    |       | No Integration   | 12   |
|    | 4.15  | Brokers' or Finders' Fees  | 12   |
|    | 4.16  | Investment Company   | 12   |
|    | 4.17  | No General Solicitation  | 12   |
|    | 4.18  | Foreign Corrupt Practices  | 12   |
|    | 4.19  | Regulation M Compliance  | 12   |
|    | 4.20  | Office of Foreign Assets Control.                                | 13   |
|    | 4.21  | Development Matters  | 13   |

|    | 4.22  | Intellectual Property   | 13 |
|----|-------|---|----|
|    |       | Real and Personal Property                                    | 14 |
|    | 4.24  | Labor and Employment  | 15 |
|    |       | ERISA Matters   | 15 |
|    | 4.26  | Environmental Matters   | 16 |
|    | 4.27  | Taxes   | 16 |
|    | 4.28  | Insurance   | 16 |
| 5. | Repre | esentations and Warranties of the Investor                    | 17 |
|    | 5.1   | Organization; Good Standing                                   | 17 |
|    | 5.2   | Authorization   | 17 |
|    | 5.3   | No Conflicts  | 17 |
|    | 5.4   | No Governmental Authority or Third Party Consents             | 18 |
|    | 5.5   | Purchase Entirely for Own Account                             | 18 |
|    | 5.6   | Disclosure of Information                                     | 18 |
|    | 5.7   | Investment Experience and Accredited Investor Status          | 18 |
|    | 5.8   | Acquiring Person  | 18 |
|    | 5.9   | Restricted Securities   | 18 |
|    | 5.10  | Legends   | 19 |
|    | 5.11  | Financial Assurances  | 19 |
|    | 5.12  | SEC Reports   | 19 |
| 6. |       | tor's Conditions to Closing                                   | 19 |
|    | 6.1   | Representations and Warranties                                | 19 |
|    | 6.2   | Representations and Warranties in the Collaboration Agreement | 20 |
|    | 6.3   | Covenants   | 20 |
|    | 6.4   | Investor Agreement  | 20 |
|    | 6.5   | Collaboration Agreement                                       | 20 |
|    | 6.6   | No Material Adverse Effect                                    | 20 |
|    | 6.7   | Listing   | 20 |
| 7. | Comp  | pany's Conditions to Closing                                  | 20 |
|    | 7.1   | Representations and Warranties                                | 20 |
|    | 7.2   | Covenants   | 20 |
|    | 7.3   | Investor Agreement  | 20 |
|    | 7.4   | Collaboration Agreement                                       | 21 |

| 8.  | Mutua  | al Conditions to Closing                         | 21 |
|-----|--------|--|----|
|     |        | HSR Act Qualification                            | 21 |
|     | 8.2    | Absence of Litigation                            | 21 |
|     | 8.3    | No Prohibition                                   | 21 |
| 9.  | Termi  | nation   | 21 |
|     | 9.1    | Ability to Terminate                             | 21 |
|     | 9.2    | Effect of Termination                            | 22 |
| 10. | Additi | ional Covenants and Agreements                   | 22 |
|     | 10.1   | Market Listing                                   | 22 |
|     | 10.2   | Notification under the HSR Act                   | 22 |
|     | 10.3   | Assistance and Cooperation                       | 23 |
|     | 10.4   | Legend Removal                                   | 23 |
|     | 10.5   | Conduct of Business                              | 24 |
| 11. | Misce  | llaneous   | 24 |
|     | 11.1   | Governing Law; Submission to Jurisdiction        | 24 |
|     | 11.2   | Waiver.  | 24 |
|     | 11.3   | Notices  | 25 |
|     | 11.4   | Entire Agreement                                 | 25 |
|     | 11.5   | Headings; Nouns and Pronouns; Section References | 25 |
|     | 11.6   | Severability                                     | 25 |
|     | 11.7   | Assignment                                       | 25 |
|     | 11.8   | Parties in Interest                              | 26 |
|     | 11.9   | Counterparts                                     | 26 |
|     | 11.10  | Third Party Beneficiaries                        | 26 |
|     | 11.11  | No Strict Construction                           | 26 |
|     | 11.12  | Survival of Warranties                           | 26 |
|     | 11.13  | Remedies   | 26 |
|     | 11.14  | Expenses   | 26 |
|     | 11.15  | No Publicity                                     | 26 |

Exhibit A – Notices

#### STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (this "**Agreement**"), dated as of January 28, 2019 (the "**Signing Date**"), by and between Neurocrine Biosciences, Inc. (the "**Investor**"), a Delaware corporation with its principal place of business at 12780 El Camino Real, San Diego, CA 92130, and Voyager Therapeutics, Inc. (the "**Company**"), a Delaware corporation, with its principal place of business at 75 Sidney Street, Cambridge, MA 02139.

WHEREAS, pursuant to the terms and subject to the conditions set forth in this Agreement, the Company desires to issue and sell to the Investor, and the Investor desires to subscribe for and purchase from the Company, certain shares of common stock, par value \$0.001 per share, of the Company (the "Common Stock"); and

WHEREAS, simultaneously with the execution of this Agreement, the Company and the Investor are entering into the Collaboration Agreement and the Investor Agreement.

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for good and valuable consideration, the adequacy and sufficiency of which are hereby acknowledged, the Investor and the Company agree as follows:

#### 1. Definitions.

1.1 <u>Defined Terms</u>. When used in this Agreement, the following terms shall have the respective meanings specified therefor below:

"2014 Stock Option and Grant Plan" shall mean the Company's 2014 Stock Option and Grant Plan, as amended to date and as the same may be amended and/or restated from time to time.

"2015 Employee Stock Purchase Plan" shall mean the Company's 2015 Employee Stock Purchase Plan, as amended to date and as the same may be amended and/or restated from time to time.

"2015 Stock Option and Incentive Plan" shall mean the Company's 2015 Stock Option and Incentive Plan, as amended to date and as the same may be amended and/or restated from time to time.

"Affiliate" shall mean, with respect to any Person, another Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if such Person (ii) owns, directly or indirectly, beneficially or legally, more than fifty percent (50%) of the outstanding voting securities or capital stock of such other Person, or has other comparable ownership interest with respect to any Person other than a corporation; or (ii) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of such other Person. For the purposes of this Agreement, in no

event shall the Investor or any of its Affiliates be deemed Affiliates of the Company or any of its Affiliates, nor shall the Company or any of its Affiliates be deemed Affiliates of the Investor or any of its Affiliates.

- "Aggregate Purchase Price" shall mean \$50,000,000.00.
- "Agreement" shall have the meaning set forth in the Preamble, including all Exhibits attached hereto.
- "Board" shall mean the Board of Directors of the Company.
- **"Business Day"** shall mean a day on which banking institutions in Boston, Massachusetts, United States and San Diego, California, United States are open for business, excluding any Saturday or Sunday.
  - "Closing Conditions" shall mean the conditions to Closing set forth in Sections 6, 7, and 8 hereof.
- "Collaboration Agreement" shall mean the Collaboration and License Agreement, of even date herewith, between the Investor and the Company.
  - "Company Financial Advisors" shall mean Guggenheim Securities, LLC and Chestnut Securities, Inc.
  - "DOJ" shall mean the U.S. Department of Justice.
  - "Effect" shall have the meaning set forth in the definition of "Material Adverse Effect."
- **"Exchange Act"** shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.
  - "FTC" shall mean the U.S. Federal Trade Commission.
  - "GAAP" shall mean generally accepted accounting principles in the United States.
- "Governmental Authority" shall mean any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority or functions of any nature pertaining to government.
- "HSR Act" shall mean the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended from time to time.
- **"HSR Clearance"** shall mean the expiration or termination of all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act.

"HSR Filing" shall mean the filings by the Company and Investor with the FTC and the Antitrust Division of the DOJ of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in the Transaction Agreements and the Collaboration Agreement, together with all required documentary attachments thereto.

"**Investor Agreement**" shall mean that certain Investor Agreement, of even date herewith, between the Investor and the Company.

"LAS" shall mean the Nasdaq Notification Form: Listing of Additional Shares.

"Law" shall mean any law, statute, rule, regulation, order, judgment or ordinance having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision.

"Material Adverse Effect" shall mean any change, event or occurrence (each, an "Effect") that, individually or when taken together with all other Effects that have occurred prior to the date of determination of the occurrence of the Material Adverse Event, has had a material adverse effect on the business, properties, management, financial position, stockholders' equity or results of operations of the Company and its subsidiaries taken as a whole or on the performance by the Company of its obligations under the Transaction Agreements, except to the extent that any such Effect results from or arises out of: (A) changes in conditions in the United States or global economy or capital or financial markets generally, including changes in interest or exchange rates, (B) changes in general legal, regulatory, political, economic or business conditions or changes in generally accepted accounting principles in the United States or interpretations thereof, (C) acts of war, sabotage or terrorism, or any escalation or worsening of any such acts of war, sabotage or terrorism, (D) earthquakes, hurricanes, floods or other natural disasters, (E) the announcement of the Transaction Agreements, the Collaboration Agreement or the Transaction, (F) any change in the Company's stock price or trading volume or any failure to meet internal projections or forecasts or published revenue or earnings projections of industry analysts (provided that the underlying events giving rise to any such change shall not be excluded) or (G) any breach, violation or nonperformance by the Investor or any of its Affiliates under the Collaboration Agreement, provided, however, that the Effects excluded in clauses (A), (B), (C) and (D) shall only be excluded to the extent such Effects are not disproportionately adverse on the Company and its subsidiaries as compared to other companies operating in the Company's industry.

"Per-Share Purchase Price" shall mean \$11.9625.

"**Person**" shall mean any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Governmental Authority or other entity, as well as any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the Exchange Act.

"Rule 144" shall mean Rule 144 promulgated under the Securities Act.

- "Sales Agreement" shall mean that certain Sales Agreement, by and between the Company and Cowen and Company, LLC, dated as of December 1, 2016.
  - "SEC" shall mean the U.S. Securities and Exchange Commission.
- "**Securities Act**" shall mean the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.
- "**Termination Date**" shall mean the date that is one hundred and eighty (180) days after the effective date of the HSR Filing.
- "**Third Party"** shall mean any Person other than the Investor, the Company or any Affiliate of the Investor or the Company.
- "**Transaction**" shall mean the issuance and sale of the Shares by the Company, and the purchase of the Shares by the Investor, in accordance with the terms hereof.
  - "Transaction Agreements" shall mean this Agreement and the Investor Agreement.
  - "Transfer Agent" shall mean the Company's transfer agent.
  - 1.2 <u>Additional Defined Terms</u>. In addition to the terms defined in Section 1.1 hereof, the following terms shall have the respective meanings assigned thereto in the sections indicated below:

| Defined Term          | Section         |
|-----------------------|-----------------|
| Closing               | Section 3.1     |
| Closing Date          | Section 3.1     |
| Common Stock          | Preamble        |
| Company               | Preamble        |
| Company SEC Documents | Section 4.11(a) |
| Investor              | Preamble        |
| Modified Clause       | Section 11.6    |
| Shares                | Section 2.1     |
| Signing Date          | Preamble        |
|                       |                 |

#### 2. Purchase and Sale of Common Stock.

- 2.1 <u>General</u>. Subject to the terms and conditions of this Agreement, at the Closing, the Company shall issue and sell to the Investor and the Investor shall purchase from the Company, a number of shares of Common Stock (the "**Shares**") calculated pursuant to Section 2.2 hereof.
- 2.2 <u>Calculation</u>. The number of Shares shall be 4,179,728, which is calculated by dividing the Aggregate Purchase Price by the Per-Share Purchase Price, rounded down to the nearest whole share.

## 3. <u>Closing Date; Deliveries</u>.

3.1 <u>Closing Date</u>. The closing of the purchase and sale of the Shares hereunder (the "**Closing**") shall take place remotely via the exchange of documents and signatures at 9:00 a.m. New York City time on the second (2nd) Business Day following the satisfaction or waiver of all of the Closing Conditions (other than those conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction at such time of such conditions), or at such other time, date, and location as the parties may agree. The date the Closing occurs is hereinafter referred to as the "**Closing Date**."

#### 3.2 <u>Deliveries</u>.

- Deliveries by the Company. At the Closing, the Company shall deliver, or (a) cause to be delivered, to the Investor the Shares, registered in the name of the Investor, and the Company shall instruct its transfer agent to register such issuance at the time of such issuance. The Company shall also deliver at the Closing: (i) a certificate in form and substance reasonably satisfactory to the Investor and duly executed on behalf of the Company by an authorized executive officer of the Company, certifying that the conditions to Closing set forth in Sections 6 and 8.2 hereof have been fulfilled and (ii) a certificate of the secretary or assistant secretary of the Company dated as of the Closing Date certifying (A) that attached thereto is a true and complete copy of the Amended and Restated By-laws of the Company as in effect at the time of the actions by the Board referred to in clause (B) below and on the Closing Date; (B) that attached thereto is a true and complete copy of all resolutions adopted by the Board authorizing the execution, delivery and performance of the Transaction Agreements and the Transaction and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby and thereby as of the Closing Date; (C) that attached thereto is a true and complete copy of the Company's Fifth Amended and Restated Certificate of Incorporation as in effect at the time of the actions by the Board referred to in clause (B) above and on the Closing Date; and (D) as to the incumbency and specimen signature of any officer of the Company executing a Transaction Agreement on behalf of the Company.
- (b) <u>Deliveries by the Investor</u>. At the Closing, the Investor shall deliver, or cause to be delivered, to the Company the Aggregate Purchase Price by wire transfer of immediately available United States funds to an account designated by

the Company. The Company shall notify the Investor in writing of the wiring instructions for such account not less than two (2) Business Days before the Closing Date. The Investor shall also deliver, or cause to be delivered, at the Closing: (i) a certificate in form and substance reasonably satisfactory to the Company duly executed by an authorized executive officer of the Investor certifying that the conditions to Closing set forth in Section 7 hereof have been fulfilled and (ii) a certificate of the secretary or assistant secretary of the Investor dated as of the Closing Date certifying as to the incumbency and specimen signature of any officer executing a Transaction Agreement on behalf of the Investor.

4. <u>Representations and Warranties of the Company</u>. The Company hereby represents and warrants to the Investor that:

## 4.1 <u>Organization, Good Standing and Qualification</u>.

- (a) The Company has been duly organized and is validly existing and in good standing under the laws of its jurisdiction of organization, is duly qualified to do business and is in good standing in each jurisdiction in which its ownership or lease of property or the conduct of its businesses requires such qualification, and has all power and authority necessary to own or hold its properties and to conduct the businesses in which it is engaged, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, have a Material Adverse Effect.
- (b) The Company has all requisite corporate power and corporate authority to enter into the Transaction Agreements and the Collaboration Agreement, to issue and sell the Shares and to perform its obligations under and to carry out the other transactions contemplated by the Transaction Agreements and the Collaboration Agreement.

## 4.2 <u>Capitalization and Voting Rights</u>.

(a) As of the Signing Date, the authorized capital of the Company consists of: (i) 120,000,000 shares of Common Stock of which, (A) 32,601,748 shares are issued and outstanding, (B) 4,886,021 shares are issuable upon the exercise of outstanding stock options or upon the settlement of outstanding equity awards issued pursuant to the 2014 Stock Option and Grant Plan or the 2015 Stock Option and Incentive Plan, (C) 2,259,224 shares are reserved for future issuance pursuant to the 2015 Stock Option and Incentive Plan, and (D) 1,289,093 shares are reserved for future issuance pursuant to the 2015 Employee Stock Purchase Plan, as amended to date and as the same may be amended and/or restated from time to time, and (ii) 5,000,000 shares of preferred stock, par value \$0.001 per share, of which no shares are issued and outstanding. The Company is also party to the Sales Agreement pursuant to which the Company may issue and sell shares of its Common Stock having an aggregate offering price of up to \$75,000,000 through Cowen and Company, LLC, from time to time, in "at-the-market" offerings or certain negotiated transactions. All of the issued and outstanding shares of Common Stock have been duly authorized and validly issued and

are fully paid and non-assessable, were issued in compliance with federal and state securities Laws, and are not subject to any pre-emptive rights.

- (b) Except as described or referred to in Section 4.2(a) above and as provided in the Investor Agreement, as of the Signing Date, there are no outstanding rights (including, without limitation, pre-emptive rights), warrants or options to acquire, or instruments convertible into or exchangeable for, any shares of capital stock or other equity interest in the Company, or any contract, commitment, agreement, understanding or arrangement of any kind relating to the issuance of any capital stock of the Company, any such convertible or exchangeable securities or any such rights, warrants or options.
- (c) Except as disclosed in the Company SEC Documents, no Person has any right to cause the Company to effect the registration under the Securities Act of any securities of the Company.
- (d) The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the SEC is contemplating terminating such registration.
- 4.3 <u>Subsidiaries</u>. As of the Signing Date, the Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Schedule 1 hereto. All the outstanding shares of capital stock or other equity interests of each subsidiary owned, directly or indirectly, by the Company have been duly authorized and validly issued, are fully paid and non-assessable (except, in the case of any foreign subsidiary, for directors' qualifying shares) and are owned directly or indirectly by the Company, free and clear of any lien, charge, encumbrance, security interest, restriction on voting or transfer or any other claim of any third party.

#### 4.4 Authorization.

- (a) The Company has full right, power and authority to execute and deliver the Transaction Agreements and the Collaboration Agreement and to perform its obligations hereunder and thereunder; and all action required to be taken for the due and proper authorization, execution and delivery by it of each of the Transaction Agreements and the Collaboration Agreement and the consummation by it of the transactions contemplated thereby has been duly and validly taken.
- (b) The Transaction Agreements and the Collaboration Agreement have been duly executed and delivered by the Company and, upon the due execution and delivery of the Transaction Agreements and the Collaboration Agreement by the Investor, will constitute valid and legally binding obligations of the Company, enforceable against the Company in accordance with their respective terms, except, with respect to the Investor Agreement and the Collaboration Agreement, as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or

similar laws affecting creditors' rights generally or by equitable principles relating to enforceability (collectively, the "Enforceability Exceptions").

- (c) No stop order or suspension of trading of the Common Stock has been imposed by the Nasdaq Stock Market, the SEC or any other Governmental Authority and remains in effect.
- 4.5 No Defaults. The Company is not (i) in violation of its charter or by-laws or similar organizational documents; (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company is a party, by which the Company is bound or to which any of the property or assets of the Company is subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority having jurisdiction over the Company or any of its subsidiaries, except, in the case of clauses (ii) and (iii) above, for any such default or violation that would not, individually or in the aggregate, have a Material Adverse Effect.
- Agreements and the Collaboration Agreement, the issuance and sale of the Shares and the consummation of the transactions contemplated by the Transaction Agreements and the Collaboration Agreement will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company is a party, by which the Company is bound or to which any of the property or assets of the Company is subject, (ii) result in any violation of the provisions of the charter or by-laws or similar organizational documents of the Company or (iii) result in the violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority having jurisdiction over the Company or any of its subsidiaries, except, in the case of clauses (i) and (iii) above, for any such conflict, breach, violation or default that would not, individually or in the aggregate, have a Material Adverse Effect.
- 4.7 <u>No Governmental Authority or Third Party Consents</u>. No consent, approval, authorization, order, license, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Company of each of the Transaction Agreements or the Collaboration Agreement or the issuance and sale of the Shares, except (i) such filings as may be required to be made with the SEC and with any state blue sky or securities regulatory authority, which filings shall be made in a timely manner in accordance with all applicable Laws, (ii) as required pursuant to the HSR Act and (iii) with respect to the Shares, the filing with the Nasdaq Stock Market of, and the absence of unresolved issues with respect to, an LAS and, if required, a Nasdaq Shares Outstanding Change Form.

- 4.8 <u>Valid Issuance of Shares</u>. When issued, sold and delivered at the Closing in accordance with the terms hereof for the Aggregate Purchase Price, the Shares shall be duly authorized, validly issued, fully paid and nonassessable, free from any liens, encumbrances or restrictions on transfer, including pre-emptive rights, rights of first refusal or other similar rights, other than as arising pursuant to the Transaction Agreements, as a result of any action by the Investor or under federal or state securities Laws.
- 4.9 <u>Litigation</u>. There are no legal, governmental or regulatory investigations, actions, suits or proceedings pending to which the Company is a party or to which any property of the Company is subject that, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect; and no such investigations, actions, suits or proceedings are, to the knowledge of the Company, threatened or contemplated by any governmental or regulatory authority or others.
- 4.10 <u>Licenses and Other Rights; Compliance with Laws</u>. The Company and its subsidiaries possess or are in the process of obtaining all licenses, certificates, permits and other authorizations issued by, and have made all declarations and filings with, the appropriate federal, state, local or foreign governmental or regulatory authorities that are necessary for the ownership or lease of their respective properties or the conduct of their respective businesses as described in the Company SEC Documents, except where the failure to possess or make the same would not, individually or in the aggregate, have a Material Adverse Effect; and except as described in the Company SEC Documents, neither the Company nor any of its subsidiaries has received notice of any revocation or modification of any such license, certificate, permit or authorization or has any reason to believe that any such license, certificate, permit or authorization will not be renewed. The Company and its subsidiaries are, and at all times since January 1, 2017, have been, in compliance with all statutes, rules and regulations applicable to the ownership, packaging, processing, use, distribution, import, or export of any product manufactured or distributed by the Company or its subsidiaries, except where such noncompliance would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

## 4.11 Company SEC Documents; Financial Statements; Nasdag Stock Market.

(a) Since January 1, 2017, the Company has timely filed all required reports, schedules, forms, statements and other documents (including exhibits and all other information incorporated therein) required to be filed by it under the Securities Act and the Exchange Act, and any required amendments to any of the foregoing, with the SEC (the "Company SEC Documents"). As of their respective filing dates, each of the Company SEC Documents complied in all material respects with the requirements of the Securities Act, the Exchange Act, and the rules and regulations of the SEC promulgated thereunder applicable to such Company SEC Documents, and no Company SEC Documents when filed, declared effective or mailed, as applicable, contained any untrue statement of a material fact or omitted to state a material fact

required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

- (b) As of the Signing Date, there are no outstanding or unresolved comments in comment letters received from the SEC or its staff.
- (c) The financial statements of the Company included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and in its quarterly reports on Form 10-Q for the quarterly periods ended March 31, 2018; June 30, 2018; and September 30, 2018 present fairly the financial position of the Company and its consolidated subsidiaries as of the dates indicated and the results of their operations and the changes in their cash flows for the periods specified; such financial statements have been prepared in conformity with GAAP applied on a consistent basis throughout the periods covered thereby, except as otherwise disclosed therein and, in the case of unaudited, interim financial statements, subject to normal year-end audit adjustments and the exclusion of certain footnotes, and any supporting schedules included in the Company SEC Documents present fairly the information required to be stated therein.
- (d) The Common Stock is listed on the Nasdaq Stock Market, and the Company has taken no action designed to, or which is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the Nasdaq Stock Market. The Company has not received any notification that, and has no knowledge that, the SEC or the Nasdaq Stock Market is contemplating terminating such listing or registration.
- The Company and its subsidiaries have established systems of "internal control over financial reporting" (as defined in Rule 13a-15(f) of the Exchange Act) that have been designed by, or under the supervision of, their respective principal executive and principal financial officers, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including, but not limited to, internal accounting control sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences and (v) interactive data in eXtensible Business Reporting Language included in the Company SEC Documents fairly presents the information called for in all material respects and is prepared in accordance with the SEC's rules and guidelines applicable thereto. Except as disclosed in the Company SEC Documents, there are no material weaknesses in the Company's internal controls. The Company's auditors and the Audit Committee of the Board have been advised of: (i) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which have adversely affected or are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial

information; and (ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

- (f) The Company maintains disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) that comply with the requirements of the Exchange Act; such disclosure controls and procedures have been designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to the Company's management to allow timely decisions regarding disclosures. The Company has conducted evaluations of the effectiveness of its disclosure controls as required by Rule 13a-15 of the Exchange Act.
- (g) There is and has been no material failure on the part of the Company or, to the knowledge of the Company, any of the Company's directors or officers, in their capacities as such, to comply with any applicable provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith, including Section 402 related to loans and Sections 302 and 906 related to certifications.

## 4.12 <u>Absence of Certain Changes</u>.

Except as disclosed in the Company SEC Documents, since September 30, 2018, (i) there has not been any material change in the capital stock (other than (x) the issuance of shares of Common Stock upon exercise of stock options, the settlement of equity awards and the exercise of warrants described as outstanding in, and the grant of options and awards under existing equity incentive plans described in, the Company SEC Documents and (y) the issuance of shares of Common Stock, options and equity awards granted to new employees of the Company as inducement awards pursuant to Nasdaq Listing Rule 5635(c)(4)), short-term debt or long-term debt of the Company or any of its subsidiaries, or any dividend or distribution of any kind declared, set aside for payment, paid or made by the Company on any class of capital stock, or any material adverse change, or any development that would reasonably be expected to result in a material adverse change, in or affecting the business, properties, management, financial position, stockholders' equity, results of operations of the Company and its subsidiaries taken as a whole; (ii) neither the Company nor any of its subsidiaries has entered into any transaction or agreement (whether or not in the ordinary course of business) that is material to the Company and its subsidiaries taken as a whole or incurred any liability or obligation, direct or contingent, that is material to the Company and its subsidiaries taken as a whole; and (iii) neither the Company nor any of its subsidiaries has sustained any loss or interference with its business that is material to the Company and its subsidiaries taken as a whole and that is either from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor disturbance or dispute or any action, order or decree of any court or arbitrator or governmental or regulatory authority.

- 4.13 <u>Offering</u>. Subject to the accuracy of the Investor's representations set forth in Sections 5.5, 5.6, 5.7, 5.9, and 5.10 hereof, the offer, sale and issuance of the Shares to be issued in conformity with the terms of this Agreement constitute transactions which are exempt from the registration requirements of the Securities Act and from all applicable state registration or qualification requirements. Neither the Company nor any Person acting on its behalf will take any action that would cause the loss of such exemption.
- 4.14 <u>No Integration</u>. The Company has not, directly or through any agent, sold, offered for sale, solicited offers to buy or otherwise negotiated in respect of, any security (as defined in the Securities Act), that is or will be integrated with the sale of the Shares in a manner that would require registration of the Shares under the Securities Act.
- 4.15 <u>Brokers' or Finders' Fees</u>. Except with respect to the Company Financial Advisors, neither the Company nor any of its subsidiaries is a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against the Company or any of its subsidiaries for a brokerage commission, finder's fee or like payment in connection with the transactions contemplated by the Transaction Agreements and the Collaboration Agreement.
- 4.16 <u>Investment Company</u>. The Company is not and, immediately after giving effect to the offering and sale of the Shares and the application of the proceeds thereof, will not be required to register as an "investment company" or an entity "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940, as amended, and the rules and regulations of the SEC thereunder.
- 4.17 <u>No General Solicitation</u>. Neither the Company nor any person acting on behalf of the Company has offered or sold any of the Shares by any form of general solicitation or general advertising. The Company has offered the Shares for sale only to the Investor.
- 4.18 Foreign Corrupt Practices. Neither the Company nor, to the knowledge of the Company, any agent or other person acting on behalf of the Company, has: (i) directly or indirectly used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company (or made by any person acting on its behalf of which the Company is aware) which is in violation of law or (iv) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977, as amended, or any applicable non-U.S. anti-bribery Law.
- 4.19 <u>Regulation M Compliance</u>. The Company has not taken, directly or indirectly, any action designed to or that would reasonably be expected to cause or result in stabilization or manipulation of the price of the Common Stock to facilitate the sale or resale of the Shares.

4.20 <u>Office of Foreign Assets Control</u>. Neither the Company nor, to the Company's knowledge, any director, officer, agent, employee or Affiliate of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

## 4.21 <u>Development Matters</u>.

- (a) All preclinical and clinical studies conducted by or on behalf of the Company to support approval for commercialization of the Company's products have been conducted by the Company, or to the Company's knowledge by third parties, in compliance with all applicable federal, state or foreign laws, rules, orders and regulations, except for such failure or failures to be in compliance which would not reasonably be expected to have, singly or in the aggregate, a Material Adverse Effect.
- The studies, tests and preclinical or clinical trials conducted by or on behalf of the Company that are described in the Company SEC Documents (the "Company Studies and Trials") were and, if still pending, are being, conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to, where applicable, accepted professional scientific standards; the descriptions of the results of the Company Studies and Trials contained in the Company SEC Documents are accurate in all material respects; the Company has no knowledge of any other studies or trials not described in the Company SEC Documents, the results of which are inconsistent with or call in question the results described or referred to in the Company SEC Documents; and the Company has not received any notices or correspondence from the United States Food and Drug Administration (the "FDA") or any foreign, state or local governmental authority exercising comparable authority requiring the termination, suspension or material modification of any Company Studies and Trials that termination, suspension or material modification would reasonably be expected to have a Material Adverse Effect and, to the Company's knowledge, there are no reasonable grounds for the same. The Company has obtained (or caused to be obtained) informed consent by or on behalf of each human subject who participated in the Company Studies and Trials. To the Company's knowledge, none of the Company Studies and Trials involved any investigator who has been disqualified as a clinical investigator or has been found by the FDA to have engaged in scientific misconduct. To the Company's knowledge, the manufacturing facilities and operations of its suppliers are operated in compliance in all material respects with all applicable statutes, rules, regulations and policies of the FDA and comparable governmental authorities outside of the United States to which the Company is subject.
- 4.22 <u>Intellectual Property</u>. The Company owns, possesses, or can acquire on reasonable terms the right to use all (i) patents, patent applications, trademarks, trademark registrations, service marks, service mark registrations, Internet domain name registrations, copyrights, copyright registrations, licenses and trade secret rights (collectively, "**Intellectual Property Rights**") and (ii) inventions, software, works of authorships, trademarks, service marks, trade names, databases, formulae, know how, Internet domain names and other intellectual property (including trade secrets and other unpatented and/or unpatentable proprietary confidential information, systems, or

procedures) (collectively, "Intellectual Property Assets") necessary to conduct its business as currently conducted, and as proposed to be conducted and described in the SEC Documents. The Company has not received any opinion from its legal counsel concluding that any activities of its business infringes, misappropriates, or otherwise violates, valid and enforceable Intellectual Property Rights of any other person, and has not received written notice of any challenge, which is to its knowledge still pending, by any other person to the rights of the Company with respect to any Intellectual Property Rights or Intellectual Property Assets owned or used by the Company. To the Company's knowledge, the Company's business as now conducted does not give rise to any infringement of, any misappropriation of, or other violation of, any valid and enforceable Intellectual Property Rights of any other person. All licenses for the use of the Intellectual Property Rights described in the SEC Documents are valid, binding upon, and enforceable by or against the Company, and to the Company's knowledge, by or against the parties thereto in accordance with their terms. The Company has complied in all material respects with, and is not in breach of, nor has it received any asserted or threatened claim of breach of any intellectual property licenses for the use of the Intellectual Property Rights, and the Company has no knowledge of any breach or anticipated breach by any other person of any such intellectual property licenses. No claim has been made or is pending against the Company alleging the infringement by the Company of any patent, trademark, service mark, trade name, copyright, trade secret, license in or other intellectual property right or franchise right of any person. The Company has taken reasonable steps to protect, maintain and safeguard its Intellectual Property Rights. including the execution of appropriate nondisclosure and confidentiality agreements. The consummation of the transactions contemplated by this Agreement will not result in the loss or impairment of or payment of any additional amounts with respect to, nor require the consent of any other person in respect of, the Company's right to own, use, or hold for use any of the Intellectual Property Rights as owned, used or held for use in the conduct of the business as currently conducted. The Company has at all times complied in all material respects with all applicable laws relating to privacy, data protection, and the collection and use of personal information collected, used, or held for use by the Company in the conduct of the Company's business. No claims have been asserted or threatened against the Company alleging a violation of any person's privacy or personal information or data rights and the consummation of the transactions contemplated hereby will not breach or otherwise cause any violation of any law related to privacy, data protection, or the collection and use of personal information collected, used, or held for use by the Company in the conduct of the Company's business. The Company takes reasonable measures to ensure that such information is protected against unauthorized access, use, modification or other misuse. The Company has taken all necessary actions to secure and record its ownership of all works of authorship and inventions made by its employees, consultants and contractors with an obligation of assignment during the time they were employed by or under contract with the Company and which relate to the Company's business. All founders and key employees have signed confidentiality and invention assignment agreements with the Company.

4.23 <u>Real and Personal Property</u>. The Company has good and marketable title in fee simple (in the case of real property) to, or has valid and marketable

rights to lease or otherwise use, all items of real or personal property, which are material to the business of the Company taken as a whole, in each case free and clear of all liens, encumbrances, security interests, claims and defects that do not, singularly or in the aggregate, materially affect the value of such property and do not interfere with the use made and proposed to be made of such property by the Company; and all of the leases and subleases material to the business of the Company, and under which the Company holds properties described in the SEC Documents, are in full force and effect and the Company has not received any notice of any material claim of any sort that has been asserted by anyone adverse to the rights of the Company under any of the leases or subleases mentioned above, or affecting or questioning the rights of the Company to the continued possession of the leased or subleased premises under any such lease or sublease.

- 4.24 <u>Labor and Employment</u>. There is (a) no unfair labor practice complaint pending against the Company, nor to the Company's knowledge, threatened against it, before the National Labor Relations Board, any state or local labor relations board or any foreign labor relations board, and no significant grievance or significant arbitration proceeding arising out of or under any collective bargaining agreement is so pending against the Company, or, to the Company's knowledge, threatened against it and (b) no labor disturbance by or dispute with, employees of the Company exists or, to the Company's knowledge, is contemplated or threatened, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its principal suppliers, manufacturers, customers or contractors, that would reasonably be expected, singularly or in the aggregate, to have a Material Adverse Effect. The Company is not aware that any key employee or significant group of employees of the Company plans to terminate employment with the Company.
- 4.25 ERISA Matters. No "prohibited transaction" (as defined in Section 406 of the Employee Retirement Income Security Act of 1974, as amended, including the regulations and published interpretations thereunder ("ERISA"), or Section 4975 of the Internal Revenue Code of 1986, as amended from time to time (the "Code")) or "accumulated funding deficiency" (as defined in Section 302 of ERISA) or any of the events set forth in Section 4043(b) of ERISA (other than events with respect to which the thirty (30)-day notice requirement under Section 4043 of ERISA has been waived) has occurred or could reasonably be expected to occur with respect to any employee benefit plan of the Company which would, singularly or in the aggregate, reasonably be expected to have a Material Adverse Effect. Each employee benefit plan of the Company is in compliance in all material respects with applicable law, including ERISA and the Code. The Company has not incurred and would not reasonably be expected to incur liability under Title IV of ERISA with respect to the termination of, or withdrawal from, any pension plan (as defined in ERISA). Each pension plan for which the Company would have any liability that is intended to be qualified under Section 401(a) of the Code is so qualified, and nothing has occurred, whether by action or by failure to act, which would, singularly or in the aggregate, reasonably be expected to cause the loss of such qualification.

- 4.26 Environmental Matters. The Company is in compliance in all material respects with all foreign, federal, state and local rules, laws and regulations relating to the use, treatment, storage and disposal of hazardous or toxic substances or waste and protection of health and safety or the environment which are applicable to its businesses (the "Environmental Laws"). There has been no storage, generation, transportation, handling, treatment, disposal, discharge, emission, or other release of any kind of toxic or other wastes or other hazardous substances by, due to, or caused by the Company (or, to the Company's knowledge, any other entity for whose acts or omissions the Company is or may otherwise be liable) upon any of the property now or previously owned or leased by the Company, or upon any other property, in violation of any law, statute, ordinance, rule, regulation, order, judgment, decree or permit or which would, under any law, statute, ordinance, rule (including rule of common law), regulation, order, judgment, decree or permit, give rise to any liability; and there has been no disposal, discharge, emission or other release of any kind on to such property or into the environment surrounding such property of any toxic or other wastes or other hazardous substances.
- 4.27 Taxes. The Company (i) has timely filed all necessary federal, state, local and foreign tax returns (or timely filed extensions with respect to such returns), and all such returns were true, complete and correct, (ii) has paid all federal, state, local and foreign taxes, assessments, governmental or other charges due and payable for which it is liable, including, without limitation, all sales and use taxes and all taxes which the Company is obligated to withhold from amounts owing to employees, creditors and third parties, and (iii) does not have any tax deficiency or claims outstanding or assessed or, to its knowledge, proposed against it, except those, in each of the cases described in clauses (i), (ii) and (iii) above, that would not, singularly or in the aggregate, reasonably be expected to have a Material Adverse Effect. The Company has not engaged in any transaction which is a corporate tax shelter or which could be characterized as such by the Internal Revenue Service or any other taxing authority. The accruals and reserves on the books and records of the Company in respect of tax liabilities for any taxable period not yet finally determined are adequate to meet any assessments and related liabilities for any such period, and since January 1, 2017, the Company has not incurred any liability for taxes other than in the ordinary course.
- 4.28 <u>Insurance</u>. The Company carries or is covered by, insurance in such amounts and covering such risks as is adequate for the conduct of its business and the value of its properties and as is customary for companies engaged in similar businesses, at a similar stage of development, in similar industries. The Company has no reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not reasonably be expected to have a Material Adverse Effect. All policies of insurance owned by the Company are, to the Company's knowledge, in full force and effect and the Company is in compliance in all material respects with the terms of such policies. The Company has not received written notice from any insurer, agent of such insurer or the broker of the Company that any material capital improvements or any other material expenditures (other than premium

payments) are required or necessary to be made in order to continue such insurance. Except for customary deductibles, the Company does not insure risk of loss through any captive insurance, risk retention group, reciprocal group or by means of any fund or pool of assets specifically set aside for contingent liabilities other than as described in the SEC Documents.

- 5. <u>Representations and Warranties of the Investor</u>. The Investor hereby represents and warrants to the Company that:
  - 5.1 <u>Organization; Good Standing</u>. The Investor is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. The Investor has all requisite corporate power and corporate authority to enter into the Transaction Agreements, to purchase the Shares and to perform its obligations under and to carry out the other transactions contemplated by the Transaction Agreements.

#### 5.2 <u>Authorization</u>.

- (a) The Investor has full right, power and authority to execute and deliver the Transaction Agreements and the Collaboration Agreement and to perform its obligations hereunder and thereunder; and all action required to be taken for the due and proper authorization, execution and delivery by it of each of the Transaction Agreements and the Collaboration Agreement and the consummation by it of the transactions contemplated thereby has been duly and validly taken.
- (b) The Transaction Agreements and the Collaboration Agreement have been duly executed and delivered by the Investor and, upon the due execution and delivery of the Transaction Agreements and the Collaboration Agreement by the Company, will constitute valid and legally binding obligations of the Investor, enforceable against the Investor in accordance with their respective terms, except with respect to the Enforceability Exceptions.
- Agreements and the Collaboration Agreement, the subscription for and purchase of the Shares and the consummation of the transactions contemplated by the Transaction Agreements and the Collaboration Agreement will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Investor pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Investor is a party, by which the Investor is bound or to which any of the property or assets of the Investor is subject, (ii) result in any violation of the provisions of the charter or by-laws or similar organizational documents of the Investor or (iii) result in the violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority having jurisdiction over the Investor or any of its subsidiaries, except, in the case of clauses (i) and (iii) above, for any such conflict, breach, violation or default that would not, individually or in the aggregate, have a material adverse effect on

the Investor's ability to perform its obligations or consummate the Transaction in accordance with the terms of this Agreement.

- 5.4 <u>No Governmental Authority or Third Party Consents</u>. No consent, approval, authorization, order, license, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Investor of each of the Transaction Agreements or the Collaboration Agreement or with the subscription for and purchase of the Shares, except as required pursuant to the HSR Act.
- 5.5 <u>Purchase Entirely for Own Account</u>. The Investor acknowledges that the Shares shall be acquired for investment for the Investor's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and the Investor has no present intention of selling, granting any participation or otherwise distributing the Shares. The Investor can bear the economic risk of an investment in the Shares indefinitely and a total loss with respect to such investment. The Investor does not have and will not have as of the Closing any contract, undertaking, agreement, arrangement or understanding with any Person to sell, transfer or grant participation to a Person any of the Shares.
- 5.6 <u>Disclosure of Information</u>. The Investor has received or has had full access to all the information from the Company and its management that the Investor considers necessary or appropriate for deciding whether to purchase the Shares hereunder. The Investor further represents that it has had an opportunity to ask questions and receive answers from the Company regarding the Company, its financial condition, results of operations and prospects and the terms and conditions of the offering of the Shares sufficient to enable it to evaluate its investment.
- 5.7 <u>Investment Experience and Accredited Investor Status</u>. The Investor is an "accredited investor" (as defined in Regulation D under the Securities Act). The Investor has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares to be purchased hereunder.
- 5.8 <u>Acquiring Person</u>. As of the Signing Date, neither the Investor nor any of its Affiliates beneficially owns, and immediately prior to the Closing, neither the Investor nor any of its Affiliates will beneficially own (in each case, as determined pursuant to Rule 13d-3 under the Exchange Act without regard for the number of days in which a Person has the right to acquire such beneficial ownership, and without regard to Investor's rights under this Agreement), any securities of the Company, except for securities that may be beneficially owned by employee benefit plans of either the Investor or any of its Affiliates.
- 5.9 <u>Restricted Securities</u>. The Investor understands that the Shares, when issued, shall be "restricted securities" under the federal securities Laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such Laws the Shares may be resold without registration under

the Securities Act only in certain limited circumstances. The Investor represents that it is familiar with Rule 144, as presently in effect.

- 5.10 <u>Legends</u>. The Investor understands that any certificates representing the Shares shall bear the following legends:
- (a) "THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF A REGISTRATION STATEMENT IN EFFECT WITH RESPECT TO THE SECURITIES UNDER THE SECURITIES ACT OR AN OPINION OF COUNSEL (WHICH COUNSEL SHALL BE REASONABLY SATISFACTORY TO THE COMPANY) THAT SUCH REGISTRATION IS NOT REQUIRED OR UNLESS SOLD PURSUANT TO RULE 144 OF THE SECURITIES ACT.";
- (b) "THE SECURITIES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO AND SHALL BE TRANSFERABLE ONLY UPON THE TERMS AND CONDITIONS OF AN INVESTOR AGREEMENT DATED AS OF JANUARY 28, 2019, BY AND BETWEEN VOYAGER THERAPEUTICS, INC. AND NEUROCRINE BIOSCIENCES, INC., A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF VOYAGER THERAPEUTICS, INC."; and
- (c) any legend required by applicable state securities Laws or the other Transaction Agreements.
- 5.11 <u>Financial Assurances</u>. As of the Signing Date, the Investor has, and as of the Closing Date, the Investor will have, access to cash in an amount sufficient to pay to the Company the Aggregate Purchase Price.
  - 5.12 <u>SEC Reports</u>. The Investor has reviewed the Company SEC Documents.
- 6. <u>Investor's Conditions to Closing</u>. The Investor's obligation to purchase the Shares at the Closing is subject to the fulfillment as of the Closing of the following conditions (unless waived in writing by the Investor):
  - Representations and Warranties. The representations and warranties made by the Company in Section 4 hereof shall be true and correct as of the Signing Date and as of the Closing Date as though made on and as of such Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date; <u>provided</u>, <u>however</u>, that for purposes of this Section 6.1, all such representations and warranties of the Company (other than Sections 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, and 4.11 hereof) shall be deemed to be true and correct for purposes of this Section 6.1 unless the failure or failures of such representations and warranties to be so true and correct, without regard to any "material," "materiality" or "Material Adverse Effect" qualifiers set forth therein, constitute a Material Adverse Effect.

- 6.2 Representations and Warranties in the Collaboration Agreement. The representations and warranties made by the Company in Section 12.2 of the Collaboration Agreement shall be true and correct as of the Closing Date as though made on and as of such Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date; provided, however, that for purposes of this Section 6.2, all such representations and warranties of the Company shall be deemed to be true and correct for purposes of this Section 6.2 unless the failure or failures of such representations and warranties to be so true and correct, without regard to any "material" or "materiality" qualifiers set forth therein, individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect.
- 6.3 <u>Covenants</u>. All covenants and agreements contained in this Agreement to be performed or complied with by the Company on or prior to the Closing Date shall have been performed or complied with in all material respects.
- 6.4 <u>Investor Agreement</u>. The Investor Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect.
- 6.5 <u>Collaboration Agreement</u>. The Collaboration Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect as of the Closing Date.
- 6.6 <u>No Material Adverse Effect</u>. From and after the Signing Date until the Closing Date, there shall have occurred no event that has caused a Material Adverse Effect.
- 6.7 <u>Listing</u>. The Shares shall be eligible and approved for listing on the Nasdaq Stock Market.
- 7. <u>Company's Conditions to Closing</u>. The Company's obligation to issue and sell the Shares at the Closing is subject to the fulfillment as of the Closing of the following conditions (unless waived in writing by the Company):
  - 7.1 Representations and Warranties. The representations and warranties made by the Investor in Section 5 hereof shall be true and correct as of the Signing Date and as of the Closing Date as though made on and as of such Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date.
  - 7.2 <u>Covenants</u>. All covenants and agreements contained in this Agreement to be performed or complied with by the Investor on or prior to the Closing Date shall have been performed or complied with in all material respects.
  - 7.3 <u>Investor Agreement</u>. The Investor Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect.

- 7.4 <u>Collaboration Agreement</u>. The Collaboration Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect.
- 8. <u>Mutual Conditions to Closing</u>. The obligations of the Investor and the Company to consummate the Closing are subject to the fulfillment as of the Closing Date of the following conditions:
  - 8.1 <u>HSR Act Qualification</u>. Any required HSR Clearances shall have been obtained.
  - 8.2 <u>Absence of Litigation</u>. There shall be no action, suit, proceeding or investigation by a Governmental Authority pending or currently threatened in writing against the Company or the Investor (i) that questions (A) the validity of any Transaction Agreement or (B) the right of the Company or the Investor to enter into any Transaction Agreement or to consummate the transactions contemplated hereby or thereby or (ii) which, if determined adversely, would impose substantial monetary damages on the Company or the Investor as a result of the consummation of the transactions contemplated by any Transaction Agreement.
  - 8.3 <u>No Prohibition</u>. No provision of any applicable Law and no judgment, injunction (preliminary or permanent), order or decree that prohibits, makes illegal or enjoins the consummation of the Transaction shall be in effect.

#### 9. Termination.

- 9.1 <u>Ability to Terminate</u>. This Agreement may be terminated at any time prior to the Closing by:
  - (a) mutual written consent of the Company and the Investor;
- (b) either the Company or the Investor, upon written notice to the other, if any of the mutual conditions to the Closing set forth in Section 8 hereof shall have become incapable of fulfillment by the Termination Date and shall not have been waived in writing by the other party within ten business days after receiving receipt of written notice of an intention to terminate pursuant to this clause (b); <a href="mailto:provided">provided</a>, <a href="however">however</a>, that the right to terminate this Agreement under this Section 9.1(b) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been the cause of, or resulted in, the failure to consummate the transactions contemplated hereby prior to the Termination Date;
- (c) the Company, upon written notice to the Investor, so long as the Company is not then in breach of its representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 6.1, 6.2, 6.3, 6.4 or 6.5 hereof, as applicable, could not be satisfied by the Termination Date, (i) upon a material breach of any covenant or agreement on the part of the Investor set forth in this Agreement, or (ii) if any representation or warranty of the Investor shall have

been or become untrue, in each case such that any of the conditions set forth in Section 7.1, 7.2, 7.3 or 7.4 hereof, as applicable, could not be satisfied by the Termination Date;

- (d) the Investor, upon written notice to the Company, so long as the Investor is not then in breach of its representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 7.1, 7.2, 7.3, or 7.4 hereof, as applicable, could not be satisfied by the Termination Date, (i) upon a material breach of any covenant or agreement on the part of the Company set forth in this Agreement, or (ii) if any representation or warranty of the Company shall have been or become untrue, in each case such that any of the conditions set forth in Section 6.1, 6.2, 6.3, 6.4 or 6.5 hereof, as applicable, could not be satisfied by the Termination Date.
- 9.2 Effect of Termination. In the event of the termination of this Agreement pursuant to Section 9.1 hereof, (i) this Agreement (except for this Section 9.2 and Section 11 hereof (other than Section 11.12), and any definitions set forth in this Agreement and used in such sections) shall forthwith become void and have no effect, without any liability on the part of any party hereto or its Affiliates, and (ii) all filings, applications and other submissions made pursuant to this Agreement, to the extent practicable, shall be withdrawn from the agency or other Person to which they were made or appropriately amended to reflect the termination of the transactions contemplated hereby; provided, however, that nothing contained in this Section 9.2 shall relieve any party from liability for fraud or any intentional or willful breach of this Agreement.

### 10. Additional Covenants and Agreements.

- 10.1 <u>Market Listing</u>. From the Signing Date through the Closing Date, Company shall use all commercially reasonable efforts to (i) maintain the listing and trading of the Common Stock on the Nasdaq Stock Market and (ii) effect the listing of the Shares on the Nasdaq Stock Market, including submitting the LAS to the Nasdaq Stock Market no later than fifteen (15) calendar days prior to the Closing Date.
- 10.2 Notification under the HSR Act. Each party will use reasonable efforts to do, or cause to be done, all things necessary, proper and advisable to, as promptly as practicable, take all actions necessary to make the filings required of such party or its Affiliates under the HSR Act, including filing with the FTC and Antitrust Division of the DOJ within ten (10) Business Days of the Signing Date (or such later time as may be agreed to in writing by the parties). The parties shall cooperate with one another to the extent necessary in the preparation of any such HSR Filing and during the review by the FTC and/or the Antitrust Division of the DOJ. Each party shall be responsible for its own costs, expenses, and filing fees associated with any HSR Filing; provided, however, that the Investor shall be solely responsible for any fees (other than penalties that may be incurred as a result of actions or omissions on the part of the Company) required to be paid to any Governmental Agency in connection with making any such HSR Filing. This Agreement shall terminate at the election of either party, immediately upon notice to the other party, if the FTC or the DOJ seeks a preliminary injunction (or its equivalent) in connection therewith against the Investor and the

Company to enjoin the transactions contemplated hereby and thereby. In the event of such termination, this Agreement shall be of no further force and effect.

Assistance and Cooperation. Prior to the Closing, upon the terms and subject to the conditions set forth in this Agreement, each of the parties agrees to use all reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, and to assist and cooperate with the other party in doing, all things necessary, proper or advisable to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated by this Agreement, including using all reasonable efforts to accomplish the following: (i) taking all reasonable acts necessary to cause the conditions precedent set forth in Sections 6, 7 and 8 hereof to be satisfied (including, in the case of the Company, promptly notifying the Investor of any notice from the Nasdaq Stock Market with respect to the LAS); (ii) taking all reasonable actions necessary to obtain all necessary actions or non-actions, waivers, consents, approvals, orders and authorizations from Governmental Authorities and the making of all necessary registrations, declarations and filings (including registrations, declarations and filings with Governmental Authorities, if any); (iii) taking all reasonable actions necessary to obtain all necessary consents, approvals or waivers from Third Parties; and (iv) except as otherwise provided for in Section 10.2 hereof, defending any suits, claims, actions, investigations or proceedings, whether judicial or administrative, challenging this Agreement or the consummation of the transactions contemplated hereby, including seeking to have any stay or temporary restraining order entered by any court or other Governmental Authority vacated or reversed.

## 10.4 <u>Legend Removal</u>.

- (a) Certificates evidencing the Shares shall not contain the legend set forth in Section 5.10(a) hereof: (i) following a sale of such Shares pursuant to a registration statement covering the resale of such Shares, while such registration statement is effective under the Securities Act, (ii) following any sale of such Shares pursuant to Rule 144, (iii) if such Shares are eligible for sale under Rule 144, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such Shares and without volume or manner-of-sale restrictions under Rule 144 or (iv) if such legend is not required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the SEC).
- (b) Certificates evidencing the Shares shall not contain the legend set forth in Section 5.10(b) hereof following: (i) a sale of such Shares pursuant to a registration statement covering the resale of such Shares, while such registration statement is effective under the Securities Act, (ii) any sale of such Shares pursuant to Rule 144 or (iii) the expiration of the Standstill Term (as defined in the Investor Agreement), the Lock-Up Term (as defined in the Investor Agreement) and the Voting Agreement Term (as defined in the Investor Agreement); provided that any transfer described in clause (i) or (ii) above shall have been in compliance with all applicable provisions of the Investor Agreement.

- (c) The Company agrees that at such time as any legend set forth in Section 5.10 hereof is no longer required under this Section 10.4, the Company will, no later than three (3) Business Days following the delivery by the Investor to the Company or notice by the Investor to the Company of delivery by the Investor to the Transfer Agent of a certificate representing Shares issued with such legend (together with any legal opinion required by the Transfer Agent), deliver or cause to be delivered to the Investor a certificate representing such Shares that is free from such legend, or, in the event that such shares are uncertificated, remove any such legend in the Company's stock records. The Company may not make any notation on its records or give instructions to the Transfer Agent that enlarge the restrictions on transfer set forth in Section 5.10 hereof.
- 20.5 Conduct of Business. During the period from the Signing Date until the Closing, except as consented to in writing by the Investor, the Company shall not (i) declare, set aside or pay any dividend or make any other distribution or payment (whether in cash, stock or property or any combination thereof) in respect of its capital stock, or establish a record date for any of the foregoing, or (ii) make any other actual, constructive or deemed distribution in respect of any shares of its capital stock or otherwise make any payments to stockholders in their capacity as such, except pursuant to repurchases of equity pursuant to the terms of its equity compensation plans.

#### 11. <u>Miscellaneous</u>.

- and construed in accordance with the Laws of the State of Delaware, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Any action brought, arising out of, or relating to this Agreement shall be brought in the Court of Chancery of the State of Delaware. Each party hereby irrevocably submits to the exclusive jurisdiction of said Court in respect of any claim relating to the validity, interpretation and enforcement of this Agreement, and hereby waives, and agrees not to assert, as a defense in any action, suit or proceeding in which any such claim is made that it is not subject thereto or that such action, suit or proceeding may not be brought or is not maintainable in such courts, or that the venue thereof may not be appropriate or that this agreement may not be enforced in or by such courts. The parties hereby consent to and grant the Court of Chancery of the State of Delaware jurisdiction over such parties and over the subject matter of any such claim and agree that mailing of process or other papers in connection with any such action, suit or proceeding in the manner provided in Section 11.3 hereof or in such other manner as may be permitted by law, shall be valid and sufficient thereof.
- 11.2 <u>Waiver</u>. Neither party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either party to assert a right hereunder or to insist upon compliance with any term of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term except to the extent set forth in writing.

- 11.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth on Exhibit A attached hereto and shall be (i) delivered personally; (ii) sent by certified mail (return receipt requested), postage prepaid; or (iii) sent via a reputable nationwide overnight express courier service (signature required). Any such notice, instruction or communication shall be deemed to have been delivered (A) upon receipt if delivered by hand; (B) three (3) Business Days after it is sent by certified mail, return receipt requested, postage prepaid; or (C) one (1) Business Day after it is sent via a reputable nationwide overnight courier service. Either party may change its address by giving notice to the other party in the manner provided above; provided that notices of a change of address shall be effective only upon receipt thereof.
- 11.4 Entire Agreement. This Agreement, the Investor Agreement and the Collaboration Agreement, in each case together with the schedules and exhibits thereto, set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the parties and supersede and terminate all prior agreements and understanding between the parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the parties other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the parties unless reduced to writing and signed by the respective authorized officers of the parties.
- 11.5 <u>Headings; Nouns and Pronouns; Section References</u>. Headings and any table of contents used in this Agreement are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.
- 11.6 <u>Severability</u>. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("**Modified Clause**"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; <u>provided</u> that the parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.
- 11.7 <u>Assignment</u>. Except for an assignment of this Agreement or any rights hereunder by the Investor to an Affiliate, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either the Investor or the Company without (i) the prior written consent of Company in the case of any assignment by the

Investor or (ii) the prior written consent of the Investor in the case of an assignment by the Company.

- 11.8 <u>Parties in Interest</u>. All of the terms and provisions of this Agreement shall be binding upon, and shall inure to the benefit of and be enforceable by the parties hereto and their respective successors, heirs, administrators and permitted assigns.
- 11.9 <u>Counterparts</u>. This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies from separate computers or printers. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.
- 11.10 <u>Third Party Beneficiaries</u>. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any party hereto.
- 11.11 <u>No Strict Construction</u>. This Agreement has been prepared jointly and will not be construed against either party.
- 11.12 <u>Survival of Warranties</u>. The representations and warranties of the Company and the Investor contained in this Agreement shall survive the Closing and the delivery of the Shares.
- 11.13 <u>Remedies</u>. The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or Law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.
- 11.14 <u>Expenses</u>. Each party shall pay its own fees and expenses in connection with the preparation, negotiation, execution and delivery of the Transaction Agreements.
- 11.15 <u>No Publicity</u>. The parties hereto agree that the provisions of Section 11.3 of the Collaboration Agreement shall be applicable to the parties to this Agreement with respect to any public disclosures regarding the proposed transactions contemplated by the Transaction Agreements and the Collaboration Agreement or regarding the parties hereto or their Affiliates (it being understood that the provisions of Section 11.3 of the Collaboration Agreement shall be read to apply to disclosures of information relating to this Agreement and the transactions contemplated hereby).

(Signature Page Follows)

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

## NEUROCRINE BIOSCIENCES, INC.

By:/s/ Kevin Gorman

Name: Kevin Gorman
Title: Chief Executive Officer

## VOYAGER THERAPEUTICS, INC.

By:/s/ G. Andre Turenne

Name: G. Andre Turenne

Title: President and Chief Executive Officer

(Signature Page to Stock Purchase Agreement)

# SCHEDULE 1

# LIST OF SUBSIDIARIES

1. Voyager Securities Corporation, a Massachusetts corporation

## **EXHIBIT A**

## **NOTICES**

## If to the Investor:

Neurocrine Biosciences, Inc. 12780 El Camino Real San Diego, CA 92130 Attention: General Counsel

# with a copy to:

Cooley LLP 4401 Eastgate Mall San Diego, CA 92121 Attention: Jason L. Kent, Esq.

# If to the Company:

Voyager Therapeutics, Inc. 75 Sidney Street Cambridge, MA 02139 Attention: Chief Executive Officer

## with a copy to:

Wilmer Cutler Pickering Hale and Dorr LLP 7 World Trade Center 250 Greenwich Street New York, NY 10007

Attention: Brian A. Johnson, Esq.

# **EXECUTION VERSION**

# **INVESTOR AGREEMENT**

By and Between

NEUROCRINE BIOSCIENCES, INC.

**AND** 

VOYAGER THERAPEUTICS, INC.

Dated as of January 28, 2019

# TABLE OF CONTENTS

| 1.<br>2.<br>3. | Definitions Restrictions on Beneficial Ownership Restrictions on Dispositions 3.1 Lock-Up 3.2 Certain Tender Offers 3.3 Sale Limitations 3.4 Offering Lock-Up 3.5 Transactions for Personal Account; Change of Control of the Investor  | 1<br>5<br>6<br>6<br>7<br>7<br>7<br>7   |
|----------------|---|--|
| 4.             | Voting Agreement 4.1 Voting of Securities 4.2 Certain Extraordinary Matters 4.3 Quorum  | 8<br>8<br>9<br>9   |
| 5.             | Termination of Certain Rights and Obligations 5.1 Termination of Standstill Term 5.2 Termination of Lock-Up Term 5.3 Termination of Voting Agreement Term 5.4 Termination of Agreement 5.5 Effect of Termination  | 9<br>9<br>10<br>10<br>10   |
| 6.             | <ul> <li>Miscellaneous</li> <li>Governing Law; Submission to Jurisdiction</li> <li>Waiver</li> <li>Notices</li> <li>Entire Agreement</li> <li>Headings; Nouns and Pronouns; Section References</li> <li>Severability</li> <li>Assignment</li> <li>Parties in Interest</li> <li>Counterparts</li> <li>Third Party Beneficiaries</li> <li>No Strict Construction</li> <li>Remedies</li> <li>Specific Performance</li> <li>No Conflicting Agreements</li> <li>Use of Proceeds</li> <li>No Publicity</li> </ul> | 11<br>11<br>11<br>11<br>12<br>12<br>12<br>12<br>12<br>12<br>12<br>13<br>13<br>13 |

Exhibit A – Form of Irrevocable Proxy

Exhibit B – Notices

#### **INVESTOR AGREEMENT**

THIS INVESTOR AGREEMENT (this "**Agreement**") is made as of January 28, 2019, by and between Neurocrine Biosciences, Inc. (the "**Investor**"), a Delaware corporation with its principal place of business at 12780 El Camino Real, San Diego, CA 92130, and Voyager Therapeutics, Inc. (the "**Company**"), a Delaware corporation, with its principal place of business at 75 Sidney Street, Cambridge, MA 02139.

WHEREAS, the Stock Purchase Agreement, of even date herewith, by and between the Investor and the Company (the "**Purchase Agreement**") provides for the issuance and sale by the Company to the Investor, and the purchase by the Investor, of a number of shares (such shares, the "**Purchased Shares**") of the Company's common stock, par value \$0.001 per share (the "**Common Stock**");

WHEREAS, as a condition to consummating the transactions contemplated by the Purchase Agreement, the Investor and the Company have agreed upon certain rights and restrictions as set forth herein with respect to the Purchased Shares and other securities of the Company beneficially owned by the Investor and its Affiliates, and it is a condition to the closing under the Purchase Agreement (the "Closing") that this Agreement be in full force and effect; and

WHEREAS, simultaneously with the execution of the Purchase Agreement and this Agreement, the Company and the Investor entered into the Collaboration Agreement.

NOW, THEREFORE, in consideration of the premises and mutual agreements hereinafter set forth, and for other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

- 1. <u>Definitions</u>. As used in this Agreement, the following terms shall have the following meanings:
- (a) "Affiliate" shall mean, with respect to any Person, another Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if such Person (ii) owns, directly or indirectly, beneficially or legally, more than fifty percent (50%) of the outstanding voting securities or capital stock of such other Person, or has other comparable ownership interest with respect to any Person other than a corporation; or (ii) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of such other Person. For the purposes of this Agreement, in no event shall the Investor or any of its Affiliates be deemed Affiliates of the Company or any of its Affiliates, nor shall the Company or any of its Affiliates be deemed Affiliates of the Investor or any of its Affiliates.

- (b) "**Agreement**" shall have the meaning set forth in the Preamble to this Agreement, including all Exhibits attached hereto.
- (c) "Beneficial owner," "beneficially owns," "beneficial ownership" and terms of similar import used in this Agreement shall, with respect to a Person, have the meaning set forth in Rule 13d-3 under the Exchange Act (i) assuming the full conversion into, and exercise and exchange for, shares of Common Stock of all Common Stock Equivalents beneficially owned by such Person and (ii) determined without regard for the number of days in which such Person has the right to acquire such beneficial ownership.
- (d) "Business Day" shall mean a day on which banking institutions in Boston, Massachusetts, United States and San Diego, California, United States are open for business, excluding any Saturday or Sunday.
- (e) "Change of Control" shall mean (i) the acquisition of beneficial ownership, directly or indirectly, by any Third Party of securities or other voting interests of the Company representing a majority or more of the combined voting power of the Company's then outstanding securities or other voting interests; (ii) any merger, consolidation or business combination involving the Company with a Third Party that results in the holders of beneficial ownership (other than by virtue of obtaining irrevocable proxies) of voting securities or other voting interests of the Company immediately prior to such merger, consolidation or other business combination ceasing to hold beneficial ownership of more than fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, consolidation or business combination; (iii) any sale, lease, exchange, contribution or other transfer to a Third Party (in one transaction or a series of related transactions) of all or substantially all of the Company's assets; or (iv) individuals who, as of the date hereof, constitute the Board of Directors of the Company (the "Incumbent **Board**") cease for any reason to constitute at least a majority of the Board of Directors of the Company (provided, however, that any individual becoming a director subsequent to the date hereof whose election, or nomination for election by the Company's shareholders, was recommended or approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of any person other than the Board of Directors of the Company).
  - (f) "Closing Date" shall have the meaning set forth in the Purchase Agreement.
- (g) "Collaboration Agreement" shall mean the Collaboration and License Agreement, of even date herewith, between the Investor and the Company.
- (h) "Common Stock" shall have the meaning set forth in the Preamble to this Agreement.

- (i) "Common Stock Equivalents" shall mean any options, restricted stock units, warrants or other securities or rights convertible into or exercisable, exchangeable or settleable for, whether directly or following conversion into or exercise, exchange or settlement for other options, restricted stock units, warrants or other securities or rights, shares of Common Stock or any swap, hedge or similar agreement or arrangement that transfers in whole or in part, the economic risk of ownership of, or voting or other rights of, the Common Stock.
- (j) "**Company**" shall have the meaning set forth in the Preamble to this Agreement.
- (k) "Competitor" shall mean any operating company with a biopharmaceutical business involving the Development and/or Commercialization of any Competitive Product (as such terms are defined in the Collaboration Agreement), or any other Person that directly or indirectly beneficially owns a majority of the voting securities of or voting interests in such a company, or any direct or indirect majority-owned subsidiary of such a company or of such a Person.
- (l) "**Disposition**" or "**Dispose of**" shall mean any (i) pledge, sale, contract to sell, sale of any option or contract to purchase, purchase of any option or contract to sell, grant of any option, right or warrant for the sale of, or other disposition of or transfer of any shares of Common Stock, or any Common Stock Equivalents, including, without limitation, any "short sale" or similar arrangement, or (ii) swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of shares of Common Stock, whether any such swap or transaction is to be settled by delivery of securities, in cash or otherwise.
- (m) "**Exchange Act**" shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.
- (n) "Existing Pivotal Trial Readout" shall mean the initial public announcement or release by the Company (or an Affiliate authorized by the Company) of topline results from the Existing Pivotal Trial (as such term is defined in the Collaboration Agreement).
- (o) "**Extraordinary Matter**" shall have the meaning set forth in Section 4.2 hereof.
- (p) "Governmental Authority" shall mean any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority or functions of any nature pertaining to government.
- (q) **"Investor"** shall have the meaning set forth in the Preamble to this Agreement.

- (r) "**Irrevocable Proxy**" shall have the meaning set forth in Section 4.1 hereof.
- (s) "Law" shall mean any law, statute, rule, regulation, order, judgment or ordinance having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision.
- (t) "**Lock-Up Agreement**" shall have the meaning set forth in Section 3.4 hereof.
- (u) "**Lock-Up Term**" shall mean the period from and after the date of this Agreement until the occurrence of any event set forth in Section 5.2 hereof.
  - (v) "**Modified Clause**" shall have the meaning set forth in Section 6.6 hereof.
- (w) "**Permitted Transferee**" shall mean (i) a controlled Affiliate of the Investor that is wholly owned, directly or indirectly, by the Investor, or (ii) a controlling Affiliate of the Investor (or any controlled Affiliate of such controlling Affiliate) that wholly owns, directly or indirectly, the Investor, or the acquiring Person in the case of a Change of Control of the Investor (replacing references to "Company" with "Investor" in the definition of "Change of Control"); it being understood that for purposes of this definition "wholly owned" shall mean an Affiliate in which the Investor owns, or an Affiliate that owns, as applicable, directly or indirectly, at least ninety-nine percent (99%) of the outstanding capital stock of such Affiliate or the Investor, as applicable.
- (x) "**Permitted Transferee Irrevocable Proxy**" shall have the meaning set forth in Section 4.1 hereof.
- (y) "**Person**" shall mean any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Governmental Authority or other entity, as well as any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the Exchange Act.
- (z) "**Second Pivotal Clinical Trial Readout**" shall mean the initial public announcement or release by the Company (or an Affiliate authorized by the Company) of topline results from a Pivotal Clinical Trial of VY-AADC other than the Existing Pivotal Trial (as such terms are defined in the Collaboration Agreement).
- (aa) "**Purchase Agreement**" shall have the meaning set forth in the Preamble to this Agreement, and shall include all Exhibits attached thereto.
- (bb) "**Purchased Shares**" shall have the meaning set forth in the Preamble to this Agreement, and shall be adjusted for (i) any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization and (ii) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange

or in replacement of, the Purchased Shares.

- (cc) "SEC" shall mean the U.S. Securities and Exchange Commission.
- (dd) "**Securities Act**" shall mean the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.
- (ee) "Shares of Then-Outstanding Common Stock" shall mean, at any time, the issued and outstanding shares of Common Stock at such time, as well as all capital stock issued and outstanding as a result of any stock split, stock dividend, or reclassification of Common Stock distributable, on a pro rata basis, to all holders of Common Stock.
- (ff) "**Standstill and Lock-Up Relaxation Date**" shall mean the later of (i) the second anniversary of the Closing Date and (ii) the date of the Existing Pivotal Trial Readout.
  - (gg) "Standstill Parties" shall have the meaning set forth in Section 2.1 hereof.
- (hh) "**Standstill Period**" shall mean the period from and after the date of this Agreement until the occurrence of any event set forth in Section 5.1 hereof.
- (ii) "**Third Party**" shall mean any Person other than the Investor, the Company or any Affiliate of the Investor or the Company.
- (jj) "**Voting Agreement Term**" shall mean the period from and after the date of this Agreement until the occurrence of any event set forth in Section 5.3 hereof.

# 2. <u>Restrictions on Beneficial Ownership.</u>

2.1 For the duration of the Standstill Period, unless the Company or its Affiliates or representatives have specifically invited or approved the Investor to do so in writing, neither the Investor nor any of its Affiliates or representatives acting on behalf of the Investor (collectively, the "Standstill Parties") will in any manner, directly or indirectly: (i) effect or seek, offer or propose (whether publicly or otherwise) to effect, or cause or knowingly participate in or in any way advise, assist or knowingly encourage any other Person to effect or seek, offer or propose (whether publicly or otherwise) to effect or participate in, (A) any acquisition of any securities (or beneficial ownership thereof) or assets of the Company, or any rights to acquire any such securities (including derivative securities representing the right to vote or economic benefit of any such securities) or assets; (B) any tender or exchange offer, merger or other business combination involving the Company; (C) any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to the Company; or (D) any "solicitation" of "proxies" (as such terms are used in the proxy rules of the SEC) or consents to vote any voting securities of the Company; (ii) form, join or in any way participate in a

"group" (as defined under the Exchange Act) with respect to any securities of the Company; (iii) otherwise act, alone or in concert with others, to seek to control or influence the management, Board of Directors or policies of the Company; (iv) take any action that would reasonably be expected to require the Company to make a public announcement regarding any of the types of matters set forth in clause (i) above; or (v) enter into any discussions or arrangements with any Third Party other than Investor's advisors with respect to any of the foregoing.

Notwithstanding anything to the contrary contained in this Agreement, Investor and its Affiliates shall not be precluded from owning or acquiring interests in mutual funds or similar entities that own capital stock of the Company, and nothing herein shall prohibit passive investments by pension or employee benefit plans of Investor.

- 2.2 The Investor also agrees during the Standstill Period not to request the Company (or its directors, officers, employees or agents), directly or indirectly, to amend or waive any provision of this Section 2 (including this sentence).
- 2.3 Notwithstanding anything to the contrary contained in this Agreement, if, at any time (i) a Third Party enters into an agreement with the Company contemplating the acquisition (by way of merger, tender offer or otherwise) of more than fifty percent (50%) of the then-outstanding Common Stock of the Company, of securities representing more than fifty percent (50%) of the voting power of all then-outstanding securities of the Company or all or substantially all of the consolidated assets of the Company or publicly announces its intention to do so, then the restrictions set forth in Section 2.1 shall terminate and cease to be of any further force or effect or (ii) a Third Party commences, or publicly announces an intention to commence, a tender or exchange offer that, if consummated, would make such third party the beneficial owner (within the meaning of Section 13(d)(1) of the Exchange Act) of at least 50% of the voting power of all then-outstanding securities of the Company, then until the expiration or termination of a tender or exchange offer that has been commenced or until the public announcement of a withdrawal or abandonment of an intention to commence a tender or exchange offer, the restrictions set forth in Section 2.1 shall be suspended and of no force or effect.
- 2.4 Notwithstanding anything to the contrary contained in this Agreement, on and after the Standstill and Lock-Up Relaxation Date, Investor shall not be precluded from making any confidential offers or proposals to the Board of Directors of the Company in a manner reasonably believed not to require the Company to make a public announcement of such offer or proposal.

# 3. <u>Restrictions on Dispositions</u>.

3.1 <u>Lock-Up</u>. During the Lock-Up Term, without the prior approval of the Company, the Investor shall not, and shall cause its Affiliates not to, Dispose of any of the Purchased Shares; <u>provided</u>, <u>however</u>, that the foregoing shall not prohibit the Investor from (i) transferring the Purchased Shares to a Permitted Transferee or (ii) Disposing of any Purchased Shares to reduce the beneficial ownership of the Standstill Parties to nineteen and ninety-nine hundredths percent (19.99%), or such lesser percentage as advised in good faith and in writing by the Investor's certified public accountants that would be necessary pursuant to applicable accounting rules and guidelines so as to not require the Investor to include in its financial

statements its portion of the Company's financial results, of the Shares of Then-Outstanding Common Stock; and <u>provided further</u> that, notwithstanding anything in this Section 3.1, the Investor shall not be precluded from the Disposition of Purchased Shares through open market sales effected through one or more "brokers' transactions" (as such term is used in Rule 144 promulgated under the Securities Act) on or after the Standstill and Lock-Up Relaxation Date in an amount not to exceed one percent (1%) of the Shares of Then-Outstanding Common Stock in any three (3) month period.

- 3.2 <u>Certain Tender Offers</u>. Subject to the restrictions set forth in Section 3.3 hereof, this Section 3 shall not prohibit or restrict any Disposition of Shares of Then-Outstanding Common Stock and/or Common Stock Equivalents by the Standstill Parties into (i) a tender offer by a Third Party or (ii) an issuer tender offer by the Company.
- 3.3 <u>Sale Limitations.</u> Subject to the restrictions set forth in Section 3.1 hereof, the Investor agrees that, except for any transfer of Shares of Then-Outstanding Common Stock and/or Common Stock Equivalents by the Investor to a Permitted Transferee or the Company, it (i) shall not, and shall cause its Affiliates not to, Dispose of any Shares of Then-Outstanding Common Stock and/or Common Stock Equivalents, in a "block trade" private placement transaction, at any time to any Person that such Investor or Affiliate knows (after a reasonable inquiry) is a Competitor of the Company and (ii) shall, and shall cause its Affiliates to, instruct the broker(s) in any such "block trade" not to Dispose Shares to a Competitor (unless the identity of the Person purchasing the Shares is not known to the broker(s) or such Person Disposing of Shares).
- 3.4 Offering Lock-Up. The Investor shall, if requested by the Company and an underwriter of Common Stock of the Company in connection with any public offering involving an underwriting of Common Stock of the Company, agree not to Dispose of any Shares of Then-Outstanding Common Stock and/or Common Stock Equivalents for a specified period of time immediately following the launch of such offering, such period of time not to exceed ninety (90) days following the pricing of such offering (a "Lock-Up Agreement"), provided that all officers and directors of the Company are subject to the same restrictions, and provided, further, that such agreement shall not restrict the Investor's ability to Dispose of any Shares of Then-Outstanding Common Stock and/or Common Stock Equivalents in accordance with Section 3.2 hereof. Any Lock-Up Agreement shall be in writing in a form reasonably satisfactory to the Company and the underwriter(s) in such offering. The Company may impose stop transfer instructions with respect to the Shares of Then-Outstanding Common Stock and/or Common Stock Equivalents subject to the foregoing restrictions until the end of the specified period of time. Any discretionary waiver or termination of the restrictions of any or all of such Lock-Up Agreements by the Company or the underwriters shall apply pro rata to the Investor based on the number of shares subject to such Lock-Up Agreements, excluding any waivers granted that fall within a customary de minimis exemption set forth in the associated Lock-Up Agreement.
- 3.5 <u>Transactions for Personal Account; Change of Control of the Investor</u>. For the avoidance of doubt, nothing in this Article 3 will restrict any Disposition of shares of Common Stock (i) held by an executive officer or director of the Investor for his or her personal account or (ii) that may occur (or be deemed to occur) in connection with a Change of Control of

the Investor (replacing references to "Company" with "Investor" in the definition of "Change of Control").

#### 4. <u>Voting Agreement</u>.

<u>Voting of Securities</u>. During the Voting Agreement Term, other than as permitted by Section 4.2 hereof with respect to Extraordinary Matters, in any vote or action by written consent of the stockholders of the Company (including, without limitation, with respect to the election of directors), the Investor shall, and shall cause any Permitted Transferees to, vote or execute a written consent with respect to the Purchased Shares, in the sole discretion of the Investor, in accordance with the recommendation of the Company's Board of Directors. In furtherance of this Section 4.1, the Investor hereby irrevocably appoints the Company and any individuals designated by the Company (such designated individuals to be limited to the President and Chief Executive Officer, the Chief Financial Officer the Chief Operating Officer and the Secretary of the Company), and each of them individually, as the attorneys, agents and proxies, with full power of substitution and resubstitution in each of them, for the Investor, and in the name, place and stead of the Investor, to vote (or cause to be voted) in such manner as set forth in this Section 4.1 (but in any case, excluding any matter that is an Extraordinary Matter described in Section 4.2 hereof) with respect to the Purchased Shares to which the Investor is or may be entitled to vote at any meeting of the Company held after the date hereof, whether annual or special and whether or not an adjourned meeting (the "Irrevocable Proxy"). This Irrevocable Proxy is coupled with an interest, shall be irrevocable and binding on any successor-in-interest of the Investor and shall not be terminated by operation of Law upon the occurrence of any event. This Irrevocable Proxy shall operate to revoke and render void any prior proxy as to voting securities heretofore granted by the Investor which is inconsistent herewith. Notwithstanding the foregoing, the Irrevocable Proxy shall be effective only if, at any annual or special meeting of the stockholders of the Company and at any adjournments or postponements of any such meetings, the Investor (i) fails to appear or otherwise fails to cause its voting securities of the Company to be counted as present for purposes of calculating a quorum, or (ii) fails to vote such voting securities in accordance with this Section 4.1, in each case at least five (5) Business Days prior to the date of such stockholders' meeting. The Irrevocable Proxy shall terminate upon the earlier of the expiration or termination of the Voting Agreement Term. The Investor shall cause any Permitted Transferee to promptly execute and deliver to the Company an irrevocable proxy, substantially in the form of Exhibit A attached hereto, and irrevocably appoint the Company and any individuals designated by the Company, and each of them individually, with full power of substitution and resubstitution, as the attorneys, agents and proxies to vote (or cause to be voted) such Purchased Shares of the Company as to which such Permitted Transferee is entitled to vote, in such manner as each such attorney, agent and proxy or his substitute shall in its, his or her sole discretion deem appropriate or desirable with respect to the matters set forth in this Section 4.1 (the "Permitted Transferee Irrevocable Proxy"). The Investor acknowledges, and shall cause any Permitted Transferees to acknowledge, that any such proxy executed and delivered shall be coupled with an interest, shall constitute, among other things, an inducement for the Company to enter into this Agreement, shall be irrevocable and binding on any successor-in-interest of such Permitted Transferee and shall not be terminated by operation of Law upon the occurrence of any event. Such proxy shall operate to revoke and render void any prior proxy as to any voting securities of the Company heretofore granted by such Permitted Transferee, to the extent it is inconsistent herewith. The Investor acknowledges and agrees that it shall be a condition to any

proposed transfer of voting securities of the Company by the Investor to such Permitted Transferee that such Permitted Transferee execute and deliver to the Company a Permitted Transferee Irrevocable Proxy, and that any purported transfer shall be void and of no force or effect if such Permitted Transferee Irrevocable Proxy is not so executed and delivered at the closing of such transfer. Such proxy shall terminate upon the earlier of the expiration or termination of the Voting Agreement Term. The Investor acknowledges and agrees that it shall be a condition to any proposed transfer of voting securities of the Company by the Investor to any Permitted Transferee during the Voting Agreement Term that such Permitted Transferee shall agree in writing to be subject to and bound by all restrictions and obligations set forth in this Section 4.1.

In the event the Company's stockholders are permitted to act by written consent, the Company and the Investor shall each negotiate in good faith with the other provisions as consistent as possible with the foregoing to govern the voting of the Investor's and its Permitted Transferees' Shares of Then-Outstanding Common Stock as closely as practicable to the foregoing.

- 4.2 <u>Certain Extraordinary Matters</u>. The Investor and its Permitted Transferees may vote, or execute a written consent with respect to, any or all of the voting securities of the Company as to which they are entitled to vote or execute a written consent, as they may determine in their sole discretion, with respect to the following matters (each such matter being an "**Extraordinary Matter**"):
  - (a) any transaction which would result in a Change of Control of the Company; and
  - (b) any liquidation or dissolution of the Company.
- 4.3 <u>Quorum</u>. In furtherance of Section 4.1 hereof, the Investor shall be, and shall cause each of its Permitted Transferees to be, present in person or represented by proxy at all meetings of stockholders to the extent necessary so that all voting securities of the Company as to which they are entitled to vote shall be counted as present for the purpose of determining the presence of a quorum at such meeting.
  - 5. <u>Termination of Certain Rights and Obligations</u>.
- 5.1 <u>Termination of Standstill Term</u>. Section 2 hereof shall terminate and have no further force or effect upon the earliest to occur of:
  - (a) the expiration or earlier valid termination of the Collaboration Agreement;
  - (b) the date that is the later of (i) the third anniversary of the Closing Date and (ii) the date of the Second Pivotal Clinical Trial Readout;
    - (c) a liquidation or dissolution of the Company; and
    - (d) the date on which the Common Stock ceases to be

- 5.2 <u>Termination of Lock-Up Term.</u> Section 3.1 hereof shall terminate and have no further force or effect upon the earliest to occur of:
  - (a) the date that is the later of (i) the third anniversary of the Closing Date and (ii) the date of the Second Pivotal Clinical Trial Readout;
    - (b) the beneficial ownership of the Standstill Parties falls below three percent (3%) of the Shares of Then-Outstanding Common Stock;
    - (c) a Change of Control of the Company;
    - (d) a liquidation or dissolution of the Company; and
    - (e) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act.
- 5.3 <u>Termination of Voting Agreement Term</u>. Section 5 hereof shall terminate and have no further force or effect upon the earliest to occur of:
  - (a) the date that is the later of (i) the third anniversary of the Closing Date and (ii) the date of the Second Pivotal Clinical Trial Readout;
  - (b) the beneficial ownership of the Standstill Parties falls below three percent (3%) of the Shares of Then-Outstanding Common Stock;
  - (c) a Change of Control of the Company;
  - (d) the expiration or earlier valid termination of the Collaboration Agreement; and
  - (e) a liquidation or dissolution of the Company.
- 5.4 <u>Termination of Agreement</u>. This Agreement shall terminate and have no further force or effect upon any termination of the Purchase Agreement prior to the Closing pursuant to Section 9.1 thereof.
- 5.5 <u>Effect of Termination</u>. No termination pursuant to any of Sections 5.1, 5.2, 5.3, or 5.4 hereof shall relieve any of the parties (or the Permitted Transferee, if any) for liability for breach of or default under any of their respective obligations or restrictions under any terminated provision of this Agreement, which breach or default arose out of events or circumstances occurring or existing prior to the date of such termination.

#### 6. <u>Miscellaneous</u>.

- 6.1 <u>Governing Law; Submission to Jurisdiction</u>. This Agreement shall be governed by and construed in accordance with the Laws of the State of Delaware, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Any action brought, arising out of, or relating to this Agreement shall be brought in the Court of Chancery of the State of Delaware. Each party hereby irrevocably submits to the exclusive jurisdiction of said Court in respect of any claim relating to the validity, interpretation and enforcement of this Agreement, and hereby waives, and agrees not to assert, as a defense in any action, suit or proceeding in which any such claim is made that it is not subject thereto or that such action, suit or proceeding may not be brought or is not maintainable in such courts, or that the venue thereof may not be appropriate or that this agreement may not be enforced in or by such courts. The parties hereby consent to and grant the Court of Chancery of the State of Delaware jurisdiction over such parties and over the subject matter of any such claim and agree that mailing of process or other papers in connection with any such action, suit or proceeding in the manner provided in Section 6.3 hereof or in such other manner as may be permitted by law, shall be valid and sufficient thereof.
- 6.2 <u>Waiver</u>. Neither party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either party to assert a right hereunder or to insist upon compliance with any term of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term except to the extent set forth in writing.
- 6.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth on Exhibit B attached hereto and shall be (i) delivered personally; (ii) sent by certified mail (return receipt requested), postage prepaid; or (iii) sent via a reputable nationwide overnight express courier service (signature required). Any such notice, instruction or communication shall be deemed to have been delivered (A) upon receipt if delivered by hand; (B) three (3) Business Days after it is sent by certified mail, return receipt requested, postage prepaid; or (C) one (1) Business Day after it is sent via a reputable nationwide overnight courier service. Either party may change its address by giving notice to the other party in the manner provided above; provided that notices of a change of address shall be effective only upon receipt thereof.
- 6.4 Entire Agreement. This Agreement, the Purchase Agreement and the Collaboration Agreement, in each case together with the schedules and exhibits thereto, set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the parties and supersede and terminate all prior agreements and understanding between the parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the parties other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the parties unless reduced to writing and signed by the respective authorized officers of the parties.

- 6.5 <u>Headings; Nouns and Pronouns; Section References</u>. Headings and any table of contents used in this Agreement are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.
- 6.6 <u>Severability</u>. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("**Modified Clause**"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.
- 6.7 <u>Assignment</u>. Except for an assignment of this Agreement by the Investor to a Permitted Transferee, neither this Agreement nor any rights or duties of a party hereto may be assigned by such party, in whole or in part, without (i) the prior written consent of the Company in the case of any assignment by the Investor; or (ii) the prior written consent of the Investor in the case of an assignment by the Company.
- 6.8 <u>Parties in Interest</u>. All of the terms and provisions of this Agreement shall be binding upon, and shall inure to the benefit of and be enforceable by the parties hereto and their respective successors, heirs, administrators and permitted assigns.
- 6.9 <u>Counterparts</u>. This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies from separate computers or printers. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.
- 6.10 <u>Third Party Beneficiaries</u>. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any party hereto. No Third Party with the exception of any Affiliate of the Investor shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any party hereto.
- 6.11 <u>No Strict Construction</u>. This Agreement has been prepared jointly and will not be construed against either party.
- 6.12 <u>Remedies</u>. The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or Law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or

exercise thereof.

- 6.13 Specific Performance. The Company and the Investor hereby acknowledge and agree that the rights of the parties hereunder are special, unique and of extraordinary character, and that if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the Company or the Investor, as the case may be, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged party at law or in equity, such damaged party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.
- 6.14 No Conflicting Agreements. The Investor hereby represents and warrants to the Company that neither it nor any of its Affiliates is, as of the date of this Agreement, a party to, and agrees that neither it nor any of its Affiliates shall, on or after the date of this Agreement, enter into any agreement that conflicts with the rights granted to the Company in this Agreement. The Company hereby represents and warrants to the Investor that it is not, as of the date of this Agreement, a party to, and agrees that it shall not, on or after the date of this Agreement, enter into any agreement or approve any amendment to its charter or by-laws or similar organizational documents of the Company with respect to its securities that conflicts with the rights granted to the Investor in this Agreement which have not expired or been terminated in accordance with the terms hereof. The Company further represents and warrants that the rights granted to the Investor hereunder do not in any way conflict with the rights granted to any other holder of the Company's securities under any other agreements.
- 6.15 <u>Use of Proceeds</u>. The Company shall use the proceeds from the sale of the Purchased Shares for research and development and other working capital purposes and shall not use such proceeds for the redemption of any shares of Common Stock or for the payment of any dividends on shares of Common Stock.
- 6.16 <u>No Publicity</u>. The parties hereto agree that the provisions of Section 11.3 of the Collaboration Agreement shall be applicable to the parties to this Agreement with respect to any public disclosures regarding the proposed transactions contemplated by the Purchase Agreement and the Collaboration Agreement or regarding the parties hereto or their Affiliates (it being understood that the provisions of Section 11.3 of the Collaboration Agreement shall be read to apply to disclosures of information relating to this Agreement and the transactions contemplated hereby).

(Signature Page Follows)

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

# NEUROCRINE BIOSCIENCES, INC.

By: /s/ Kevin Gorman

Name: Kevin Gorman Title: Chief Executive Officer

# VOYAGER THERAPEUTICS, INC.

By: /s/ G. Andre Turenne

Name: G. Andre Turenne

Title: President and Chief Executive Officer

[Signature Page to Investor Agreement]

#### **EXHIBIT A**

#### FORM OF IRREVOCABLE PROXY

To secure the performance of the duties of the undersigned pursuant to Section 4.1 of the Investor Agreement, dated as of January 28, 2019 (the "Agreement"), by and between Neurocrine Biosciences, Inc. and Voyager Therapeutics, Inc. (the "Company"), the undersigned hereby irrevocably appoints the Company and any individual designated by the Company, and each of them individually, as the attorneys, agents and proxies, with full power of substitution and resubstitution in each of them, for the undersigned, and in the name, place and stead of the undersigned, to vote (or cause to be voted) in such manner as set forth in Section 4.1 of the Agreement (but in any case excluding any matter that is an Extraordinary Matter described in Section 4.2) with respect to all Purchased Shares, which the undersigned is or may be entitled to vote at any meeting of the Company held after the date hereof, whether annual or special and whether or not an adjourned meeting. This proxy is coupled with an interest, shall be irrevocable and binding on any successor-in-interest of the undersigned and shall not be terminated by operation of Law upon the occurrence of any event. This proxy shall operate to revoke and render void any prior proxy as to voting securities heretofore granted by the undersigned which is inconsistent herewith. Notwithstanding the foregoing, this irrevocable proxy shall be effective only if, at any annual or special meeting of the stockholders of the Company (or any consent in lieu thereof) and at any adjournments or postponements of any such meetings, the undersigned (A) fails to appear or otherwise fails to cause its voting securities of the Company to be counted as present for purposes of calculating a quorum, or (B) fails to vote such voting securities in accordance with Section 4.1 of the Agreement, in each case at least five (5) Business Days prior to the date of such stockholders' meeting. This proxy shall terminate upon the earlier of the expiration or termination of the Voting Agreement Term. Capitalized terms used but not defined herein shall have the meanings given them in the Agreement.

#### NEUROCRINE BIOSCIENCES, INC.

By:/s/ Kevin Gorman

Name: Kevin Gorman Title: Chief Executive Officer

## **EXHIBIT B**

## **NOTICES**

## If to the Investor:

Neurocrine Biosciences, Inc. 12780 El Camino Real San Diego, CA 92130 Attention: General Counsel

# with a copy to:

Cooley LLP 4401 Eastgate Mall San Diego, CA 92121 Attention: Jason L. Kent, Esq.

If to the Company: Voyager Therapeutics, Inc. 75 Sidney Street Cambridge, MA 02139 Attention: Chief Executive Officer

# with a copy to:

Wilmer Cutler Pickering Hale and Dorr LLP 7 World Trade Center 250 Greenwich Street New York, NY 10007 Attention: Brian A. Johnson, Esq.

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

# **COLLABORATION AND OPTION AGREEMENT**

By and between

VOYAGER THERAPEUTICS, INC.

**AND** 

ABBVIE IRELAND UNLIMITED COMPANY

February 21, 2019

# TABLE OF CONTENTS

| ARTICLE 1 Definitions   |    |  |
|---|----|--|
| ARTICLE 2 Research; Development Option                            |    |  |
| 2.1 Research Plan   | 28 |  |
| 2.2 Conduct of Research   | 29 |  |
| 2.3 Development Option  | 31 |  |
| ARTICLE 3 Development; License Option                             | 32 |  |
| 3.1 Development Plan  | 32 |  |
| 3.2 Conduct of Development  | 33 |  |
| 3.3 License Option; Submission of Final Development Report(s)     | 35 |  |
| 3.4 HSR   | 36 |  |
| 3.5 No Exercise of License Option                                 | 37 |  |
| ARTICLE 4 AbbVie Responsibilities During Research and Development | 37 |  |
| 4.1 Access to Information and Materials                           | 37 |  |
| 4.2 AbbVie Assistance Generally                                   | 39 |  |
| 4.3 Impact of AbbVie's Assistance on Voyager's Obligations        | 39 |  |
| 4.4 AbbVie's Obligation to Provide Prompt Notice                  | 39 |  |
| ARTICLE 5 Management of The Collaboration                         | 39 |  |
| 5.1 Joint Governance Committee and Subcommittees                  | 39 |  |
| 5.2 Formation and Dissolution of Subcommittee(s)                  | 41 |  |
| 5.3 Working Groups  | 41 |  |
| 5.4 Membership  | 42 |  |
| 5.5 Meetings  | 43 |  |
| 5.6 Decision-Making   | 44 |  |
| 5.7 Alliance Managers   | 45 |  |
| 5.8 Authority   | 45 |  |
| ARTICLE 6 Grant of Licenses                                       |    |  |
| 6.1 Licenses to AbbVie  | 46 |  |
| 6.2 In-License Agreements   | 46 |  |
| 6.3 Sublicensing Rights   | 50 |  |
| 6.4 Licenses to Voyager   | 50 |  |
| 6.5 [**] Agreement  | 51 |  |
| 6.6 No Other Rights   | 51 |  |
| 6.7 Confirmatory Patent License                                   | 51 |  |

| 6.8  | Section 365(n) of the Bankruptcy Code   | 52 |
|--|---|----|
| ARTICLE  | E 7 Post-License Option Exercise Activities   | 52 |
| 7.1  | Transition Plan   | 52 |
| 7.2  | Voyager Transition Obligation Upon License Option Exercise                            | 52 |
| 7.3  | AbbVie Development and Commercialization  | 54 |
| 7.4  | Allocation of Rights with Respect to Transferred Contracts                            | 54 |
| ARTICLE 8 Manufacturing                                    |   |    |
| 8.1  | Manufacturing Responsibilities Prior to License Option Exercise                       | 55 |
| 8.2  | Manufacturing After License Option Exercise   | 56 |
| 8.3  | Manufacturing Technology Transfer and Continued Improvement                           | 56 |
| 8.4  | AbbVie Manufacturing Improvements   | 59 |
| ARTICLE  | E 9 General Provisions Relating to Activities   | 60 |
| 9.1  | Compliance  | 60 |
| 9.2  | Regulatory Activities   | 60 |
| 9.3  | Subcontracting  | 62 |
| 9.4  | Records and Audits  | 62 |
| ARTICLE 10 Initial Fee; Milestones and Royalties; Payments |   | 63 |
| 10.1   | Upfront Fee   | 63 |
| 10.2   | Milestone Payments  | 63 |
| 10.3   | Royalties   | 67 |
| 10.4   | Royalty Term  | 68 |
| 10.5   | Royalty Adjustments   | 69 |
| 10.6   | Estimated Sales Levels  | 70 |
| 10.7   | Reports; Payment of Royalty   | 70 |
| 10.8   | Financial Records   | 70 |
| 10.9   | Audit; Audit Dispute  | 70 |
| 10.10  | Methods of Payments   | 71 |
| 10.11  | Taxes   | 72 |
| 10.12  | Late Payments   | 73 |
| 10.13  | $Financial\ Obligations\ under\ In-License\ Agreements\ and\ any\ AbbVie\ Agreements$ | 73 |
| ARTICLE 11 Exclusivity 7                                   |   |    |
| 11.1   | Vectorized Alpha-Synuclein Antibody Exclusivity                                       | 74 |
| 11.2   | AbbVie Designated Antibody Exclusivity  | 74 |

| 11.3                                      | Failure to Deliver Final Reports; Infeasibility Terminations                             | 74  |
|---|--|-----|
| 11.4                                      | Exception for Basic Research   | 75  |
| ARTICLI                                   | E 12 Ownership of Intellectual Property Rights   | 75  |
| 12.1                                      | Ownership of Intellectual Property; Disclosure   | 75  |
| 12.2                                      | Patent Prosecution and Maintenance   | 78  |
| 12.3                                      | Enforcement and Defense  | 81  |
| 12.4                                      | Biosimilar Applicants  | 85  |
| 12.5                                      | Infringement Claimed by Third Parties  | 86  |
| 12.6                                      | Marking  | 88  |
| 12.7                                      | Product Trademarks   | 88  |
| 12.8                                      | Third Party Agreements   | 89  |
| ARTICLI                                   | E 13 Confidentiality   | 90  |
| 13.1                                      | Confidentiality; Exceptions  | 90  |
| 13.2                                      | Exceptions to Confidential Information   | 90  |
| 13.3                                      | Authorized Disclosure  | 91  |
| 13.4                                      | Additional Permitted Disclosures and Use by AbbVie                                       | 92  |
| 13.5                                      | Use of Names   | 93  |
| 13.6                                      | Press Release; Disclosure of Agreement   | 93  |
| 13.7                                      | Publications   | 94  |
| ARTICLE 14 Representations and Warranties |  | 95  |
| 14.1                                      | Representations and Warranties of Both Parties   | 95  |
| 14.2                                      | Representations, Warranties and Covenants, as applicable, of Voyager                     | 96  |
| 14.3                                      | Mutual Covenants   | 101 |
| 14.4                                      | Additional Covenants of Voyager  | 102 |
| 14.5                                      | Additional Representations and Warranties with respect to the AbbVie Designated Antibody | 102 |
| 14.6                                      | Data Privacy and Security  | 102 |
| 14.7                                      | Disclaimer   | 104 |
| 14.8                                      | Anti-Bribery and Anti-Corruption Compliance  | 104 |
| ARTICLI                                   | E 15 Indemnification; Insurance  | 105 |
| 15.1                                      | Indemnification by AbbVie  | 105 |
| 15.2                                      | Indemnification by Voyager   | 105 |
| 15.3                                      | Procedure  | 106 |
| 15.4                                      | Insurance  | 108 |

| 15.5            | Limitation of Liability   | 109          |
|-----------------|---|--------------|
| ARTICLE         | 16 Term and Termination   | 109          |
| 16.1            | Term  | 109          |
| 16.2            | Termination   | 110          |
| 16.3            | Modification In Lieu of Termination   | 112          |
| 16.4            | Effects of Termination  | 113          |
| 16.5            | Accrued Rights; Surviving Provisions of this Agreement                                  | 114          |
| ARTICLE         | 17 Miscellaneous  | 116          |
| 17.1            | Governing Law; Jurisdiction and Service   | 116          |
| 17.2            | Dispute Resolution  | 116          |
| 17.3            | Assignment  | 117          |
| 17.4            | Certain Strategic Transactions  | 118          |
| 17.5            | Performance by Affiliates and Sublicensees  | 119          |
| 17.6            | Force Majeure   | 119          |
| 17.7            | Notices   | 119          |
| 17.8            | Export Clause   | 121          |
| 17.9            | Waiver; Non-Exclusion of Remedies   | 121          |
| 17.10           | Severability  | 121          |
| 17.11           | Equitable Relief  | 121          |
| 17.12           | Entire Agreement  | 122          |
| 17.13           | Independent Contractors   | 122          |
| 17.14           | Headings; Construction; Interpretation  | 122          |
| 17.15           | Books and Records   | 123          |
| 17.16           | Further Actions   | 123          |
| 17.17           | Parties in Interest   | 123          |
| 17.18           | Counterparts  | 123          |
| Schedules       |   |              |
| Schedule        | 1.41 Development Plan   |              |
| <u>Schedule</u> |   |              |
| <u>Schedule</u> |   |              |
| Schedule        |   | C 1 1        |
| Schedule !      | Terms of Third Party Licensee Agreements to which AbbVie's Rights under Section Subject | on 6.1.1 are |

| Schedule 9.3.2         | Preapproved Subcontractors  |
|------------------------|---|
| Schedule 12.8          | Terms of Third Party IP Prosecution and Enforcement Agreements to which AbbVie's ARTICLE  |
|                        | 12 Rights are Subject   |
| Schedule 13.6          | Press Release   |
| Schedule 14.1.4        | Conflicting Provisions of Third Party Agreements  |
| <u>Schedule 14.1.5</u> | List of Obligations that would Materially Impede the Diligent and Complete Fulfillment of |
|                        | Obligations Hereunder   |
| Schedule 14.2          | Exceptions to Representations and Warranties in Section 14.2                              |
| <u>Schedule 14.2.1</u> | Existing In-License Agreements  |
| <u>Schedule 14.2.4</u> | Existing Patent Rights  |
| <u>Schedule 14.2.6</u> | Existing In-License Agreements and Future Voyager In-License Agreements                   |
| Schedule 17.2.2        | ADR Procedures  |

This COLLABORATION AND OPTION AGREEMENT (this "<u>Agreement</u>") is entered into and made effective as of February 21, 2019 (the "<u>Effective Date</u>"), by and between Voyager Therapeutics, Inc., a Delaware corporation, having its principal place of business at 75 Sidney Street, Cambridge, MA 02139 ("<u>Voyager</u>"), and AbbVie Ireland Unlimited Company, an Irish private unlimited company, having its principal place of business at 70 Sir John Rogerson's Quay, Dublin 2, Ireland ("<u>AbbVie</u>"). Voyager and AbbVie shall be referred to herein individually as a "Party" and collectively as the "Parties".

#### RECITALS

WHEREAS, Voyager is a gene therapy company focused on the research and development of products for the treatment of diseases of the central nervous system, including Parkinson's Disease ("PD") and other neurodegenerative diseases;

WHEREAS, AbbVie possesses expertise in the research, development, manufacturing and commercialization of human pharmaceuticals;

WHEREAS, AbbVie controls certain intellectual property rights relating to the AbbVie Designated Antibodies (as defined herein); and

WHEREAS, Voyager and AbbVie desire to engage in a collaborative effort in which Voyager will carry out certain preclinical research activities, and may also conduct certain clinical development activities, relating to the identification and development of Research Compounds (as defined herein), and pursuant to which AbbVie will have certain options to further develop and commercialize Licensed Products (as defined herein) worldwide.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

# ARTICLE 1 DEFINITIONS

As used in this Agreement, the following terms will have the meanings set forth in this ARTICLE 1 unless context dictates otherwise:

- 1.1 "<u>AbbVie Background IP</u>" means the AbbVie Background Know-How and the AbbVie Background Patent Rights.
- 1.2 "AbbVie Background Know-How" means all Know-How that (a) is Controlled by AbbVie as of the Effective Date or during the Term, (b) is not generally known and (c) is necessary or reasonably useful to Exploit in the Field in the Territory an AbbVie Designated Antibody or any Research Compound, Selected Research Compound, Research Product, Selected Research Product, Licensed Compound or Licensed Product, as applicable, other than any AbbVie Designated Antibody Know-How or Collaboration Know-How.
- 1.3 "<u>AbbVie Background Patent Rights</u>" means all Patent Rights Controlled by AbbVie as of the Effective Date or during the Term that claim or Cover the Exploitation in the

Field in the Territory of an AbbVie Designated Antibody or any Research Compound, Selected Research Compound, Research Product, Selected Research Product, Licensed Compound or Licensed Product, as applicable, other than any AbbVie Designated Antibody Patent Rights or Collaboration Patent Rights.

- 1.4 "<u>AbbVie Designated Antibody</u>" means, initially, the antibodies licensed to AbbVie pursuant to the [\*\*] Agreement (the "[\*\*] <u>Antibodies</u>"), or any other subsequent Alpha-Synuclein Antibody(ies) that AbbVie may designate pursuant to Section 2.1.3, and any Derivative of such Alpha-Synuclein Antibody(ies) even if such Derivative results from the Research Program or Development Program.
- 1.5 "<u>AbbVie Designated Antibody IP</u>" means the AbbVie Designated Antibody Know-How and the AbbVie Designated Antibody Patent Rights.
- 1.6 "AbbVie Designated Antibody Know-How" means all Know-How that is conceived, discovered, developed or otherwise made or acquired (whether by license, exercise of option, acquisition or otherwise) (a) by or on behalf of either Party (or its Affiliates or its or their (sub)licensees/Sublicensees) or (b) jointly by or on behalf of AbbVie (or its Affiliates or its or their Sublicensees), on the one hand, and Voyager (or its Affiliates or its or their (sub)licensees), on the other hand, in each case ((a) and (b)), under this Agreement during the Term that is solely related to an AbbVie Designated Antibody, including such Know-How that relates to the use of an AbbVie Designated Antibody in viral vectors, the expression of an AbbVie Designated Antibody in particular cell types (through the use of viral vectors or otherwise) for therapeutic effect, the optimal binding regions of an AbbVie Designated Antibody (for expression in viral vectors or otherwise), and any change to an AbbVie Designated Antibody's Sequence, including humanization, class switching, linking of antibody domains or changes to the variable regions, but excluding any Vectorization Know-How.
- 1.7 "<u>AbbVie Designated Antibody Patent Rights</u>" means any Patent Rights that solely claim AbbVie Designated Antibody Know-How or an AbbVie Designated Antibody, but excluding any Vectorization Patent Rights.
- 1.8 "<u>Accounting Standards</u>" means, with respect to a Party or its Affiliates or its or their (sub)licensees/Sublicensees, United States generally accepted accounting principles or International Financial Reporting Standards as issued by the International Accounting Standards Board, as applicable, in each case consistently applied.
- 1.9 "<u>Adaptive Trial</u>" means a human clinical trial that is a Phase 2 Clinical Trial that does not meet the criteria for a Phase 3 Clinical Trial at the time such human clinical trial is Initiated and includes a prospectively planned opportunity for such human clinical trial to be modified based on interim analyses to change to a Phase 3 Clinical Trial following an analysis of interim data from subjects in such human clinical trial.
- 1.10 "Affiliate" means, with respect to a Person, any Person that, directly or indirectly through one (1) or more intermediaries, controls, is controlled by or is under common control with such first Person for so long as such Person controls, is controlled by or is under common control with such first Person, regardless of whether such Affiliate is or becomes an Affiliate on

or after the Effective Date. A Person shall be deemed to "control" another Person if it (a) owns, directly or indirectly, beneficially or legally, more than fifty percent (50%) of the outstanding voting securities or capital stock of such other Person, or has other comparable ownership interests with respect to any Person other than a corporation; or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of such other Person.

- 1.11 "<u>Alpha-Synuclein</u>" means the protein that is encoded by the alpha synuclein gene designated SCNA (Gene ID: ENSG00000145335), including forms existing as intrinsically disordered proteins as well as all post-translationally modified forms.
- 1.12 "<u>Alpha-Synuclein Antibody</u>" means an immunoglobulin molecule (including the nucleic acid sequence encoding such immunoglobulin molecule) having a unique set of complementarity determining regions ("<u>CDRs</u>"), whether murine, human, or humanized, and whether derived from non-human or non-murine species, or generated via phage display or other methods (each of the foregoing, a "<u>Variation</u>") and that is targeted to, and specifically binds, Alpha-Synuclein. Each immunoglobulin molecule with a unique set of CDRs shall be a separate Alpha-Synuclein Antibody; however, each Variation of an immunoglobulin molecule containing such same unique set of CDRs shall be considered the same Alpha-Synuclein Antibody.
- 1.13 "Annual Net Sales" means, with respect to a Licensed Compound and a Calendar Year (a) the total Net Sales of all of the Licensed Products that contain or are comprised of such Licensed Compound in the aggregate in the Territory in such Calendar Year, plus (b) any Settlement Proceeds received by AbbVie or any of its Affiliates in such Calendar Year to the extent attributable to any Licensed Product that contains or is comprised of such Licensed Compound.
  - 1.14 "[\*\*]" means that [\*\*].
- 1.15 "Biosimilar Product" means, with respect to a particular Licensed Product in a particular country in the Territory, any pharmaceutical product with respect to which a Third Party has received Regulatory Approval for a BLA for such product as a biosimilar to, or that is interchangeable with, such Licensed Product (a) under Section 351(k) of the PHSA in the United States (or any successor provisions thereto) or under Article 10(4) of Directive 2001/83/EC in the European Union or any member state thereof (or any successor provisions thereto), in each case citing such Licensed Product as the reference product or (b) for which the BLA otherwise references or relies on such Licensed Product under applicable Law in any other country in the Territory. A Biosimilar Product shall not include any such product sold by a Sublicensee or Distributor under a license or other authorization from AbbVie, any of its Affiliates or any Sublicensee prior to the Unauthorized Launch Date for such Licensed Product.
- 1.16 "<u>BLA</u>" means a Biologics License Application submitted to FDA pursuant to 21 U.S.C. § 601.2 (or any successor regulation thereto), for purposes of obtaining Regulatory Approval for a new biologic in the United States, or any equivalent filing in a country or regulatory jurisdiction other than the United States.

- 1.17 "BPCI Act" means the Biologics Price Competition and Innovation Act of 2009 as may be amended from time to time, and the rules and regulations promulgated thereunder (including all additions, supplements, extensions and modifications thereto).
- 1.18 "Business Day" means a day on which banking institutions in Boston, Massachusetts, and Chicago, Illinois, are open for business, excluding any Saturday or Sunday.
- 1.19 "<u>Calendar Quarter</u>" means a period of three (3) consecutive months ending on the last day of March, June, September, or December, respectively, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date and the last Calendar Quarter shall end on the last day of the Term.
- 1.20 "Calendar Year" means a period of twelve (12) consecutive months beginning on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.
  - 1.21 "[\*\*]" means that [\*\*].
- 1.22 "<u>cGMP</u>" means the current Good Manufacturing Practices as provided for (and as amended from time to time) in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Harmonized Tripartite Guideline, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, Q7 (ICH Q7), the EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use in Volume 4 of the European Commission's Rules governing medicinal products in the European Union, and the United States Code of Federal Regulations 21 C.F.R. Parts 210 and 211, in each case, as applicable.
- 1.23 "Change of Control" means, with respect to a Party (a) the acquisition of beneficial ownership, directly or indirectly, by any Third Party of securities or other voting interest of such Party (or, if applicable, a parent of such Party) representing a majority or more of the combined voting power of such Party's (or, if applicable, a parent of such Party) then outstanding securities or other voting interests, (b) any merger, reorganization, consolidation or business combination involving such Party (or, if applicable, a parent of such Party) with a Third Party that results in the holders of beneficial ownership of the voting securities or other voting interests of such Party (or, if applicable, a parent of such Party) immediately prior to such merger, reorganization, consolidation or business combination ceasing to hold beneficial ownership of more than fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization, consolidation or business combination, or (c) any sale, lease, exchange, contribution or other transfer to a Third Party (in one transaction or a series of related transactions) of all or substantially all of the consolidated assets of such Party to which this Agreement relates. The acquiring or combining Third Party in any of clause (a), (b) or (c), is referred to herein as the "Acquirer".

- 1.24 "<u>Clinical Trial</u>" means a Phase 0 Clinical Trial, Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial, Adaptive Trial, Converted Trial or any other study in which human subjects or patients are dosed with a drug, whether approved or investigational.
- 1.25 "Collaboration IP" means the Collaboration Know-How and the Collaboration Patent Rights. For clarity, Collaboration IP shall not include Voyager Background IP or AbbVie Background IP.
- 1.26 "Collaboration Know-How" means all Know-How that is conceived, discovered, developed or otherwise made or acquired (whether by license, exercise of option, acquisition or otherwise) (a) by or on behalf of either Party (or its Affiliates or its or their (sub)licensees/Sublicensees) or (b) jointly by or on behalf of AbbVie (or its Affiliates or its or their Sublicensees), on the one hand, and Voyager (or its Affiliates or its or their (sub)licensees), on the other hand, in each case ((a) and (b)), under the Research Program or Development Program, but excluding Vectorization Know-How and AbbVie Designated Antibody Know-How; provided that any such Know-How that relates to Alpha-Synuclein and is not solely related to an AbbVie Designated Antibody, such as identifying particular epitopes of Alpha-Synuclein, is Collaboration Know-How.
- 1.27 "Collaboration Patent Rights" means any Patent Rights that (a) claim Collaboration Know-How or (b) are acquired (whether by license, exercise of option, acquisition or otherwise) (i) by or on behalf of either Party (or its Affiliates or its or their (sub)licensees/Sublicensees) or (ii) jointly by or on behalf of AbbVie (or its Affiliates or its or their Sublicensees), on the one hand, and Voyager (or its Affiliates or its or their (sub)licensees), on the other hand, in each case ((i) and (ii)), under the Research Program or Development Program, in each case ((a) and (b)), other than Vectorization Patent Rights and AbbVie Designated Antibody Patent Rights.
- 1.28 "<u>Combination Product</u>" means a Licensed Product that, in addition to the applicable Licensed Compound, is sold with one (1) or more other active pharmaceutical ingredients either as a fixed dose/unit or as separate doses/units in a single package for a single price.
- 1.29 "Commercialization" and "Commercialize" means any and all activities undertaken relating to the marketing, obtaining pricing and reimbursement approvals, promotion (including advertising, detailing or continuing medical education), any other offering for sale or any sale of a product, including any distribution, importation, exportation or transport of a product for sales purposes. "Commercialization" shall not include Research or Development, but may include Manufacturing to the extent applicable to the activities described in the preceding sentence.
- 1.30 "<u>Commercially Reasonable Efforts</u>" means, (a) with respect to the efforts and resources to be expended by AbbVie with respect to any objective, activity or decision to be undertaken with respect to the Research, Development, Manufacture or Commercialization of a Research Compound, Selected Research Compound, Research Product, Selected Research Product, Licensed Compound or Licensed Product, the reasonable efforts and resources to accomplish such objective, activity or decision that would be comparable with the efforts and

resources that AbbVie would normally use in the exercise of its reasonable business discretion to accomplish a similar objective, activity or decision with respect to its own internally developed compound or product that is at a similar stage in its development or product life, is in a similar therapeutic and disease area and is of similar market potential taking into account all relevant factors (including legal, medical, scientific, technical and commercial factors), including: (i) the potential profitability of the product, (ii) the costs and risks of Developing, Manufacturing, having Manufactured, using and Commercializing the product, (iii) scientific, safety and regulatory concerns, (iv) product profile, (v) the competitiveness of the marketplace and (vi) the proprietary position of the product; and (b) with respect to the efforts and resources to be expended by Voyager with respect to any objective, activity or decision to be undertaken with respect to the Research or Development of a Research Compound, Selected Research Compound, Research Product, Selected Research Product, Licensed Compound or Licensed Product, such reasonable and good faith efforts and resources to accomplish such objective, activity or decision that would be comparable with the efforts and resources normally used in the biotechnology industry for research and development of novel biopharmaceutical products at a similar stage in development without regard to the particular facts and circumstances of Voyager. In addition, with regard to AbbVie's obligations relating to the Development and Commercialization of Licensed Compound(s) and Licensed Product(s) hereunder, "Commercially Reasonable Efforts" shall be determined on a country-by-country or market-by-market basis (as most applicable) for a particular product, and it is anticipated that the level of effort will change over time, including to reflect changes in the status of the product and the countries (or markets) involved. For the avoidance of doubt, where a Party has an obligation to use Commercially Reasonable Efforts, the efforts of such Party and its Affiliates, subcontractors and (sub)licensees/Sublicensees shall be considered in determining whether such Party has satisfied such obligation.

- 1.31 "<u>Competitive Product</u>" means a product that (a) is sold by a Third Party not under authorization, direct or indirect, from Voyager, AbbVie, any of their respective Affiliates or any (sub)licensee/Sublicensee, (b) is directed to Alpha-Synuclein and (c) contains or Encodes, as applicable, a Vectorized Alpha-Synuclein Antibody.
- 1.32 "<u>Control</u>" means, subject to Section 17.3.2, with respect to a Person and any Regulatory Filings, Know-How, Patent Right, other intellectual property right, material, data, results or other information, the possession by such Person or any of its Affiliates of the right, whether through ownership or license (other than by a license under this Agreement), to grant the licenses, sublicenses or other rights (including the right to reference Regulatory Filings) as provided herein without violating the terms of any agreement or other arrangement with any Third Party.
- 1.33 "<u>Converted Trial</u>" means an Adaptive Trial that is modified to meet and otherwise satisfies the criteria for a Phase 3 Clinical Trial based on pre-specified analyses following an analysis of interim data from subjects in such Adaptive Trial. For clarity, an Adaptive Trial shall only constitute a Converted Trial if, from and after the date following such modification, such Adaptive Trial is continued as a Phase 3 Clinical Trial (such date with respect to such Converted Trial, the "<u>Conversion Date</u>").

- 1.34 "Cover" means that, in the absence of ownership of or a license granted under a Valid Claim, the Research, Development, Manufacture, use or Commercialization of an AbbVie Designated Antibody, Vectorized Alpha-Synuclein Antibody, Research Compound, Selected Research Compound, Research Product, Selected Research Product, Licensed Compound, Licensed Product or active pharmaceutical ingredient (as applicable) would infringe such Valid Claim (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue).
- 1.35 "<u>CPI</u>" means (a) with respect to FTEs in the United States the Consumer Price Index All Urban Consumers, 1982-84=100, by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index), or (b) an equivalent index in a foreign country applicable to FTEs in such country, accounting if possible for the area in such country where the personnel are located.
- 1.36 "<u>CPI Adjustment</u>" means the percentage increase or decrease, if any, in the CPI applicable to such personnel for the twelve (12) months ending June 30 of the Calendar Year prior to the Calendar Year for which the adjustment is being made.
- 1.37 "<u>Data Protection Laws</u>" means any law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding restriction (as amended, consolidated or re-enacted from time to time) to which a Party is subject that relates to the protection of individuals with regard to the Processing of Personal Data.
- "Derivative" means, with respect to an Alpha-Synuclein Antibody, (a) the fragments and alternate 1.38 formats of such Alpha-Synuclein Antibody such as Fab, Fab2, scFVs, nanobodies, intrabodies, diabodies, (b) monoor multi-specific and mono- or multi-valent immunoglobulin molecules arising from fusions or other modifications of or to such Alpha-Synuclein Antibody, in each of the foregoing cases ((a) and (b)) that specifically binds to Alpha-Synuclein and (c) any immunoglobulin molecule (including any fragments and alternative formats thereof, such as Fab, Fab2, scFVs, nanobodies, intrabodies, diabodies, and mono- or multi-specific and mono- or multivalent immunoglobulin molecules arising from fusions or other modifications of or to such immunoglobulin molecule) that comprises any modification to a CDR of such Alpha-Synuclein Antibody that results in greater than eighty percent (80%) sequence identity relative to the original CDR of such Alpha-Synuclein Antibody prior to the modification (such CDR sequence identity determined by the Clustal W software program, Version clustalw1.83, January 30, 2003, set to default settings, or such other similar software program as may be mutually agreed upon by the Parties) and binds to Alpha-Synuclein, as evidenced for purposes of this clause (c) by the ability of such immunoglobulin molecule to inhibit binding of the original unmodified Alpha-Synuclein Antibody to Alpha-Synuclein by at least seventy percent (70%) in assays conducted in each of the following orientations: (x) unmodified Alpha-Synuclein Antibody immobilized and such immunoglobulin molecule is in solution and (y) such immunoglobulin molecule is immobilized and the unmodified Alpha-Synuclein Antibody is in solution.
- 1.39 "<u>Develop</u>" or "<u>Development</u>" means any research and development activities commencing with IND-enabling studies, including (as applicable) pharmacology, biodistribution and transduction studies and tissue distribution across species, translational studies, toxicology

and tolerability studies, additional pharmacology/efficacy studies, statistical analysis and report writing, formulation, formulation development and optimization, process development, methods development, Clinical Trials, regulatory affairs (including preparation for a Regulatory Approval Application submission and other submission-related activities), product approval and registration activities, Manufacturing (including validation activities) in support of the foregoing and as necessary to support Commercialization, and all other activities necessary to conduct IND-enabling studies or seek, obtain and maintain Regulatory Approval. "Development" shall not include Research or Commercialization, but may include Manufacturing to the extent applicable to the activities described in the preceding sentence.

- 1.40 "Development Option Period" means the time period commencing upon the date Voyager delivers to AbbVie the first complete Final Research Report with respect to a Research Compound, and ending [\*\*] after the date Voyager delivers to AbbVie the complete Final Research Report with respect to the last Research Compound, during which time AbbVie shall have the right to exercise the Development Option with respect to each Research Compound; provided, however, that if any Final Research Report delivered by Voyager to AbbVie is not complete, such time period shall not end until [\*\*] after the date Voyager has provided AbbVie a complete Final Research Report for each such Research Compound.
- 1.41 "<u>Development Plan</u>" means the written plan that sets forth in reasonable detail specific Development activities to be conducted by Voyager during the Voyager Development Period, including the Voyager Development Budget, as each may be amended from time to time in accordance with this Agreement. The initial Development Plan, including the initial Voyager Development Budget, is attached hereto as <u>Schedule 1.41</u>.
- 1.42 "<u>Development Program</u>" means all Development activities performed in accordance with the Development Plan during the Voyager Development Period.
- 1.43 "<u>Diligent Efforts</u>" means, with respect to the efforts and resources to be expended by Voyager with respect to any task or activity set forth in a Plan, applying the necessary resources and personnel to complete such task or activity in a timely manner, including (a) assigning responsibility for such task or activity to specific employee(s) with appropriate experience and expertise who are held accountable for progress and monitoring such progress on an on-going basis; (b) setting and consistently seeking to achieve specific and meaningful objectives for carrying out such task or activity; and (c) making and implementing decisions and allocating resources designed to advance progress with respect to such task or activity. For clarity, the foregoing standard is not intended to guarantee a particular result with respect to a task or activity.
- 1.44 "<u>Distributor</u>" means any Person appointed by AbbVie or any of its Affiliates or its or their Sublicensees to distribute, market and sell a Licensed Product with or without finishing or packaging rights, in one (1) or more countries in the Territory, in circumstances where such Person (a) purchases all of its requirements of such Licensed Product from AbbVie or its Affiliates or its or their Sublicensees, and (b) is not a sublicensee of AbbVie or any of its Affiliates or its or their Sublicensees under the rights granted to AbbVie under Section 6.1.1 (except to the extent sublicensed to finish or package such Licensed Product) and does not make any royalty or other similar payments tied to Net Sales as consideration for the grant of rights

- under Section 6.1.1. Distributors shall not include Persons, such as wholesalers, that (i) distribute pharmaceutical products to pharmacies, hospitals and health systems but do not have primary responsibility for marketing or obtaining and maintaining regulatory approval for the pharmaceutical products they distribute and (ii) are used by pharmaceutical companies generally in such country to distribute their products (e.g., Cardinal, McKesson).
- 1.45 "<u>DOJ</u>" means the Antitrust Division of the United States Department of Justice, and any successor entity thereto.
  - 1.46 "Dollars" or "\$" means the legal tender of the U.S.
  - 1.47 "EMA" means the European Medicines Agency, and any successor entity thereto.
- 1.48 "<u>Encodes</u>" (with a correlative meaning for "<u>Encoding</u>") means, with respect to a compound or product, or a component of either of the foregoing, (including a Research Compound, Research Product, Selected Research Compound, Selected Research Product, Licensed Compound, Licensed Product, Virus Vector or Vector Genome) and a protein, that such product, compound or component is designed to express such protein.
- 1.49 "<u>Executive Officers</u>" means the Chief Executive Officer, or his or her designee, in the case of Voyager, and Chief Scientific Officer, or his or her designee, in the case of AbbVie.
- 1.50 "Exercise Notice" means with respect to AbbVie and the Development Option or License Option, written notice by AbbVie to Voyager exercising the Development Option or License Option, as applicable, which notice shall include any additional information required therein, as applicable.
- 1.51 "Existing In-License Agreement" means any license or other agreement between Voyager or any of its Affiliates, on the one hand, and a Third Party, on the other hand, existing as of the Effective Date regarding any Third Party intellectual property rights licensed to AbbVie hereunder, including the Voyager Background Know-How, including those in-license agreements set forth on Schedule 14.2.6 attached hereto. For purposes of Section 6.2, Existing In-License Agreements shall not include any license or other agreement that was not disclosed to AbbVie at least [\*\*] prior to the Effective Date.
- 1.52 "<u>Exploit</u>" or "<u>Exploitation</u>" means to make, have made, import, use, sell, or offer for sale, Research, Develop, Manufacture or Commercialize.
  - 1.53 "FDA" means the United States Food and Drug Administration, and any successor entity thereto.
- 1.54 "<u>FFDCA</u>" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).
  - 1.55 "Field" means all human diagnostic, prophylactic and therapeutic uses.

- 1.56 "Final Development Report" means, with respect to a Selected Research Compound and corresponding Selected Research Product, the final, written development report that Voyager shall deliver to AbbVie upon the completion of the activities set forth in the Development Plan for such Selected Research Compound and corresponding Selected Research Product, including (a) the results and related data from all IND-enabling studies, all Phase 1 Clinical Trials and other Development activities performed by Voyager under the Development Plan, in each case, with respect to such Selected Research Compound and corresponding Selected Research Product, which in each case shall include at least the results and data that are specifically identified and required to be delivered for such Selected Research Compound as described in the Development Plan, and (b) an updated Schedule 14.2, which shall include (and shall be limited to) (i) any exceptions to the representations and warranties set forth in Section 14.2.2; Section 14.2.4; Section 14.2.6; Section 14.2.8; Section 14.2.10; Section 14.2.12; the last sentence of Section 14.2.13; and Section 14.2.14, in each case, for such Selected Research Compound and corresponding Selected Research Product and any other Selected Research Compound and corresponding Selected Research Product for which Voyager has previously delivered a Final Development Report, and (ii) updated versions of Schedule 14.2.4 and Schedule 14.2.6.
- 1.57 "Final Research Report" means, with respect to a Research Compound and corresponding Research Product, the final, written research report that Voyager shall deliver to AbbVie upon the completion of the activities set forth in the Research Plan for such Research Compound and corresponding Research Product, including (a) the results and related data from all Research activities performed by Voyager under the Research Plan, in each case, with respect to such Research Compound and corresponding Research Product, which in each case shall include at least the results and data that are specifically identified and required to be delivered for such Research Compound as described in the Research Plan, and (b) an updated Schedule 14.2, which shall include (and shall be limited to) (i) any exceptions to the representations and warranties set forth in Section 14.2.2; Section 14.2.4; Section 14.2.6; Section 14.2.8; Section 14.2.10; Section 14.2.12; the last sentence of Section 14.2.13; and Section 14.2.14, in each case, for such Research Compound and corresponding Research Product and any other Research Compounds and corresponding Research Product for which Voyager has previously delivered a Final Research Report but for which AbbVie has not yet exercised its Development Option, and (ii) updated versions of Schedule 14.2.4 and Schedule 14.2.6.
- 1.58 "<u>First Commercial Sale</u>" means, with respect to a Licensed Product, an Indication and a country in the Territory, the first sale for monetary value and for end use or consumption of such Licensed Product for such Indication in such country after all Regulatory Approvals for such Licensed Product for such Indication have been granted by the applicable Regulatory Authority or Governmental Authority of such country. Sales prior to receipt of all Regulatory Approvals for such Licensed Product in such country, such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales," shall not be construed as a First Commercial Sale.
  - 1.59 "FTC" means the United States Federal Trade Commission, and any successor entity thereto.

- 1.60 "FTE" means the equivalent of the work of one (1) full time employee (i.e., one (1) fully-committed or multiple partially-committed employees aggregating to one (1) full-time employee) for one (1) Calendar Year (consisting of [\*\*] hours per Calendar Year or such other number as may be agreed by the Parties) employed by Voyager (or its Affiliate) who performs work related to the Research Program or the Development Program, as applicable, or related to the activities under ARTICLE 8. With respect to any employee who works more or less than [\*\*] hours per Calendar Year (or such other number as may be agreed by the Parties), such employee shall be treated as an FTE on a pro rata basis based upon the actual number of hours worked divided by [\*\*]. For clarity, sixty (60) minutes of work performed by one employee (or aggregated across multiple employees) on a relevant activity shall be considered one "FTE-hour."
- 1.61 "<u>FTE Costs</u>" means with respect to Voyager for any period, the applicable FTE Rate multiplied by the applicable number of FTEs of Voyager performing work related to the Research Program or the Development Program or to the activities under ARTICLE 8, in each case in accordance with the applicable Plan. No overhead FTEs shall be included in the determination of FTE Costs.
- 1.62 "FTE Rate" means the applicable rate(s) set forth on Schedule 1.62, such rates to be adjusted annually (with the first of such adjustments to be made as of [\*\*] and each subsequent Calendar Year thereafter, but such adjustment determined no later than the preceding [\*\*]) with respect to the FTEs in a particular location, by the applicable CPI Adjustment, which represents the fully burdened rate for such FTE and includes all Included FTE Costs and Expenses for such FTE.
- 1.63 "<u>Future Voyager In-License Agreement</u>" means any license or other agreement between Voyager or any of its Affiliates, on the one hand, and a Third Party, on the other hand, that (a) is entered into pursuant to Section 6.2.2(a)(i) or (b) is entered into pursuant to Section 6.2.2(a)(ii) only from and after the date that such license or other agreement is consistent with the terms and conditions of this Agreement in all material respects (or the date on which AbbVie agrees to such license or other agreement in writing).
  - 1.64 "[\*\*]" means that [\*\*].
- 1.65 "Governmental Authority" means any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority or functions of any nature pertaining to government.
- 1.66 "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (15 U.S.C. Sec. 18a), as may be amended from time to time, and the rules and regulations promulgated thereunder (including all additions, supplements, extensions and modifications thereto).
- 1.67 "HSR Clearance" means the earlier of (a) notification to the Parties from the FTC or DOJ of early termination of the applicable waiting period under the HSR Act with respect to

the HSR Filings, or (b) expiration of the applicable waiting period under the HSR Act with respect to the HSR Filings; <u>provided</u>, <u>however</u>, that if the FTC or DOJ commences any investigation by means of a Second Request or otherwise, HSR Clearance means the termination of such investigation, without action to prevent the Parties from implementing the transactions contemplated by this Agreement with respect to the United States.

- 1.68 "<u>HSR Filings</u>" means the filings by Voyager and AbbVie with the FTC and the DOJ of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto.
- 1.69 "<u>In-License Agreement</u>" means any Existing In-License Agreement and any Future Voyager In-License Agreement, in each case, as amended from time to time to the extent permitted under this Agreement.
- 1.70 "Included FTE Costs and Expenses" means the sum of (a) all costs and expenses for the employee performing any Research, Development or Manufacturing, as applicable, activities hereunder, including salaries, wages, bonuses, commissions, benefits, profit sharing, stock option grants, FICA costs and other similar ex-U.S. costs, travel, meals and entertainment, training, recruiting, relocation, operating supplies, and equipment and other disposable goods to the extent required for the performance of the applicable Research, Development or Manufacturing activities, (b) a pro rata allocation of equipment maintenance costs, utilities, general, administrative and facilities expenses, including allocated building operating costs and depreciation and repairs and maintenance and (c) other overhead, including costs and expense for information technology, human resources, finance and legal, in any case ((a), (b) or (c)), whether internal costs and expenses or amounts paid to Third Parties.
- 1.71 "IND" means an investigational new drug application submitted to the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations, including any supplements and amendments thereto. References herein to IND shall include, to the extent applicable, any comparable filing(s) such as Clinical Trial Applications outside the U.S. for the investigation of any biological or pharmaceutical product in any other country or group of countries.
- 1.72 "Indication" means, with respect to a product, a use to which such product is intended to be put for the treatment, prevention, mitigation, cure or diagnosis of a recognized disease or condition, or of a manifestation of a recognized disease or condition, or for the relief of symptoms associated with a recognized disease or condition, in each case for any size patient population, which, (a) for a Clinical Trial for such product, would be the use of such product for which such Clinical Trial is intended to determine safety or effectiveness and (b) if such product is approved in the U.S., would be reflected in the "Indications and Usage" section of labeling pursuant to 21 C.F.R. §201.57(c)(2) or, to the extent applicable, any comparable labeling section outside the U.S., in each case ((a) and (b)), subject to the following: (i) subtypes of the same disease or condition are not additional Indications for such product; (ii) different symptom domains or domains of impairment of the same disease or condition are not additional Indications for such product, for the further avoidance of doubt, components of neurobehavioral symptom domains of such disease, such as agitation, restlessness and aggression, are the same

Indication, even if separate pivotal trials are required for approval of each such symptom; (iii) the approved use of such product for such disease in different combinations or co-therapies of treatments are not additional Indications for such product (*e.g.*, monotherapy vs. add-on or combination therapy with another agent in the same disease); (iv) treatment, prevention and cure of the same disease or disease subtype with such product are not additional Indications for such product; (v) the approved use of such product for such disease in a different line of treatment or a different temporal position in a treatment algorithm for the same disease or condition are not additional Indications for such product (*e.g.*, first line vs. second line therapy in the same disease or condition); and (vi) treatment of the same disease or condition with such product in an expanded, modified or additional patient population are not additional Indications for such product.

- 1.73 "<u>Initiation</u>" means, with respect to a Clinical Trial, the first dosing of the first subject enrolled in such Clinical Trial with a Licensed Product.
- 1.74 "<u>Initiation of Phase 2 Clinical Trial</u>" means, with respect to a Licensed Product, the Initiation of a Phase 2 Clinical Trial or an Adaptive Trial, in either case, for such Licensed Product.
- 1.75 "<u>Initiation of Phase 3 Clinical Trial</u>" means, with respect to a Licensed Product, the Initiation of a Phase 3 Clinical Trial or the Conversion Date for an Adaptive Trial, in either case, for such Licensed Product. For clarity, the Initiation of an Adaptive Trial shall not constitute Initiation of a Phase 3 Clinical Trial.
- 1.76 "Know-How" means all technical, scientific and other information, know-how and data, including trade secrets, knowledge, inventions, discoveries, methods, specifications, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, expertise, technology, other non-clinical, pre-clinical and clinical data, documentation and results (including pharmacological, toxicological, pharmaceutical, biological, chemical, physical, safety and manufacturing data and results), analytical, regulatory and quality control data and results, Regulatory Filings, study designs, protocols, assays, biological methodologies and other technical information, in each case, whether or not confidential, proprietary, patented or patentable. "Know-How" excludes any Patent Rights.
- 1.77 "Knowledge" means (a) with respect to Voyager, the knowledge of the President, the Chief Executive Officer, the Chief Scientific Officer, the Chief Financial Officer, the Chief Technical Operations Officer or internal legal counsel of Voyager or any of its Affiliates or any personnel holding positions equivalent to such job titles after performing a reasonably diligent investigation with respect to the applicable facts and information; provided that, until such time as Voyager has internal legal counsel (or at any time thereafter when Voyager does not have internal legal counsel), with respect to intellectual property matters, the Persons identified in this clause (a) shall have a duty to make reasonable inquiry of Voyager's outside legal counsel with respect to applicable facts and information, and (b) with respect to AbbVie, the knowledge of Vice President, Neuroscience Discovery Research or Vice President, Intellectual Property Legal of AbbVie or any of its Affiliates or any personnel holding positions equivalent to such job titles

after performing a reasonably diligent investigation with respect to the applicable facts and information.

- 1.78 "Law" means any law, statute, rule, regulation, order, judgment or ordinance having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, including any rules, regulatory guidelines or other requirements of any Governmental Authority, that may be in effect from time to time, which, with respect to each Research, Development or Manufacturing activity that will or would reasonably be expected to be submitted to a Regulatory Authority in support of a Regulatory Approval Application, a Regulatory Approval or Pricing Approval, shall be deemed to include the applicable regulations and guidances of the FDA and final guidances of the European Union (and national implementations thereof) that constitute good laboratory practices, cGMP and good clinical practices (and, if and as appropriate under the circumstances, International Conference on Harmonization (ICH) guidance or other comparable regulation and guidance of any applicable Regulatory Authority in the Territory).
- 1.79 "<u>Legal Dispute</u>" means any dispute, controversy or claim related to compliance with this Agreement or the validity, breach, termination or interpretation of this Agreement.
- 1.80 "<u>License Option Effective Date</u>" means the date upon which AbbVie delivers to Voyager the Exercise Notice with respect to the License Option in accordance with Section 17.7; <u>provided</u> that, if AbbVie reasonably determines in good faith prior to the delivery of the Exercise Notice for the License Option that the transactions to be consummated upon the exercise of the License Option require HSR Filings, the License Option Effective Date shall mean, subject to Section 16.2.7, the Business Day following the date on which HSR Clearance occurs.
- 1.81 "License Option Period" means the time period commencing upon the date Voyager delivers to AbbVie the first complete Final Development Report with respect to a Selected Research Compound, and ending [\*\*] after the date Voyager delivers to AbbVie the complete Final Development Report with respect to the last Selected Research Compound, during which time AbbVie shall have the right to exercise the License Option; provided, however, that if any such Final Development Report delivered by Voyager to AbbVie is not complete, such time period shall not end until [\*\*] after the date Voyager has provided AbbVie a complete Final Development Report for each such Selected Research Compound.
- 1.82 "<u>Licensed Compound</u>" means each Research Compound from and after the License Option Effective Date. For clarity, all Licensed Compounds shall continue to be Research Compounds after the License Option Effective Date.
- 1.83 "<u>Licensed Product</u>" means, with respect to a Licensed Compound, any product containing or comprised of such Licensed Compound, alone or in combination with one (1) or more active pharmaceutical ingredients; <u>provided</u>, <u>however</u>, that the license grants herein shall not be construed to grant AbbVie any right or license to combine any Licensed Compound with any other active pharmaceutical ingredient owned by or licensed to Voyager or any of its Affiliates other than the Licensed Compounds. For clarity, all Licensed Products shall continue to be Research Products after the License Option Effective Date.

- 1.84 "<u>Major European Market</u>" means any of the following: the United Kingdom, Germany, France, Italy or Spain.
- 1.85 "Manufacture" or "Manufacturing" means all activities related to the manufacturing of a compound or product, including test method development and stability testing, formulation, process development, manufacturing scale-up, manufacturing for use in non-clinical and clinical studies, manufacturing for commercial sale, packaging, release of product, quality assurance/quality control development, quality control testing (including in-process, in-process release and stability testing) and release of product or any component or ingredient thereof, and regulatory activities related to all of the foregoing. "Manufacturing" may be included as part of Research, Development or Commercialization, to the extent applicable.
  - 1.86 "[\*\*]" means that [\*\*].
- 1.87 "Net Sales" means with respect to any Licensed Product, the gross amount invoiced by AbbVie, any of its Affiliates or any Sublicensee (other than a Settlement Sublicensee) (each, a "Selling Party") to a Third Party (including a customer, Distributor, wholesaler or end user) for sales or distribution of such Licensed Product, less the following deductions, as calculated in accordance with the standard internal policies and procedures of the applicable Selling Party and in accordance with Accounting Standards applicable to the deductions:
- $1.87.1\,$  normal trade, cash, quantity and other customary discounts actually given to customers in the ordinary course of business;
- 1.87.2 rebates, credits and allowances given by reason of rejections, returns, damaged or defective product or recalls;
- 1.87.3 government-mandated rebates and any other compulsory payments, credits, adjustments and rebates actually paid or deducted;
- 1.87.4 price adjustments, allowances, credits, chargeback payments, discounts, rebates, fees and reimbursements or similar payments granted or made to managed care organizations, group purchasing organizations or other buying groups, pharmacy benefit management companies, health maintenance organizations and any other providers of health insurance coverage, health care organizations or other health care institutions (including hospitals), health care administrators, patient assistance or other similar programs, or to federal state/provincial, local and other governments, including their agencies, or to wholesalers, Distributors or other trade customers;
- 1.87.5 the portion of administrative fees paid or otherwise accrued during the relevant time period to group purchasing organizations, pharmaceutical benefit managers or Medicare Prescription Drug Plans to the extent allocated to such Licensed Product;
- 1.87.6 the price paid to a Third Party (other than a Sublicensee or Distributor) for any Delivery System, if the price for such Delivery System is included in the gross amount invoiced by such Selling Party for such Licensed Product, where for purposes of this clause, a "<u>Delivery System</u>" means any delivery system comprising equipment, instrumentation, one (1)

or more devices, or other mechanical components (such as a syringe or infusion bag) designed to assist in the administration of such Licensed Product;

- 1.87.7 any invoiced amounts from a prior period that are not collected and are written off by the applicable Selling Party, including bad debts, provided that such amounts are recorded as a reduction in revenue and provided, however, that the amount of any uncollected amounts or bad debt deducted pursuant to this exception and actually collected in a subsequent Calendar Quarter shall be included in Net Sales for such subsequent Calendar Quarter;
- 1.87.8 that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended), to the extent reasonably allocable to sales of such Licensed Product;
- 1.87.9 reasonable and customary freight, shipping, insurance and other transportation expenses, if actually borne by the applicable Selling Party without reimbursement from any Third Party;
- 1.87.10 sales, value-added, excise taxes, tariffs and duties, and other taxes and government charges directly related to the sale, delivery or use of such Licensed Product (but not including taxes assessed against the net income derived from such sale); and
- 1.87.11 any other similar and customary deductions that are consistent with Accounting Standards, but which may not be duplicative of the above deductions.

There shall be no double-counting of any deductions described in Sections 1.87.1 through 1.87.11.

Resales or sales of a Licensed Product made between or among AbbVie, any of its Affiliates or any Sublicensee shall not be included in the calculation of Net Sales.

If non-monetary consideration is received for any Licensed Product, Net Sales will be calculated based on the average price charged for such Licensed Product during the preceding Calendar Quarter in the relevant country, or in the absence of such sales, the fair market value of the Licensed Product, as determined by the Parties in good faith.

For purposes of calculating Net Sales, all Net Sales shall be converted into Dollars in accordance with Section 10.10.

In the event a Licensed Product is a Combination Product, the Net Sales for such Combination Product shall be calculated as follows:

(a) If a Selling Party separately sells in such country or other jurisdiction, (i) a product containing as its sole active pharmaceutical ingredient the Licensed Compound contained in or comprising such Combination Product (the "Mono Product") and (ii) products containing as their sole active pharmaceutical ingredients the other active pharmaceutical ingredients in such Combination Product, the Net Sales attributable to such Combination Product shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction A/(A+B) where: "A" is such Selling Party's average Net Sales price

during the period to which the Net Sales calculation applies for the Mono Product in such country or other jurisdiction and "B" is the Selling Party's average net sales price (determined in the same manner as "Net Sales") during the period to which the Net Sales calculation applies in such country or other jurisdiction, for products that contain as their sole active pharmaceutical ingredients the other active pharmaceutical ingredients (i.e., other than the Licensed Compound) in such Combination Product.

- (b) If a Selling Party separately sells in such country or other jurisdiction the Mono Product but does not separately sell in such country or other jurisdiction products containing as their sole active pharmaceutical ingredients the other active pharmaceutical ingredients in such Combination Product, the Net Sales attributable to such Combination Product shall be calculated by multiplying the Net Sales of such Combination Product by the fraction A/C where: "A" is such Selling Party's average Net Sales price during the period to which the Net Sales calculation applies for the Mono Product in such country or other jurisdiction, and "C" is the Selling Party's average Net Sales price in such country or other jurisdiction during the period to which the Net Sales calculation applies for such Combination Product.
- (c) If a Selling Party does not separately sell in such country or other jurisdiction the Mono Product but does separately sell products containing as their sole active pharmaceutical ingredients the other active pharmaceutical ingredients contained in such Combination Product, the Net Sales attributable to such Combination Product shall be calculated by multiplying the Net Sales of such Combination Product by the fraction (D-E)/D where: "D" is the average Net Sales price during the period to which the Net Sales calculation applies for such Combination Product in such country or other jurisdiction and "E" is the average net sales price (determined in the same manner as "Net Sales") during the period to which the Net Sales calculation applies for products that contain as their sole active pharmaceutical ingredients the other active pharmaceutical ingredients (i.e., other than the Licensed Compound) in such Combination Product.
- (d) If a Selling Party does not separately sell in such country or other jurisdiction both the Mono Product and the other active pharmaceutical ingredients in such Combination Product, the Net Sales attributable to such Combination Product shall be determined by the Parties in good faith based on the relative fair market value of such Mono Product and such other active pharmaceutical ingredients. If the Parties cannot agree on such relative value, the dispute shall be resolved pursuant to Section 17.2.
  - 1.88 "[\*\*]" means that [\*\*].
- 1.89 "Opt-In" means opting into the jurisdiction of Unified Patent Court, such as through withdrawal under Article 83(4) of the Agreement on a Unified Patent Court between the participating Member States of the European Union (2013/C 175/01) of the Opt-Out of a Patent Right.
- 1.90 "Opt-Out" means opting out of the jurisdiction of Unified Patent Court, such as the opt-out of a Patent Right from the exclusive competence of the Unified Patent Court under

Article 83(3) of the Agreement on a Unified Patent Court between the participating Member States of the European Union (2013/C 175/01).

- 1.91 "Out-of-Pocket Costs" means costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with the Accounting Standards consistently applied) by Voyager (or its Affiliate) directly incurred in the conduct of any applicable activities under this Agreement; provided that Out-of-Pocket Costs shall not include costs for general overhead, postage, communications, photocopying, printing or internet expense, professional dues, operating supplies, laboratory supplies, printers, photocopiers, fax machines or other office equipment, laboratory equipment, computers or computer service charges or any costs that are subsumed within the definition of Included FTE Costs and Expenses.
- 1.92 "<u>Parkinson's Disease Indication</u>" means, with respect to a product, an Indication for the treatment, prevention, mitigation, cure or diagnosis of PD, or of a manifestation of PD, or for the relief of symptoms associated with PD.
- 1.93 "Patent Right" means (a) any patent or patent application (including any provisional application) in any country or multinational jurisdiction in the Territory; (b) any patent application filed either from such patent or patent application (including provisional application) or from an application claiming priority from either of these, including any converted application, continuation, continuation-in-part, continued prosecution application or divisional of any such application; (c) any patent that has issued or in the future issues from the foregoing patent applications ((a) and (b)), including utility models, petty patents, innovation patents and design patents and certificates of invention; (d) any extension or restoration by existing or future extension or restoration mechanisms, including any revalidation, reissue, renewal, extension, substitution, reexamination, patent term extension, supplementary protection certificate, pediatric exclusivity period or the like of the foregoing patents or patent applications ((a), (b) and (c)); (e) any foreign equivalent of any patent or patent application described in clauses (a)-(d); and (f) all rights of priority in any of the foregoing.
- 1.94 "<u>Person</u>" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Governmental Authority, or any other entity not specifically listed in this Section 1.94.
- 1.95 "Phase 0 Clinical Trial" means an exploratory, first-in-human trial conducted in accordance with the FDA 2006 Guidance on Exploratory Investigational New Drug Studies (or the equivalent in any country or other jurisdiction outside of the United States) and designed to expedite the development of therapeutic or imaging agents by establishing very early on whether the agent behaves in human subjects as was anticipated from pre-clinical studies.
- 1.96 "Phase 1 Clinical Trial" means a human clinical trial of a product in any country, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients, that would satisfy the requirements of 21 C.F.R. 312.21(a), or a similar clinical study prescribed by the relevant Regulatory Authorities or applicable Law in a country other than the United States.

- 1.97 "Phase 2 Clinical Trial" means a human clinical trial of a product in any country that would satisfy the requirements of 21 C.F.R. 312.21(b) and that is designed or intended to explore a variety of doses, dose response, and duration of effect, and to generate initial evidence of clinical safety and activity in a target patient population, or a similar clinical study prescribed by the relevant Regulatory Authorities or applicable Law in a country other than the United States.
- 1.98 "Phase 3 Clinical Trial" means a human clinical trial of a product in any country that would satisfy the requirements of 21 C.F.R. 312.21(c) and that is designed or intended to (a) establish that the product is safe and efficacious for its intended use, (b) define warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support Regulatory Approval for such product.
- 1.99 "<u>PHSA</u>" means the Public Health Service Act as set forth at 42 U.S.C. Chapter 6A, as may be amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).
  - 1.100 "Plan" means each of the Research Plan and the Development Plan.
- 1.101 "<u>Pricing Approval</u>" means such approval, agreement, determination or decision establishing prices for a Licensed Product that can be charged to consumers or will be reimbursed by Governmental Authorities in a country in the Territory where Governmental Authorities of such country approve or determine pricing for pharmaceutical or biological products for reimbursement or otherwise.
- 1.102 "<u>Prosecution and Maintenance</u>" or "<u>Prosecute and Maintain</u>" means, with regard to a Patent Right, the preparation, filing, prosecution and maintenance of such Patent Right. For clarification, "<u>Prosecution and Maintenance</u>" or "<u>Prosecute and Maintain</u>" shall not include any Defense Proceedings or other enforcement actions taken with respect to a Patent Right.
  - 1.103 "[\*\*]" means that [\*\*].
- 1.104 "Regulatory Approval" means, with respect to a country or other jurisdiction in the Territory, all approvals of the applicable Regulatory Authority necessary for the commercial marketing and sale of a product in such country or jurisdiction, including, where applicable, (a) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto), and (b) approval of the expansion or modification of the label for additional indications or uses, but excluding any Pricing Approval that is not necessary for the commercial marketing and sale of a product in such country or jurisdiction in the applicable Indication.
- 1.105 "Regulatory Approval Application" means (a) a BLA, or (b) any other corresponding foreign application in the Territory to seek Regulatory Approval of a product in any country or multinational jurisdiction, as defined in applicable Laws and filed with the relevant Regulatory Authorities of such country or jurisdiction.

- 1.106 "<u>Regulatory Authority</u>" means the FDA in the United States or any Governmental Authority in another country or jurisdiction in the Territory that is a counterpart to the FDA and holds responsibility for granting Regulatory Approval for a product, or otherwise regulating the Research, Development or Commercialization of a product, in such country, including the EMA, and any successor(s) thereto.
- 1.107 "Regulatory Exclusivity" means, with respect to any Licensed Product in any country or jurisdiction in the Territory, any exclusive, non-patent related marketing rights or data exclusivity rights conferred by any Regulatory Authority or applicable Law in such country or jurisdiction that precludes a Third Party from using or otherwise relying on any clinical data collected and filed in support of a Regulatory Approval Application for such Licensed Product for the benefit of any Regulatory Approval for a generic or biosimilar product (for any use or indication).
- 1.108 "Regulatory Filing" means, with respect to a product, any documentation comprising any filing or application with any Regulatory Authority with respect to such product, or its use or potential use in the Field, including any such document submitted to or received from any Regulatory Authority, including any IND or Regulatory Approval Application, as well as any registration, license, authorization, and correspondence with any Regulatory Authority with respect to such product (including minutes of any meetings, telephone conferences or discussions with any Regulatory Authority to the extent relating specifically to such product and any adverse event files and complaint files to the extent relating specifically to such product).
- 1.109 "Research" means any non-clinical and pre-clinical activities relating to a Research Compound up to but not including any IND-enabling studies, including, as applicable, (a) discovery, identification, research, engineering, characterization, development, modification, optimization and testing of one (1) or more AbbVie Designated Antibodies or Research Compounds, (b) cell specificity, localization and tolerability testing, (c) vector genome optimization and (d) muscle capsid discovery research activities. "Research" may include Manufacturing solely to the extent necessary in support of the foregoing, but shall not include Development or Commercialization.
- 1.110 "Research Compound" means a Virus Vector comprising a Vector Genome that Encodes one (1) or more AbbVie Designated Antibodies or Sequences thereof that results from activities under the Research Plan. For clarity, such Virus Vector shall not Encode any active pharmaceutical ingredient other than one (1) or more AbbVie Designated Antibodies. For further clarity, each Virus Vector comprising a Vector Genome that Encodes particular Sequence(s) of AbbVie Designated Antibody(ies) shall constitute a separate Research Compound.
- 1.111 "Research Costs" means the FTE Costs and the Out-of-Pocket Costs incurred by or on behalf of Voyager or any of its Affiliates during the Voyager Research Period in accordance with Accounting Standards, the Research Plan and this Agreement, that are specifically attributable or reasonably allocable to the performance of the Research activities under the Research Plan. Any FTE Costs or Out-of-Pocket Costs that are not specifically attributable to Voyager's Research activities under this Agreement during the Voyager Research

Period shall be allocated to the Research Costs in a fair and reasonable manner in accordance with this Agreement.

- 1.112 "Research Plan" means the written plan that sets forth in reasonable detail specific Research activities to be conducted by Voyager during the Voyager Research Period, including the Research Budget, as each may be amended from time to time in accordance with this Agreement. The initial Research Plan is attached hereto as <u>Schedule 1.112</u>.
  - 1.113 "Research Product" means any product containing or comprised of a Research Compound.
- 1.114 "<u>Research Program</u>" means all Research activities performed in accordance with the Research Plan during the Voyager Research Period.
- 1.115 "<u>Second Request</u>" means a request for additional information or documentary material, as described in 16 C.F.R. 803.20.
- 1.116 "<u>Sequence</u>" means, with respect to an Alpha-Synuclein Antibody, the nucleic acid or the corresponding amino acid sequence of the CDRs of such Alpha-Synuclein Antibody (or any fragment of such CDRs that specifically bind to Alpha-Synuclein).
- 1.117 "<u>Settlement Proceeds</u>" means, with respect to a Licensed Product, any amounts paid to AbbVie or any of its Affiliates or Sublicensees by any Settlement Sublicensee to the extent attributable to any Settlement Sublicense and to the extent attributable to such Licensed Product.
- 1.118 "<u>Settlement Sublicensee</u>" means any Sublicensee to which AbbVie grants a sublicense (a "<u>Settlement Sublicense</u>") to settle or avoid litigation related to (a) the alleged infringement by a Licensed Product or the Exploitation thereof of any Patent Right or other intellectual property of a Third Party or (b) the alleged non-infringement, invalidity or unenforceability of any Patent Rights Covering a Licensed Product.
- 1.119 "Subject IP" means all intellectual property rights relating to (a) (i) as of the Effective Date, the Vectorization Technology or any materials that are necessary or reasonably expected to be useful to conduct (A) the Research Program as described in the Research Plan as of the Effective Date or (B) the Development Program as described in the Development Plan as of the Effective Date and (ii) as of the date on which AbbVie exercises a Development Option, the Vectorization Technology or any materials that are necessary or reasonably expected to be useful to conduct the Development Program as described in the Development Plan as of the date on which AbbVie exercises such Development Option, in each case ((i) and (ii)), including the Manufacture of Vectorized Alpha-Synuclein Antibodies in connection therewith, except for any intellectual property rights that are controlled by Voyager or its Affiliates pursuant to a license or other agreement with a Third Party and that Voyager is not permitted to use or incorporate in the Research Program or the Development Program or in any Research Compound, Research Product, Selected Research Compound, Selected Research Product, Licensed Compound or Licensed Product, Selected Research Compound, Selected Research Compound, Research Product, Selected Research Compound, Selected Research Product, Licensed Product, or the Exploitation thereof, in each case ((a) and (b)),

owned by, licensed to or otherwise controlled by Voyager or its Affiliates, or (c) as of the date on which AbbVie exercises a Development Option or the License Option, the Vectorization Technology or any materials that have been used in the Research Program or the Development Program prior to such date.

- 1.120 "[\*\*]" means that [\*\*].
- 1.121 "<u>Terminated Territory</u>" means each country with respect to which this Agreement is terminated by Voyager pursuant to Section 16.2.1 or AbbVie pursuant to Section 16.2.3, in either case, if such termination applies to one (1) or more countries, but not all of the countries in the Territory.
- 1.122 "<u>Territory</u>" means all of the countries in the world, including their respective territories and possessions, excluding any Terminated Territory.
- 1.123 "<u>Third Country</u>" means a country outside the European Economic Area ("<u>EEA</u>") or a country in the EEA not deemed to provide an adequate level of protection for Personal Data by the European Commission.
  - 1.124 "Third Party" means any Person that is neither a Party nor an Affiliate of a Party.
- 1.125 "<u>Third Party Managed Patent Rights</u>" means Existing Patent Rights for which neither Voyager nor any of its Affiliates has the first right to control Prosecution and Maintenance.
- 1.126 "<u>Third Party Right</u>" means any Patent Right, trade secret or other intellectual property right (but not any Trademark) of a Third Party in any country in the Territory.
- 1.127 "<u>Trademark</u>" means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design or business symbol, that functions as an identifier of source or origin, whether or not registered and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.
- 1.128 "<u>Unauthorized Launch Date</u>" means, with respect to a Licensed Product, the date on which a Settlement Sublicensee or a Third Party without a license or authorization from AbbVie, any of its Affiliates or any Sublicensee launches a pharmaceutical product with respect to which such Third Party has received Regulatory Approval for a BLA for such product as a biosimilar to, or that is interchangeable with, such Licensed Product (a) under Section 351(k) of the PHSA in the United States (or any successor provisions thereto) or under Article 10(4) of Directive 2001/83/EC in the European Union or any member state thereof (or any successor provisions thereto), in each case citing such Licensed Product as the reference product or (b) for which the BLA otherwise references or relies on such Licensed Product under applicable Law in any other country in the Territory.

- 1.129 "<u>United States</u>" or "<u>U.S.</u>" means the United States of America and all of its territories and possessions.
- 1.130 "Valid Claim" means (a) a claim of any issued and unexpired patent whose validity, enforceability, or patentability has not been affected by any of the following: (i) irretrievable lapse, abandonment, revocation, dedication to the public, or disclaimer; or (ii) a holding, finding, or decision of invalidity, unenforceability, or non-patentability by a court, national or regional patent office, or other applicable Government Authority that has competent jurisdiction, such holding, finding, or decision being final and unappealable or unappealed within the time allowed for appeal; or (b) a claim of a patent application that is filed in good faith and has not been (i) cancelled, withdrawn, abandoned or finally disallowed, without the possibility of appeal or refiling, or (ii) pending for more than seven (7) years from its earliest priority date, as of the relevant time. For clarity, any claim in a patent application that has been pending for more than seven (7) years from its earliest priority date as of the relevant time shall not be considered a Valid Claim unless and until such claim is granted and meets the requirement of subsection (a).
- 1.131 "<u>Vector Genome</u>" means a polynucleotide, whether single stranded (ss) or self-complementary (sc), having a configuration capable of selectively Encoding one (1) or more proteins when encapsulated by a Virus Capsid.
  - 1.132 "Vectorization IP" means the Vectorization Know-How and Vectorization Patent Rights.
- 1.133 "Vectorization Know-How" means all Know-How that is conceived, discovered, developed or otherwise made or acquired under the Research Program or the Development Program during the Term (a) prior to the earlier of (i) the date on which AbbVie delivers Voyager the Exercise Notice with respect to the License Option and (ii) the expiration of the Voyager Development Period, (A) by or on behalf of either Party (or its Affiliates or its or their (sub)licensees/Sublicensees) or (B) jointly by or on behalf of AbbVie (or its Affiliates or its or their Sublicensees), on the one hand, and Voyager (or its Affiliates or its or their (sub)licensees), on the other hand, in each case ((A) and (B)), or (b) if the Voyager Development Period is in effect after the date upon which AbbVie delivers Voyager the Exercise Notice with respect to the License Option, until the end of the Voyager Development Period (the later of the date upon which AbbVie delivers Voyager the Exercise Notice with respect to the License Option and the end of the Voyager Development Period, the "Cut-Off Date") (i) by or on behalf of either Party (or its Affiliates or its or their (sub)licensees/Sublicensees) or (ii) jointly by or on behalf of AbbVie (or its Affiliates or its or their Sublicensees), on the one hand, and Voyager (or its Affiliates or its or their (sub)licensees), on the other hand, in each case ((i) and (ii)), solely in connection with any remaining activities that are conducted under the Research Plan or the Development Plan, as applicable, in each case ((a) and (b)), (x) that is solely related to Vectorization Technology and is not specific to one (1) or more Alpha-Synuclein Antibodies and (y) excluding any Know-How that relates to Manufacturing to the extent that it is conceived, discovered, developed or otherwise made or acquired by or on behalf of AbbVie (or its Affiliates or its or their Sublicensees).
  - 1.134 "Vectorization Patent Rights" means any Patent Rights that solely claim Vectorization Know-How.

- 1.135 "<u>Vectorization Technology</u>" means Voyager's proprietary Virus Vector platform, including any of the following aspects of such platform: (a) Virus Capsids, (b) Vector Genomes, (c) Know-How regarding the design, Manufacture or optimization of Virus Capsids or Vector Genomes for the creation of vectorized payloads, and (d) Know-How regarding the administration or delivery of any of (a)-(c) as therapeutics. For further clarification, Vectorization Technology shall not include the actual Licensed Compounds or Licensed Products.
- 1.136 "<u>Vectorized Alpha-Synuclein Antibody</u>" means a Virus Vector comprising a Vector Genome that Encodes an Alpha-Synuclein Antibody or a Derivative thereof.
- 1.137 "<u>Virus Capsid</u>" means an engineered or naturally occurring capsid protein or proteins (or the encoding nucleic acid sequence thereof), including from an adeno-associated virus (AAV), that is capable of encapsulating a Vector Genome.
  - 1.138 "Virus Vector" means a virus comprising a Virus Capsid and Vector Genome encapsulated therein.
- 1.139 "<u>Voyager Background IP</u>" means the Voyager Background Know-How and Voyager Background Patent Rights.
- 1.140 "<u>Voyager Background Know-How</u>" means all Know-How that (a) is Controlled by Voyager as of the Effective Date or during the Term, (b) is not generally known and (c) is necessary or reasonably useful to Exploit in the Field in the Territory any Vectorized Alpha-Synuclein Antibody, Research Compound, Selected Research Compound, Research Product, Selected Research Product, Licensed Compound or Licensed Product, as applicable, other than any AbbVie Designated Antibody Know-How or Collaboration Know-How. Voyager Background Know-How includes Vectorization Know-How.
- 1.141 "<u>Voyager Background Patent Rights</u>" means all Patent Rights, including Vectorization Patent Rights, Controlled by Voyager as of the Effective Date or during the Term that claim or Cover the Exploitation in the Field in the Territory of any Vectorized Alpha-Synuclein Antibody, Research Compound, Selected Research Compound, Research Product, Selected Research Product, Licensed Compound or Licensed Product, as applicable, other than AbbVie Designated Antibody Patent Rights or Collaboration Patent Rights.
- 1.142 "<u>Voyager Background LP Patent Rights</u>" means any Voyager Background Patent Rights that specifically claim or Cover the composition of matter of one (1) or more Licensed Products or Licensed Compounds or the Exploitation thereof.
- 1.143 "<u>Voyager Background VA Patent Rights</u>" means any Voyager Background Patent Rights that specifically claim or Cover one (1) or more Vectorized Alpha-Synuclein Antibodies or the Exploitation thereof, including those Patent Rights set forth on <u>Schedule 1.143</u>. For clarity, all Voyager Background LP Patent Rights are Voyager Background VA Patent Rights.
- 1.144 "<u>Voyager Development Costs</u>" means the FTE Costs and the Out-of-Pocket Costs incurred by or on behalf of Voyager or any of its Affiliates during the Voyager Development Period in accordance with Accounting Standards, the Voyager Development Plan and this

Agreement, that are specifically attributable or reasonably allocable to the performance of the Development activities under the Voyager Development Plan. Any FTE Costs or Out-of-Pocket Costs that are not specifically attributable to Voyager's Development activities under this Agreement during the Voyager Development Period shall be allocated to the Voyager Development Costs in a fair and reasonable manner in accordance with this Agreement.

- 1.145 "<u>Voyager Development Period</u>" means the period of time beginning upon AbbVie's first exercise of a Development Option in accordance with Section 2.3.4 and ending upon the date Voyager delivers to AbbVie the complete Final Development Report with respect to the last Selected Research Compound; <u>provided</u>, <u>however</u>, that if any Final Development Report delivered by Voyager to AbbVie is not complete, the Voyager Development Period shall not end until Voyager has provided AbbVie a complete Final Development Report for each such Selected Research Compound(s). For clarity, if the Voyager Development Period has not ended in accordance with this Section 1.145 prior to AbbVie's exercise of the License Option, then the Voyager Development Period may continue after the License Option Effective Date.
- 1.146 "<u>Voyager Managed Patent Rights</u>" means Existing Patent Rights for which Voyager or any of its Affiliates has the first right to control Prosecution and Maintenance.
- 1.147 "<u>Voyager Research Period</u>" means the period of time commencing on the Effective Date and ending upon the date Voyager delivers to AbbVie the complete Final Research Report with respect to the last Research Compound; <u>provided</u>, <u>however</u>, that if any Final Research Report delivered by Voyager to AbbVie is not complete, the Voyager Research Period shall not end until Voyager has provided AbbVie a complete Final Research Report for each such Research Compound(s). For clarity, if the Voyager Research Period has not ended in accordance with this Section 1.147 prior to AbbVie's exercise of a Development Option, then the Voyager Research Period may continue after AbbVie's exercise of a Development Option.
- 1.148 <u>Additional Definitions</u>. Each of the following definition is set forth in the Section of this Agreement indicated below:

| <b>Definition</b> :                        | Section:     |
|--|--------------|
| AbbVie                                     | Preamble     |
| AbbVie Manufacturing Improvements          | 8.4.1        |
| Acquirer                                   | 1.23         |
| Acquirer IP                                | 17.3.2       |
| Acquired Third Party                       | 17.4         |
| Additional Amounts                         | 10.11.2(a)   |
| Additional Development Option Exercise Fee | 2.3.4        |
| ADR  | 17.2.1       |
| Agreement                                  | Preamble     |
| Alliance Manager                           | 5.7          |
| ADA Compound/Product                       | 16.4.1(c)(i) |
| Auditor                                    | 10.9.3       |
| [**] Antibodies                            | 1.4          |
| Biosimilar Application                     | 12.4.1       |
| [**]                                       | 1.21         |

| <b>Definition:</b>                      | Section:   |
|---|------------|
| CDR                                     | 1.12       |
| Change of Control Party                 | 17.3.2     |
| Commercial Milestone Payment            | 10.2       |
| Committee                               | 5.3.1      |
| Confidential Information                | 13.1       |
| Conversion Date                         | 1.33       |
| Cure Period                             | 16.2.1(a)  |
| Cut-Off Date                            | 1.133      |
| Data Breach                             | 14.6.3     |
| Data Subject                            | 14.6.1     |
| Defense Proceeding                      | 12.2.1     |
| Delivery System                         | 1.87.6     |
| Development Infeasibility Determination | 3.2.4(a)   |
| Development Infeasibility Termination   | 3.2.4(a)   |
| Development Option                      | 2.3.1      |
| Disclosing Party                        | 13.1       |
| Dispute                                 | 17.2       |
| EEA                                     | 1.123      |
| Effective Date                          | Preamble   |
| Exclusive License                       | 6.1.1      |
| Existing Confidentiality Agreement      | 13.2       |
| Existing Patent Rights                  | 14.2.4     |
| First Party                             | 12.2.2(b)  |
| FTE-hour                                | 1.60       |
| Future Capsid Agreement                 | 6.2.2(d)   |
| [**]                                    | 1.64       |
| HSR Proceeding                          | 3.4.2      |
| Inbound Licensor                        | 6.2.1(a)   |
| Indemnification Claim Notice            | 15.3.1     |
| Indemnified Party                       | 15.3.1     |
| Indemnifying Party                      | 15.3.1     |
| Indemnitee                              | 15.3.1     |
| Indirect Taxes                          | 10.11.3    |
| Initial Development Option Exercise Fee | 2.3.4      |
| Initial Fee                             | 10.1       |
| JGC                                     | 5.1.1      |
| Joint CMC Working Group                 | 5.3.1(c)   |
| Joint Know-How                          | 12.1.1     |
| Joint IP                                | 12.1.1     |
| Joint IP Working Group                  | 5.3.1(b)   |
| Joint Patent Rights                     | 12.1.1     |
| Joint R&D Working Group                 | 5.3.1(a)   |
| Later Amount                            | 10.11.2(b) |
| License Option                          | 3.3.1      |

| Definition:                          | Section:   |
|--------------------------------------|------------|
| License Option Exercise Fee          | 3.3.3(a)   |
| Losses                               | 15.1       |
| Manufacturing Process                | 8.3        |
| Manufacturing Process Know-How       | 8.3        |
| Manufacturing Technology Transfer    | 8.3        |
| Milestone Event                      | 10.2       |
| Milestone Payment                    | 10.2       |
| Mono Product                         | 1.87.11(a) |
| [**]                                 | 1.88       |
| Non-Parkinson's Disease Indication   | 10.2.2     |
| Party                                | Preamble   |
| Parties                              | Preamble   |
| Patent Challenge                     | 16.2.2     |
| PD                                   | Recitals   |
| Performance Issue                    | 4.4        |
| Personal Data                        | 14.6.1     |
| Pre-Existing Affiliate               | 17.4       |
| Processing                           | 14.6.1     |
| Product Trademarks                   | 12.7.1     |
| Program Activities                   | 6.2.2(a)   |
| Prosecuting Party                    | 12.2.2(c)  |
| Receiving Party                      | 13.1       |
| Regulatory Milestone Payment         | 10.2       |
| Research Budget                      | 2.1.1      |
| Research Infeasibility Determination | 2.2.4(a)   |
| Research Infeasibility Termination   | 2.2.4(a)   |
| Royalty Term                         | 10.4       |
| Selected Research Compound           | 2.3.4      |
| Selected Research Product            | 2.3.4      |
| Selling Party                        | 1.87       |
| Settlement Sublicense                | 1.118      |
| Subcommittee                         | 5.1.1      |
| Subject Technology                   | 6.2.2(a)   |
| Subject Technology Agreement         | 6.2.2(a)   |
| Sublicensee                          | 6.3        |
| Substitution Notice                  | 3.2.4(b)   |
| Substitution True-Up Amount          | 3.2.4(b)   |
| Term                                 | 16.1       |
| Third Party Claims                   | 15.1       |
| Third Party Infringement Claim       | 12.5.1     |
| Third Party Payments                 | 10.5.3     |
| Transferred Materials                | 4.1.2(a)   |
| Transition Plan                      | 7.1        |
| Variation                            | 1.12       |

| <b>Definition</b> :                | Section:   |
|------------------------------------|------------|
| Voyager                            | Preamble   |
| Voyager Development Budget         | 3.1.1      |
| Voyager Development Cost Report    | 3.2.3(a)   |
| Voyager Manufacturing Improvements | 8.3.8      |
| Voyager Regulatory Filings         | 14.2.7     |
| [**]                               | 6.2.2(d)   |
| [**]                               | 6.2.2(d)   |
| Voyager Trademark                  | 12.7.1     |
| Withholding Party                  | 10.11.2(b) |
| Working Group                      | 5.3.1      |

# ARTICLE 2 RESEARCH; DEVELOPMENT OPTION

### 2.1 Research Plan.

- 2.1.1 Research Plan. The initial Research Plan attached hereto identifies (a) the specific Research activities directed to constructing one (1) or more Research Compounds with respect to the AbbVie Designated Antibodies; (b) the specific requirements for the Final Research Reports to be submitted by Voyager to AbbVie in accordance with Section 2.3.2, including a list identifying all results and related data that Voyager must provide to AbbVie and the format in which such results and related data must be delivered; (c) a budget for the Research Costs for the conduct by Voyager of the Research activities, including the preparation and submission of the Final Research Reports to AbbVie, in accordance with the Research Plan (the "Research Budget"); (d) any materials to be provided by AbbVie and any activities to be performed by AbbVie; and (e) all of the permitted uses of any Transferred Materials provided by or on behalf of AbbVie. Unless otherwise agreed by the Parties, Voyager shall use Diligent Efforts to complete the Research activities specifically identified in the Research Plan for each AbbVie Designated Antibody and each Research Compound.
- 2.1.2 <u>Amendments to Research Plan</u>. Each Party may propose an amendment to the Research Plan by submitting such proposed amendment in writing to the Joint R&D Working Group for review and approval, subject to the final decision-making process set forth in Section 5.6.3; <u>provided</u>, <u>however</u>, that any material amendments to the Research Plan shall be mutually agreed to by the Parties either in writing, such agreement not to be unreasonably withheld, conditioned or delayed, or through the JGC as reflected in JGC meeting minutes signed by the Alliance Managers in accordance with Section 5.5.1. Material amendments to the Research Plan include: [\*\*]. Upon the Alliance Managers' signing the minutes of the JGC pursuant to Section 5.5.1 memorializing the agreement of the JGC to, or mutual written agreement by the Parties of, as applicable, an amendment to the Research Plan, the Research Plan shall be deemed to be amended by such amendment.
- 2.1.3 <u>New AbbVie Designated Antibodies</u>. If AbbVie determines, at any time during the Voyager Research Period, that it desires to add a new Alpha-Synuclein Antibody to this Agreement as an AbbVie Designated Antibody or to substitute a new Alpha-Synuclein

2.1.3), then it shall notify Voyager thereof in writing and, subject to approval of any resulting material amendment to the Research Plan as set forth in Section 2.1.2, if applicable, and the remainder of this Section 2.1.3, AbbVie may designate an additional or substitute AbbVie Designated Antibody. The Parties acknowledge that the royalty rates set forth in Section 10.3 and the milestones set forth in Section 10.2.3 reflect the Parties' mutual expectation that the Licensed Products will Encode a [\*\*] Antibody, and that such royalty rates and milestones were negotiated by the Parties in light of the royalties, milestones and other fees payable by AbbVie to [\*\*] pursuant to the [\*\*] Agreement. Accordingly, if AbbVie's proposed additional or substitute Alpha-Synuclein Antibody does not require the payment of royalties, milestones or other fees to a Third Party or requires the payment of royalties, milestones and other fees that are, in the aggregate, less than what is required under the [\*\*] Agreement, then, prior to AbbVie's designation of any additional or substitute AbbVie Designated Antibody, the Parties shall negotiate in good faith concerning any commercially reasonable increase to the royalty rates set forth in Section 10.3 and, in connection with any such increase in such royalties, the corresponding commercially reasonable decrease to the milestones set forth in Section 10.2.3 as may be appropriate with respect to Licensed Products Encoding such additional or substitute AbbVie Designated Antibody. The Parties' negotiation shall be based on how the royalty rates set forth in Section 10.3 (as may be adjusted pursuant to Section 10.5) and the milestones set forth in Section 10.2.3 compare to the royalty rates and milestones applicable in the Tau Agreement (including any adjustments herein and therein with respect thereto), taking into account (a) whether such antibody is, prior to such designation by AbbVie, Controlled by Voyager, and (b) the royalty rates, milestone and other fees payable by AbbVie or any of its Affiliates to any Third Party for the use of such additional or substitute AbbVie Designated Antibody (including the fact that any such royalties payable by AbbVie may not be deducted from royalties payable hereunder pursuant to Section 10.5.3). If the Parties cannot reach agreement on whether there should be, or the amount of, an increase to the royalty rates set forth in Section 10.3 and a corresponding decrease to the milestones set forth in Section 10.2.3, then either Party may submit the matter for resolution pursuant to "baseball arbitration" as set forth in Section 17.2.2. Notwithstanding any other provision of this Agreement, Voyager shall have no obligation to conduct Research activities with respect to any additional or substitute AbbVie Designated Antibody unless and until the Parties (either by mutual agreement or through baseball arbitration) have determined the royalty rates and milestones applicable to Licensed Products Encoding such AbbVie Designated Antibody. For the avoidance of doubt, once an additional or substitute AbbVie Designed Antibody is finally designated pursuant to this Section 2.1.3, and, if required pursuant to Section 2.1.2, an amendment to the Research Plan to reflect such addition or substitution is agreed, Voyager's diligence obligations set forth in Section 2.2.2 shall apply to such additional or substitute AbbVie Designated Antibody. For the further avoidance of doubt, under no circumstances shall the royalty rates set forth in Section 10.3 decrease as a result of AbbVie designating any additional or substitute AbbVie Designated Antibody.

Antibody for a [\*\*] Antibody (or any substitute AbbVie Designated Antibody designated pursuant to this Section

### 2.2 Conduct of Research.

2.2.1 <u>Voyager Responsibility</u>. Subject to Section 2.2.2, during the Voyager Research Period, Voyager (a) shall have sole responsibility for the conduct of the Research activities in the Territory and (b) shall do so in accordance with the Research Plan. Voyager

shall bear all costs and expenses incurred by or on behalf of it in the performance of the Research activities in the Territory specifically set forth in the Research Plan.

2.2.2 <u>Diligence</u>. During the Voyager Research Period, Voyager shall use Commercially Reasonable Efforts to (a) achieve the objectives of the Research Plan as soon as reasonably practical, including using Commercially Reasonable Efforts to generate Research Compounds (and Research Products with respect thereto) that Encode AbbVie Designated Antibodies and (b) complete the Research activities set forth in the Research Plan in accordance with the Research Budget and timeline set forth therein. Without limiting the generality of the foregoing, Voyager shall use Diligent Efforts to conduct the Research activities specifically set forth in the Research Plan, which activities shall be conducted in accordance with and subject to this ARTICLE 2 and the other terms and conditions of this Agreement.

### 2.2.3 <u>Information and Reports</u>.

- (a) Within [\*\*] following the end of each Calendar Quarter, Voyager shall provide to the JGC and AbbVie (i) (A) a detailed, written progress report on the status of its Research activities performed under the Research Program, and (B) access to or copies of written reports of Research activities hereunder as may be prepared by Voyager, in each case ((A) and (B)), to enable the JGC and AbbVie to assess the progress of the Research Program and Voyager's compliance with the Research Plan and (ii) a summary report of the Research Costs incurred by Voyager during such Calendar Quarter.
- (b) In addition to the reports provided pursuant to Section 2.2.3(a) and without limiting Section 9.4, by the [\*\*] of each month during the Voyager Research Term, Voyager shall present to the Joint R&D Working Group a detailed summary of the data resulting from its Research activities performed under the Research Program in the previous month in a PowerPoint<sup>TM</sup> format as more specifically defined in the Research Plan.

#### 2.2.4 <u>Termination of Research Activities</u>.

(a) If the Parties mutually determine, at any time during the Voyager Research Period, that it is not scientifically or technically possible to identify a Research Compound or Research Product, Manufacture a Research Compound or Research Product or to conduct other Research activities relating to a Research Product that meets the criteria set forth in the Research Plan (a "Research Infeasibility Determination"), the Parties may agree in writing to terminate Voyager's conduct of Research activities and the Research Plan with respect to such Research Compound and Research Product or terminate this Agreement in its entirety (a "Research Infeasibility Termination"). If a Party reasonably believes that a Research Infeasibility Determination is appropriate, but the other Party does not agree, then such dispute will be a Dispute and the provisions of Section 17.2 shall apply. If the Parties agree to terminate Voyager's conduct of Research activities and the Research Plan with respect to all Research Compounds and Research Products in accordance with this Section 2.2.4(a), then the Parties shall agree in writing to terminate this Agreement.

- (b) After the termination or expiration of the Voyager Research Period, Voyager shall have no further obligation to conduct Research activities with respect to the Research Compounds and Research Products under the Research Plan.
- (c) In the event of a Research Infeasibility Termination with respect to a Research Compound and the corresponding Research Product, subject to Section 11.3, AbbVie acknowledges and agrees that Voyager shall not have any further obligations (including those set forth in Sections 2.2.1, 2.2.2 or 2.2.3) to conduct Research activities with respect to such Research Compound and Research Product under the Research Plan.
- 2.2.5 <u>No Guarantees.</u> Subject to Voyager's obligations to (a) use Commercially Reasonable Efforts to (i) complete the Research Program in accordance with the Research Budget and timeline set forth in the Research Plan and (ii) achieve the objectives of the Research Plan and (b) use Diligent Efforts to complete the Research activities set forth in the Research Plan, Voyager provides no representation, warranty or guarantee that the goals contemplated in the Research Plan will be achieved, or that any other particular results will be achieved with respect to any Research Compound or Research Product.

### 2.3 <u>Development Option</u>.

- 2.3.1 <u>Grant of Development Option</u>. Voyager hereby grants to AbbVie, with respect to each Research Compound and corresponding Research Product, an exclusive option, exercisable by AbbVie in its sole discretion during the Development Option Period, to cause Voyager to commence Development activities with respect to such Research Compound and corresponding Research Product (each, a "<u>Development Option</u>").
- 2.3.2 <u>Submission of Final Research Report</u>. Within [\*\*] of the completion of the Research activities set forth in the Research Plan with respect to a Research Compound and corresponding Research Product, Voyager shall deliver to AbbVie the complete Final Research Report with respect to such Research Compound and corresponding Research Product.
- 2.3.3 <u>Recommendations for Selected Research Compound(s)</u>. Within [\*\*] after the date Voyager delivers to AbbVie a Final Research Report, at the request of either Party, the JGC shall meet to discuss such Final Research Report and make recommendations to AbbVie regarding whether to designate the Research Compound that is the subject of such Final Research Report as a Selected Research Compound; <u>provided</u> that such designation shall be in AbbVie's sole discretion.
- 2.3.4 Exercise of Development Option. AbbVie may exercise a Development Option by providing an Exercise Notice thereof to Voyager during the Development Option Period, which notice shall include a designation of one (1) or more Research Compound(s) for Development (each, a "Selected Research Compound") and corresponding Research Product(s) (each, a "Selected Research Product"); provided, however, subject to Section 3.2.4(b), in no event shall more than four (4) specific Research Compounds be designated as Selected Research Compounds in the aggregate during the Term unless otherwise agreed by the Parties in writing. Upon AbbVie's first exercise of a Development Option, it shall pay to Voyager a one-time payment of Eighty Million Dollars (\$80,000,000), plus if AbbVie designates more than one (1)

Selected Research Compound in the Exercise Notice with respect to such Development Option, Thirty Million Dollars (\$30,000,000) for each additional Selected Research Compound designated in such Development Option (the "Initial Development Option Exercise Fee"), within thirty (30) days after the date of such Exercise Notice provided pursuant to this Section 2.3.4. In addition, if AbbVie exercises additional Development Option(s) with respect to additional Selected Research Compound(s), AbbVie will pay to Voyager a one-time payment of Thirty Million Dollars (\$30,000,000) for each additional Selected Research Compound (the "Additional Development Option Exercise Fee"), within thirty (30) days after the date of the Exercise Notice with respect to such Development Option provided pursuant to this Section 2.3.4. If Voyager has not completed the Research Plan with respect to all Research Compounds and corresponding Research Products as of the date AbbVie exercises the initial Development Option, unless the Parties otherwise agree in writing, Voyager shall continue to use Diligent Efforts to complete the Research activities set forth in the Research Plan with respect to any remaining Research Compounds and corresponding Research Products.

2.3.5 No Exercise of Development Option. If AbbVie does not exercise any Development Option on or before the end of the Development Option Period in accordance with Section 2.3.4, subject to Section 11.3, if applicable, then (a) Voyager shall have no rights under this Agreement to Exploit any AbbVie Designated Antibody, including, for clarity, any Vectorized Alpha-Synuclein Antibody that Encodes any AbbVie Designated Antibody or any Sequence with respect thereto (including any rights under AbbVie Background IP or AbbVie Designated Antibody IP to do so), and (b) AbbVie shall have the right to freely pursue the Research, Development, Manufacture, use and Commercialization of any AbbVie Designated Antibody, including, for clarity, any Vectorized Alpha-Synuclein Antibody that Encodes any AbbVie Designated Antibody or any Sequence with respect thereto (but for clarity shall have no rights under any Voyager Background IP to do so).

# ARTICLE 3 DEVELOPMENT; LICENSE OPTION

### 3.1 <u>Development Plan</u>.

3.1.1 <u>Development Plan</u>. The initial Development Plan attached hereto includes (a) all IND-enabling studies and all Phase 1 Clinical Trials for a single Selected Research Product that will be conducted by Voyager during the Voyager Development Period; (b) a description of all Regulatory Filings that are necessary for Voyager to conduct the Development activities set forth in the Development Plan; (c) the specific requirements for the Final Development Report(s) to be submitted by Voyager to AbbVie in accordance with Section 3.3.2, including a list identifying all results and related data that Voyager must provide to AbbVie and the format in which such results and related data must be delivered; (d) any materials to be provided by AbbVie and any activities to be performed by AbbVie; (e) all of the permitted uses of any Transferred Materials provided by or on behalf of AbbVie; and (f) a budget for the conduct by Voyager of the Development activities set forth in the Development Plan, including the preparation and submission of the Final Development Report(s) to AbbVie, in accordance with the Development Plan (the "Voyager Development Budget"); provided that the Voyager Development Budget set forth in the initial Development Plan is for one (1) Selected Research Compound and corresponding Selected Research Product and if AbbVie selects more than one

- (1) Selected Research Compound the Voyager Development Budget will equal the initial Voyager Development Budget multiplied by the total number of Selected Research Compounds. Unless otherwise agreed by the Parties, Voyager shall use Diligent Efforts to complete the Development activities specifically identified in the Development Plan for each Selected Research Compound and corresponding Selected Research Product. The Parties acknowledge and agree that, following AbbVie's designation of any Selected Research Compound(s) and corresponding Selected Research Product(s), certain adjustments will need to be made to the initial Development Plan to reflect such Selected Research Compound(s) and the corresponding Selected Research Product(s), such adjustments to be made in accordance with Section 3.1.2.
- 3.1.2 Amendments to Development Plan. Each Party may propose an amendment to the Development Plan by submitting such proposed amendment in writing to the Joint R&D Working Group, for review and approval, subject to the final decision-making process set forth in Section 5.6.3; provided, however, that any material amendments to the Development Plan shall be mutually agreed to by the Parties either in writing, such agreement not to be unreasonably withheld, conditioned or delayed, or through the JGC as reflected in JGC meeting minutes signed by the Alliance Managers in accordance with Section 5.5.1. Material amendments to the Development Plan include: [\*\*]. Upon the Alliance Managers' signing the minutes of the JGC pursuant to Section 5.5.1 memorializing the agreement of the JGC to, or mutual written agreement by the Parties of, as applicable, an amendment to the Development Plan, the Development Plan shall be deemed to be amended by such amendment.

### 3.2 <u>Conduct of Development.</u>

- 3.2.1 <u>Voyager Responsibility</u>. Subject to Section 3.2.2, during the Voyager Development Period, Voyager (a) shall have sole responsibility for the conduct of the Development activities in the Territory and (b) shall do so in accordance with the Development Plan. Subject to Section 3.2.4(b), Voyager shall bear all costs and expenses incurred by or on behalf of it in the performance of the Development activities in the Territory.
- 3.2.2 <u>Diligence</u>. During the Voyager Development Period, Voyager shall use Commercially Reasonable Efforts to (a) achieve the objectives of the Development Plan as soon as reasonably practical and (b) complete the Development activities set forth in the Development Plan in accordance with the Voyager Development Budget and timelines set forth therein. Without limiting the generality of the foregoing, Voyager shall use Diligent Efforts to conduct the Development activities specifically set forth in the Development Plan, which activities shall be conducted in accordance with and subject to this ARTICLE 3 and the other terms and conditions of this Agreement.

### 3.2.3 <u>Information and Reports</u>.

(a) Within [\*\*] following the end of each Calendar Quarter, Voyager shall provide to the JGC and AbbVie (i) (A) a detailed, written progress report on the status of its Development activities performed under the Development Program, and (B) access to or copies of written reports of Development activities hereunder as may be prepared by Voyager, in each case ((A) and (B)), to enable the JGC and AbbVie to assess the progress of the Development Program and Voyager's compliance with the Development Plan, and (ii) a summary report of the

Voyager Development Costs incurred by Voyager during such Calendar Quarter (each, a "<u>Voyager Development</u> <u>Cost Report</u>").

(b) In addition to the reports provided pursuant to Section 3.2.3(a) and without limiting Section 9.4, by the [\*\*] of each month during the Voyager Development Term, Voyager shall present to the Joint R&D Working Group a detailed summary of the data resulting from its Development activities performed under the Development Program in the previous month in a PowerPoint<sup>TM</sup> format as more specifically defined in the Development Plan.

## 3.2.4 <u>Termination of Development Activities</u>.

- (a) If the Parties mutually determine, at any time during the Voyager Development Period, that it is not scientifically or technically possible to Develop, Manufacture or to conduct other Development activities relating to a Selected Research Compound, and the corresponding Selected Research Product that contains or is comprised of such Selected Research Compound (a "Development Infeasibility Determination"), the Parties may agree in writing to terminate Voyager's conduct of Development activities and the Development Plan with respect to such Selected Research Compound and Selected Research Product (a "Development Infeasibility Termination"). If a Party reasonably believes that a Development Infeasibility Determination is appropriate, but the other Party does not agree, then such dispute will be a Dispute and the provisions of Section 17.2 shall apply.
- (b) If the Parties agree to terminate the Development activities with respect to a Selected Research Compound and corresponding Selected Research Product in accordance with clause (a) of this Section 3.2.4, then AbbVie shall have the right, within [\*\*] after the later of (i) such termination and (ii) Voyager's delivery of the last Final Research Report, and upon written notice to Voyager (a "Substitution Notice"), to substitute for each such terminated Selected Research Compound and Selected Research Product a different Research Compound and corresponding Research Product, in which case the Voyager Development Plan shall automatically be deemed updated to include such different Research Compound and corresponding Research Product. Within [\*\*] after AbbVie provides a Substitution Notice with respect to a terminated Selected Research Compound, AbbVie shall pay Voyager an amount equal to the Voyager Development Costs actually incurred by Voyager with respect to the applicable terminated Selected Research Compound and corresponding Selected Research Product (the "Substitution True-Up Amount"). For the avoidance of doubt, AbbVie shall not be required to pay an Initial Development Option Exercise Fee or Additional Development Option Exercise Fee, as applicable, for such substitute Selected Research Compound and corresponding Selected Research Product.
- (c) Subject to Section 11.3, if the Parties agree to terminate Voyager's conduct of Development activities and the Development Plan with respect to all former Selected Research Compounds and Selected Research Products in accordance with clause (a) of this Section 3.2.4, and no additional Selected Research Compounds and corresponding Selected Research Products are selected by AbbVie in accordance with clause (b) of this Section 3.2.4, then, once the Voyager Research Period has ended, the Parties shall agree in writing to terminate this Agreement.

- (d) In the event of a Development Infeasibility Termination with respect to a Selected Research Compound and corresponding Selected Research Product, subject to clause (c) of this Section 3.2.4, AbbVie acknowledges and agrees that Voyager shall not have any further obligations (including those set forth in Sections 3.2.1, 3.2.2 or 3.2.3) to conduct Development activities with respect to such Selected Research Compound and corresponding Selected Research Product under the Development Plan, except that Voyager must use Diligent Efforts to perform the Development activities with regard to a substitute Selected Research Compound and corresponding Research Product as identified in a Substitution Notice.
- 3.2.5 <u>No Guarantees</u>. Subject to Voyager's obligations to (a) use Commercially Reasonable Efforts to (i) conduct the Development Program in accordance with the Development Budget and timeline set forth in the Development Plan and (ii) achieve the objectives of the Development Plan and (b) use Diligent Efforts to complete the Development activities set forth in the Development Plan, Voyager provides no representation, warranty or guarantee that the goals contemplated in the Development Plan will be achieved, or that any other particular results will be achieved with respect to any Selected Research Compound or Selected Research Product.
  - 3.3 <u>License Option; Submission of Final Development Report(s).</u>
- 3.3.1 <u>Grant of License Option</u>. Voyager hereby grants to AbbVie an exclusive option, exercisable by AbbVie in its sole discretion during the License Option Period, to obtain the Exclusive License (the "<u>License Option</u>").
- 3.3.2 <u>Submission of Final Development Report(s)</u>. Within [\*\*] of the completion of the Development activities set forth in the Development Plan for a Selected Research Compound and Selected Research Product, Voyager shall deliver to AbbVie the complete Final Development Report with respect to such Selected Research Compound and corresponding Selected Research Product.

### 3.3.3 Exercise of License Option.

- (a) AbbVie may exercise the License Option for a Selected Research Compound and corresponding Selected Research Product during the License Option Period by, subject to Section 3.4, providing an Exercise Notice relating thereto to Voyager during the License Option Period. If AbbVie exercises the License Option, AbbVie shall pay to Voyager a one-time, non-refundable, non-creditable payment of Seventy-Five Million Dollars (\$75,000,000) (the "License Option Exercise Fee") within thirty (30) days of the License Option Effective Date.
- (b) Upon the License Option Effective Date, AbbVie shall have the sole right to conduct, or have conducted in accordance with Section 9.3.1, at its sole cost and expense, Research, Development and Commercialization activities relating to the Licensed Compound(s), and the corresponding Licensed Product(s) containing or comprised of a Licensed Compound. If Voyager has not completed the Research Plan with respect to all Research Compounds and corresponding Research Products or the Development Plan with respect to all Selected Research Compounds and corresponding Selected Research Products as of the License

Option Effective Date, unless the Parties otherwise agree in writing, Voyager shall continue to use Diligent Efforts to complete the Research activities set forth in the Research Plan with respect to the remaining Research Compounds and corresponding Research Products and the Development activities set forth in the Development Plan with respect to the remaining Selected Research Compounds and corresponding Selected Research Products.

#### 3.4 HSR.

- 3.4.1 If AbbVie reasonably determines in good faith prior to the delivery of the Exercise Notice for the License Option that the transactions to be consummated upon the exercise of the License Option require HSR Filings, AbbVie shall provide the Exercise Notice for the License Option to Voyager prior to the end of the License Option Period, which notice shall include AbbVie's irrevocable binding commitment to complete the exercise of the License Option, subject only to HSR Clearance and the terms of this Section 3.4 and Section 16.2.7, and the License Option Period shall, subject to Section 16.2.7, automatically be extended for so long as is necessary for AbbVie to obtain HSR Clearance. Neither Party may seek early termination (or early determination) of HSR Clearance without the other Party's prior written consent.
- 3.4.2 In connection with the Parties activities under this Section 3.4, AbbVie and Voyager shall each use commercially reasonable efforts to resolve as promptly as practicable any objections that may be asserted by the FTC or the DOJ with respect to the transactions notified in the HSR Filings. Nothing in this Section 3.4 or otherwise in this Agreement shall require AbbVie to (a) offer, accept or agree to sell, divest (including through a license or a reversion of licensed or assigned rights), hold separate, transfer, or dispose of any assets, operations, rights, product lines, or businesses, or interests therein, of itself or any of its Affiliates (or consent to any of the foregoing actions), (b) offer, accept or agree to any restraint, prohibition or limitation on the ownership, operation or conduct of all or any portion of the businesses or assets of itself or any of its Affiliates in any part of the world, or (c) litigate or otherwise formally oppose any determination (whether judicial or administrative in nature) by a Governmental Authority seeking to impose any of the restrictions referenced in clause (a) or (b) above (such litigation or judicial or administrative proceeding, an "HSR Proceeding"); provided that Voyager shall not agree to or effectuate any remedy without the prior written consent of AbbVie.
- 3.4.3 AbbVie shall be responsible for all filing fees in connection with the filing of submissions to the FTC and DOJ under the HSR Act, and each Party shall be responsible for its costs and expenses, including attorneys' fees, incurred by it in preparing submissions or responses or responding to any Second Request or other action by the FTC or DOJ under the HSR Act. If HSR Filings are required, each Party shall use commercially reasonable efforts to prepare and file its respective HSR Filing as promptly as is practicable and advisable, with the goal of filing the HSR Filings within [\*\*] of Voyager receiving the Exercise Notice for the License Option or promptly thereafter. In connection with obtaining HSR Clearance, each of AbbVie and Voyager shall (a) cooperate with each other in connection with any investigation or other inquiry relating to an HSR Filing and the transactions contemplated by this Agreement; (b) keep the other Party or its counsel informed of any material communication received from or given to the FTC or DOJ relating to the HSR Filings and the transactions contemplated by this Agreement (and provide a copy to the other Party if such material communication is in writing);

and (c) permit the other Party or its counsel to review in advance, and in good faith consider the views of the other Party or its counsel concerning, any submission, filing or communication (and documents submitted therewith) intended to be given to the FTC or DOJ. Without limiting the foregoing, Voyager shall cooperate fully in any HSR Proceeding initiated by AbbVie, at AbbVie's expense.

- 3.4.4 <u>Tolling of Obligations</u>. If the exercise by AbbVie of the License Option under Section 3.3.3 requires the making of filings under the HSR Act, then all rights and obligations related to the exercise of the License Option (including payment of any License Option Exercise Fee) and the granting of the Exclusive License shall be tolled until the HSR Clearance or the earlier termination of this Agreement in accordance with Section 16.2.7.
- 3.5 No Exercise of License Option. If AbbVie does not exercise the License Option on or before the end of the License Option Period in accordance with Section 3.3.3, subject to Section 11.3, if applicable, then (a) Voyager shall have no rights under this Agreement to Exploit any AbbVie Designated Antibody, including, for clarity, any Vectorized Alpha-Synuclein Antibody that Encodes any AbbVie Designated Antibody or any Sequence with respect thereto (including any rights under AbbVie Background IP or AbbVie Designated Antibody IP to do so), and (b) AbbVie shall have the right to freely pursue the Research, Development, Manufacture, use and Commercialization of any AbbVie Designated Antibody, including, for clarity, any Vectorized Alpha-Synuclein Antibody that Encodes any AbbVie Designated Antibody or any Sequence with respect thereto (but for clarity shall have no rights under any Voyager Background IP to do so).

# ARTICLE 4 ABBVIE RESPONSIBILITIES DURING RESEARCH AND DEVELOPMENT

#### 4.1 Access to Information and Materials.

4.1.1 Request for Information. During the Voyager Research Period and the Voyager Development Period, the Joint R&D Working Group may, from time to time, reasonably request that AbbVie provide to Voyager certain additional information, data and results in AbbVie's possession and Control that are not set forth in the Research Plan or Development Plan, as applicable, relating to any AbbVie Designated Antibody to facilitate Voyager's conduct of the Research and Development activities hereunder relating to any AbbVie Designated Antibody or its use in Research Compounds, Selected Research Compounds, Research Products and Selected Research Products. AbbVie shall use Commercially Reasonable Efforts to promptly provide Voyager such information, data and results that are reasonably requested to perform Voyager's activities under the Research Plan or the Development Plan.

### 4.1.2 <u>Transfer of Certain Materials</u>.

(a) In addition to AbbVie's obligations under Section 4.1.1 and Section 8.1.1, from time to time during the Voyager Research Period or the Voyager Development Period, the Joint R&D Working Group may request that a Party provide the other Party with certain other tangible chemical or biological materials (the "Transferred Materials"),

which the transferring Party may, but shall not have an obligation to, provide to the other Party. For clarity, (i) AbbVie shall not provide any such materials to Voyager unless specifically identified and requested by the Joint R&D Working Group, and (ii) Licensed Compounds, Licensed Products and any materials related to the Manufacturing Process shall not constitute Transferred Materials. The transferring Party represents and warrants to the receiving Party that the transferring Party has the right to provide the Transferred Materials to the receiving Party for the uses authorized herein. Except as expressly set forth in the preceding sentence, the Transferred Materials are provided by the transferring Party on an "AS IS" basis without any representation or warranty of any type, express or implied, including any representation or warranty of merchantability, non-infringement, title or fitness for a particular purpose, each of which is hereby expressly disclaimed by the transferring Party.

- (b) The receiving Party shall use the Transferred Materials solely in connection with conducting the activities specified in the Research Plan or the Development Plan, as applicable, or for the specific purpose approved by the transferring Party. Without limiting the generality of the foregoing, except in the performance of the foregoing activities, the receiving Party shall not (i) make or attempt to make any analogues, progeny or derivatives of, or modifications to, the Transferred Materials or (ii) use the Transferred Materials for its own benefit or for the benefit of any of its Affiliates or any Third Party. Further, the receiving Party shall not administer any Transferred Material to any human. The receiving Party shall comply with all Laws applicable to the handling and use of the Transferred Materials. Except as agreed upon by the transferring Party, the receiving Party shall retain possession over the Transferred Materials and shall not provide any Transferred Materials to any Third Party or, in the event of a Change of Control, to any Affiliates of an Acquirer or Acquired Third Party, in each case, without the transferring Party's prior written consent, which consent may be withheld in the transferring Party's sole discretion.
- (c) All right, title and interest in and to the Transferred Materials shall remain the sole and exclusive property of the transferring Party, notwithstanding the transfer to and use by the receiving Party of the same.
- (d) With respect to Transferred Materials and other materials provided by Voyager to AbbVie, at the end of the Development Option Period (if AbbVie does not exercise the Development Option) or the License Option Period (if AbbVie does not exercise the License Option), as applicable, AbbVie shall either promptly destroy or return to Voyager, at Voyager's sole discretion, all unused Transferred Materials and such other materials of Voyager.
- (e) With respect to Transferred Materials and other materials (including any AbbVie Designated Antibody) provided by AbbVie to Voyager, at the end of the Development Option Period or the License Option Period, as applicable, or if this Agreement is otherwise terminated prior to the end of the License Option Period (or such earlier time as AbbVie may request in writing once Voyager no longer needs such Transferred Materials for purposes of the Research and Development activities conducted by Voyager), Voyager shall either promptly destroy or return to AbbVie, at AbbVie's sole discretion, all unused Transferred Materials and such other materials of AbbVie.

- 4.2 <u>AbbVie Assistance Generally.</u> During the Voyager Research Period and the Voyager Development Period, the Joint R&D Working Group may from time to time reasonably request that AbbVie advise and consult with Voyager regarding the conduct of the Research and Development activities set forth in the Research Plan or Development Plan, as applicable. AbbVie shall use Commercially Reasonable Efforts to promptly provide Voyager with such advice and consultation that is reasonably requested. In addition, AbbVie shall use Commercially Reasonable Efforts to provide Voyager with direct access to AbbVie's and its Affiliates' scientists and Third Party contractors as reasonably determined by the Joint R&D Working Group.
- 4.3 <u>Impact of AbbVie's Assistance on Voyager's Obligations</u>. AbbVie acknowledges and agrees that, in the event and to the extent that Voyager is unable to perform any of its obligations set forth in Section 2.2.1, Section 2.2.2, Section 2.2.3, Section 3.2.1, Section 3.2.2 or Section 3.2.3 due to AbbVie's failure to provide information, data, results, Transferred Materials or assistance reasonably requested by the Joint R&D Working Group in accordance with Section 4.1.1, Section 4.2 or the proviso in Section 7.2.1, then such failure shall be a factor in determining whether Voyager used Diligent Efforts or Commercially Reasonable Efforts, as applicable, with respect to such obligations.
- 4.4 <u>AbbVie's Obligation to Provide Prompt Notice</u>. If AbbVie is concerned that Voyager has failed to meet any of its obligations under Section 2.2.1, Section 2.2.2, Section 2.2.3, Section 3.2.1, Section 3.2.2 or Section 3.2.3, then AbbVie may notify Voyager in writing of such concern (each a, "<u>Performance Issue</u>"). Promptly upon Voyager's receipt of notice of a Performance Issue pursuant to this Section 4.4, Voyager's Alliance Manager shall contact AbbVie's Alliance Manager to discuss the specific nature of such Performance Issue and seek to identify an appropriate course of action and both Parties shall seek to resolve such Performance Issue in good faith.

## ARTICLE 5 MANAGEMENT OF THE COLLABORATION

- 5.1 Joint Governance Committee and Subcommittees.
- 5.1.1 The Parties hereby establish the Joint Governance Committee (the "<u>JGC</u>") to serve as the oversight and decision-making body for the activities to be conducted by the Parties pursuant to this Agreement, as more fully described in this ARTICLE 5. The Parties anticipate that the JGC will not be involved in day-to-day implementation of the activities under this Agreement, but shall serve as the oversight and decision-making body during the Term of this Agreement. The JGC may establish subcommittees as set forth in Section 5.2 (each a "Subcommittee").
- 5.1.2 <u>Responsibilities</u>. The JGC shall perform the following functions, subject to the final decision-making authority of the respective Parties as set forth in Section 5.6:

- (a) review and, except as otherwise agreed by the Parties in writing outside the JGC as set forth in Section 2.1.2, approve any amendments to the Research Plan proposed by a Party;
- (b) review the progress reports on the Research activities submitted by Voyager in accordance with Section 2.2.3;
- (c) serve as an initial forum for discussion of any issues or disputes arising from the conduct of the Research activities or a Party's performance of its obligations under ARTICLE 4 during the Voyager Research Period:
- (d) make recommendations to AbbVie regarding which Research Compound(s) to advance to Development as the Selected Research Compounds;
- (e) review and, except as otherwise agreed by the Parties in writing outside the JGC as set forth in Section 3.1.2, approve any amendments to the Development Plan proposed by a Party;
- (f) review the progress reports on the Development activities submitted by Voyager in accordance with Section 3.2.3;
- (g) serve as an initial forum for discussion of any issues or disputes arising from the conduct of the Development activities or a Party's performance of its obligations under ARTICLE 4 during the Voyager Development Period;
- (h) review the progress reports on the Development and Commercialization activities submitted by AbbVie in accordance with Section 7.3.3;
- (i) review and discuss any reports or recommendations of the Joint R&D Working Group;
  - (j) review and discuss any reports or recommendations of the Joint IP Working Group;
- (k) review and discuss any reports or recommendations of the Joint CMC Working Group;
- (l) review and resolve any disputes of the Joint R&D Working Group, the Joint IP Working Group, the Joint CMC Working Group or any other Subcommittee or Working Group;
- (m) form Subcommittees and additional Working Groups as the JGC deems necessary to achieve the objectives and intent of this Agreement;
- (n) assign responsibilities that may fall within the purview of more than one (1) Subcommittee to a particular Subcommittee or more than one (1) Working Group to a particular Working Group; and

(o) perform such other responsibilities as may be assigned to the JGC pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time.

For clarity, the JGC shall not have any authority beyond the specific matters set forth in this Section 5.1.2, and in particular shall not have any power to amend or modify the terms of this Agreement or waive a Party's compliance with this Agreement or to decide or resolve any issues other than those specifically subject to JGC approval in this Section 5.1.2. In addition, AbbVie (and not Voyager or the JGC) shall have the sole right to decide (1) whether or not to exercise the Development Option in accordance with Section 2.3.4, and (2) whether or not to exercise the License Option in accordance with Section 3.3.3.

5.2 <u>Formation and Dissolution of Subcommittee(s)</u>. The JGC may establish Subcommittees from time to time to handle specific matters within the scope of the JGC's area of authority and responsibility, and no Subcommittee's authority and responsibility may be greater than that of the JGC itself. Each Subcommittee shall have such authority and responsibility as determined by the JGC from time to time, and decisions and recommendations of any Subcommittee shall be made in accordance with Section 5.6. The JGC shall determine when each Subcommittee it forms shall be dissolved.

## 5.3 <u>Working Groups</u>.

- 5.3.1 <u>Formation of Working Groups</u>. In addition to the Joint R&D Working Group set forth in Section 5.3.1(a), the Joint IP Working Group set forth in Section 5.3.1(b) and the Joint CMC Working Group set forth in Section 5.3.1(c), from time to time, the Parties (by mutual agreement), the JGC or any Subcommittee (each, a "<u>Committee</u>") may establish one (1) or more working groups (each, a "<u>Working Group</u>") to oversee particular projects or activities. Each Working Group shall undertake the activities allocated to it herein or delegated to it by the Committee to which it reports and shall operate as the Committee that establishes the Working Group determines or as otherwise set forth in this Section 5.3.1. The Parties acknowledge and agree that each Working Group is intended to function primarily in a supporting role by providing advice to the Committee to which it reports, but that each Working Group will be best positioned to implement certain operational matters as determined by the Committee to which such Working Group reports.
- (a) <u>Joint R&D Working Group</u>. The Parties shall establish a joint research and development working group (the "<u>Joint R&D Working Group</u>") within [\*\*] following the Effective Date. The Joint R&D Working Group will be responsible for (i) the day-to-day implementation of (A) the Research activities conducted during the Voyager Research Period in accordance with the Research Plan, and (B) the Development activities conducted during the Voyager Development Period in accordance with the Development Plan, (ii) sharing of information generated under the Research Program or the Development Program, (iii) coordination and prioritization of activities under the Research Program and the Development Program, (iv) discussing whether any additional material, information, data, results, Transferred Materials and assistance should be provided by AbbVie to Voyager during the Voyager Research Period and Voyager Development Period, (v) reviewing and approving all amendments to the Research Plan or Development Plan, as applicable, including any proposed by a Party, except for

any material amendments as provided in Section 2.1.2 or Section 3.1.2; (vi) determining and implementing a system to record and consolidate all amendments to the Research Plan or the Development Plan and (vii) monitoring Voyager's progress under the Research Program or the Development Program. The Joint R&D Working Group shall provide the JGC with all relevant information and any recommendations necessary for the JGC to exercise its decision-making authority set forth in Section 5.6. The Joint R&D Working Group will report to the JGC. Minutes of the Joint R&D Working Group meetings, which shall be approved in accordance with Section 5.5.1, shall include acknowledgements of Voyager's completion of activities set forth in the Research Plan or Development Plan, as applicable, to the extent such acknowledgements are mutually agreed by the Parties' representatives during the applicable Joint R&D Working Group meeting.

- (b) <u>Joint IP Working Group</u>. The Parties shall establish a joint intellectual property working group (the "<u>Joint IP Working Group</u>") within [\*\*] following the Effective Date. The Joint IP Working Group will be responsible for providing the JGC and the Parties with guidance with respect to matters relating to (i) the preparation, filing, prosecution and maintenance of the Collaboration Patent Rights, Joint Patent Rights, and the AbbVie Designated Antibody Patent Rights, (ii) freedom-to-operate matters, (iii) discussing any challenges to any Third Party's Patent Rights that may Cover any Selected Research Compounds, Selected Research Products, Licensed Compounds or Licensed Products; and (iv) advising the JGC regarding which of the In-License Agreements are relevant to any Selected Research Compound(s) or Selected Research Product(s). The Joint IP Working Group will report to the JGC.
- (c) <u>Joint CMC Working Group</u>. The Parties shall establish a joint Manufacturing working group (the "<u>Joint CMC Working Group</u>") within [\*\*] following the Effective Date. The Joint CMC Working Group will be responsible for providing the JGC and the Parties with guidance with respect to matters relating to the generation and maintenance of chemistry, manufacturing and controls (CMC) data required by applicable Law to be included or referenced in, or otherwise support, an IND or Regulatory Approval Application and coordinating the sharing and exchange of such data between Voyager and AbbVie. The Joint CMC Working Group will report to the JGC. AbbVie shall have the right to disband the Joint CMC Working Group at any time after the License Option Effective Date upon written notice to Voyager.
- Membership. Each Committee shall be composed of [\*\*] representatives of each Party or such other number as agreed upon by such Committee, each with the requisite experience and seniority to enable such person to make decisions on behalf of the Party it represents with respect to the issues falling within the jurisdiction of the JGC. Each Party shall appoint at least [\*\*] to each Working Group and shall have the right, but not the obligation, to appoint the same number of representatives to any Working Group as are appointed by the other Party to such Working Group; provided that neither Party shall appoint more than [\*\*] representatives to any one (1) Working Group. Each individual appointed by a Party as a representative to a Committee or Working Group shall be an employee of such Party, or, other than a representative appointed to the JGC, a contractor to such Party or an employee or contractor of such Party's Affiliate. Each Party may replace any of its Committee or Working Group representatives at any time upon written notice to the other Party,

which notice may be given by e-mail sent to the other Party's co-chairperson of such Committee and, with respect to a change of representatives to any Working Group, to the other Party's co-chairperson of the Committee to which such Working Group reports. Each Committee and Working Group shall be co-chaired by one (1) designated representative of each Party. Either Party may replace any or all of its representatives on a Committee or Working Group at any time upon written notice to the other Party. Any member of a Committee or Working Group may designate a substitute to attend and perform the functions of that member at any meeting of such Committee or Working Group, as applicable.

### 5.5 <u>Meetings</u>.

5.5.1 The co-chairpersons shall be responsible, with respect to their Committee or Working Group, as applicable, for (a) calling meetings on no less than [\*\*] notice unless exigent circumstances require shorter notice; (b) preparing and circulating an agenda in advance of each meeting; provided that the co-chairpersons shall include any agenda items proposed by either Party on such agenda; (c) ensuring that all decision-making is carried out in accordance with the voting and dispute resolution mechanisms set forth in this Agreement; and (d) preparing and circulating for review minutes of each meeting within [\*\*] (or such shorter time as is agreed by the relevant Committee or Working Group) thereafter. For clarity, either co-chairperson may call a meeting of its Committee or Working Group individually, without the consent of the other co-chairperson. The Parties, through their members of the relevant Committee or Working Group, shall agree in good faith on the minutes of each meeting promptly, but in no event later than the next meeting of the relevant Committee or Working Group, and such approved minutes shall be signed by the Alliance Managers. For clarity, any amendment to the Research Plan or Development Plan that is agreed to in a meeting of the JGC (or any other Committee or Working Group) shall not be effective until the minutes of such meeting reflecting such amendment are signed by the Alliance Managers.

5.5.2 Each Committee and Working Group shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of each Committee and Working Group shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party. The location of regularly scheduled meetings shall alternate between Voyager's offices located in Cambridge, Massachusetts and AbbVie's offices located in Chicago, Illinois, unless otherwise agreed by such Committee or Working Group. Representatives of the Parties may also attend a meeting telephonically, by video conference or by any other media so long as each participant can hear what is said by and be heard by the other participants. For the avoidance of doubt, each Party may designate the same individual as a representative on more than one (1) Committee or Working Group. Each representative of a Party on a Committee or Working Group shall be subject to confidentiality obligations no less stringent than those set forth in ARTICLE 13. Each Party will bear all expenses it incurs in regard to participating in all meetings of each Subcommittee and Working Group, including all travel and living expenses. Employees or consultants of a Party who are not representatives of such Party on a Committee or Working Group may attend meetings of such Committee or Working Group; provided, however, that such attendees (a) shall not vote or otherwise participate in the decision-making process of such Committee or Working Group and (b) must be bound by obligations of confidentiality and non-disclosure no less stringent than those set forth in ARTICLE 13.

5.5.3 Prior to the expiration or termination of the Voyager Research Period and the Voyager Development Period, the JGC shall meet at least [\*\*], and more or less frequently as the Parties mutually deem appropriate, on such dates and at such places and times as provided herein or as the Parties shall agree. Thereafter and following the Cut-Off Date, the JGC shall meet on an as-needed basis, but no less frequently than [\*\*], including to review and discuss the reports provided to AbbVie pursuant to Section 7.3.3.

#### 5.6 <u>Decision-Making</u>.

- 5.6.1 <u>Escalation to JGC</u>. Except as otherwise provided herein, all decisions of each Committee and each Working Group shall be made by consensus, with all of a Party's voting members collectively having one (1) vote. Decisions of each Committee and Working Group shall be made by unanimous vote. If a Committee or Working Group other than the JGC is incapable of reaching unanimous agreement on a matter before it within [\*\*], the matter shall be referred to the JGC for resolution. If the JGC is incapable of reaching unanimous agreement on a matter before it within [\*\*], the matter shall be resolved in accordance with Section 5.6.2.
- 5.6.2 <u>Escalation to the Executive Officers</u>. If the JGC cannot agree on a matter within [\*\*] after it has met and attempted to reach such decision, then either Party may, by written notice to the other, refer such matter to the Executive Officers for resolution. The Parties' respective Executive Officers shall meet within [\*\*] after such matter is referred to them, and shall negotiate in good faith to resolve the matter.
- 5.6.3 <u>Escalation to the Parties</u>. If the Executive Officers are unable to resolve the matter within [\*\*] after the matter is referred to them, then the matter shall be finally resolved as follows (other than with respect to Legal Disputes, which shall be governed by Section 17.2):
- (a) Voyager shall have final decision-making authority within any Committee or Working Group with respect to the implementation of the Research Plan or the Development Plan or the Research and Development activities performed under this Agreement, and any amendments to the Research Plan or the Development Plan other than material amendments as provided in Section 2.1.2 or Section 3.1.2, as applicable, to the extent properly within the jurisdiction of such Committee or Working Group, during the Voyager Research Period or the Voyager Development Period, respectively, arising prior to the License Option Effective Date; provided that if Voyager undergoes a Change of Control during the Voyager Research Period or the Voyager Development Period, then, after the effective date of such Change of Control, AbbVie may elect, upon written notice to Voyager, to obtain final decision-making authority within any Committee or Working Group with respect to the implementation of the Research Plan or the Development Plan or the Research and Development activities performed under this Agreement to the extent properly within the jurisdiction of such Committee or Working Group. For further clarity, neither Party shall have final decision-making authority with respect to material amendments to the Research Plan or the Development Plan as provided in Section 2.1.2 or Section 3.1.2, or the acknowledgements of Voyager's completion of activities pursuant to Section 5.3.1(a); and

(b) After the License Option Effective Date, AbbVie shall have final decision-making authority within any Committee or Working Group with respect to any and all matters to the extent properly within the jurisdiction of such Committee or Working Group. Notwithstanding the foregoing, to the extent Voyager is still performing activities under a Plan with regard to any Research Compound, Research Product, Selected Research Compound or Selected Research Product, then Voyager shall retain final decision-making authority with regard to such activities as set forth in Section 5.6.3(a), except with respect to any decisions that could reasonably be expected to materially affect any Licensed Compound or Licensed Product or the Exploitation thereof, including any decisions, or amendments to a Plan, with respect to Manufacturing or Regulatory affairs. For clarity, to the extent Voyager is still performing activities under a Plan after the License Option Effective Date, AbbVie shall not have final decision-making authority with respect to material amendments to a Plan;

provided, however, that in no event shall any Committee, Working Group, the Alliance Managers or any Party alone have the power or authority to: (A) amend this Agreement, (B) determine that a Party has fulfilled its obligations under this Agreement or that the other Party has breached this Agreement, (C) impose any requirements on either Party to undertake obligations beyond those for which it is responsible, or to forgo any of its rights, under this Agreement, (D) make a decision that is expressly stated to require the mutual agreement of the Parties or approval of the other Party, or (E) require either Party to perform any act that it reasonably believes to be inconsistent with any Law. Any decision made by the Executive Officers in accordance with Section 5.6.2 or by a Party in accordance with this Section 5.6.3 shall be considered a decision made by the JGC.

- 5.7 <u>Alliance Managers</u>. Promptly after the Effective Date, each Party shall appoint an individual (who may not be a then-current member of the JGC) to act as alliance manager for such Party (each, an "<u>Alliance Manager</u>"). Each Alliance Manager shall thereafter be permitted to attend meetings of the JGC as a nonvoting observer, subject to the confidentiality provisions of ARTICLE 13. The Alliance Managers shall be the primary point of contact for the Parties regarding the activities contemplated by this Agreement. The Alliance Managers shall also be responsible for assisting the JGC in performing its oversight responsibilities. The name and contact information for each Party's Alliance Manager, as well as any replacement chosen by such Party, in its sole discretion, from time to time, shall be promptly provided to the other Party in accordance with Section 17.7.
- 5.8 <u>Authority</u>. Notwithstanding anything in this ARTICLE 5 to the contrary, each Party will retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion will be delegated to or vested in the JGC or any other Subcommittee or any Working Group unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. Without limitation to the foregoing, the Parties hereby agree that matters explicitly reserved to the consent, approval or other decision-making authority of one (1) or both Parties, as expressly provided in this Agreement, are outside the jurisdiction and authority of the JGC or any other Subcommittee or any Working Group, including amendment, modification or waiver of compliance with this Agreement (which may only be amended or modified as provided in Section 17.12 or compliance with which may only be waived as provided in Section 17.9).

# ARTICLE 6 GRANT OF LICENSES

- 6.1 <u>Licenses to AbbVie</u>. Subject to the terms and conditions of this Agreement, Voyager (on behalf of itself and its Affiliates), hereby grants to AbbVie and its Affiliates:
- 6.1.1 subject to Section 3.4.4, on the License Option Effective Date, an exclusive (even as to Voyager and its Affiliates), royalty-bearing, non-transferable (except in accordance with Section 17.3), sublicenseable (subject to Section 6.3) license (or sublicense) under the Voyager Background IP and Voyager's interests in the Collaboration IP and Joint IP to Research, Develop, Manufacture, have Manufactured, use, Commercialize and otherwise Exploit the Licensed Compounds and the Licensed Products in the Field in the Territory (the "Exclusive License");
- 6.1.2 subject to Section 11.1, an exclusive (even as to Voyager and its Affiliates), perpetual, irrevocable, royalty-bearing (to the extent applicable to a Licensed Product during the applicable Royalty Terms (in which case such royalties shall be governed by ARTICLE 10), and otherwise royalty-free), transferable, sublicenseable (through multiple tiers) license under Voyager's interests in the Collaboration IP and Joint IP to Research, Develop, Commercialize, Manufacture and otherwise Exploit the AbbVie Designated Antibodies; and
- 6.1.3 subject to Section 6.1.1, Section 6.1.2 and Section 11.1, a non-exclusive, perpetual, irrevocable, royalty-bearing (to the extent applicable to a Licensed Product during the applicable Royalty Terms (in which case such royalties shall be governed by ARTICLE 10), and otherwise royalty-free), transferable, sublicenseable (through multiple tiers) license under Voyager's interests in the Collaboration IP and Joint IP for all purposes;

<u>provided</u>, <u>however</u>, that the exclusive licenses granted to AbbVie pursuant to Section 6.1.1 are subject to the Third Party agreement terms specifically set forth in <u>Schedule 6.1</u>.

## 6.2 <u>In-License Agreements</u>.

### 6.2.1 Existing In-License Agreements.

- (a) Without limiting the representations, warranties and covenants set forth in ARTICLE 14, AbbVie acknowledges and agrees that the sublicenses granted by Voyager to AbbVie in this Agreement are subject to the terms of the Existing In-License Agreements, the scope of the licenses granted to Voyager or the applicable Affiliate thereunder and the rights granted to or retained by the Third Party counterparties thereof and any other Third Party with rights thereunder (including Governmental Authorities, as applicable) (each, an "Inbound Licensor").
- (b) The Parties shall cooperate with each other in good faith to support each other in complying with Voyager's obligations under each Existing In-License Agreement. Without limitation to the foregoing, (i) the Parties shall, from time to time, upon the reasonable request of either Party, discuss the terms of an Existing In-License Agreement and agree upon, to the extent reasonably possible, a consistent interpretation of the terms of such Existing In-

License Agreement in order to, as fully as possible, allow Voyager to comply with the terms of such Existing In-License Agreement and AbbVie to receive its rights and benefits under this Agreement; (ii) to the extent there is a conflict between any terms of this Agreement and any terms of any Existing In-License Agreement, the terms of such Existing In-License Agreement shall control with respect to the relevant Know-How, Patent Rights or other rights granted to AbbVie hereunder; and (iii) although Voyager is subject to making certain payments under the In-License Agreements as set forth in Section 10.13, AbbVie and its Affiliates and Sublicensees shall comply with any applicable reporting and other requirements under the Existing In-License Agreements, and the provisions regarding currency conversion, international payments and late payments, and any other relevant definitions and provisions, of the relevant In-License Agreements shall apply to the calculation of the payments due under the relevant Existing In-License Agreements; provided that when and as reasonably requested by AbbVie, Voyager shall use reasonable efforts to obtain waivers or amendments to, or exercise its rights under, the Existing In-License Agreements so as to harmonize AbbVie's obligations under this Section 6.2.1(b) with the corresponding provisions of this Agreement.

## 6.2.2 Future In-License Agreements.

Prior to Voyager or any of its Affiliates entering into a license or other agreement (a) with a Third Party pursuant to which Voyager or any of its Affiliates would acquire, license or obtain any right or interest in any invention, material or Know-How (or any Third Party Rights) that relates to Vectorization Technology, Vectorized Alpha-Synuclein Antibodies or Alpha-Synuclein or that may otherwise be necessary or reasonably useful (x) to conduct the Research Program or the Development Program or to achieve the objectives thereof or (y) to Exploit any Research Compound, Research Product, Selected Research Compound, Selected Research Product, Licensed Compound or Licensed Product (such activities (x) and (y), the "Program Activities"), any such invention, material or Know-How, a "Subject Technology" and such license or other agreement, a "Subject Technology Agreement"), Voyager shall use reasonable and good faith efforts to determine whether or not such Subject Technology would reasonably be expected to be necessary for the Program Activities, which efforts shall include (A) consulting with the Chief Scientific Officer of Voyager (or the executive officer of Voyager with equivalent responsibilities) and the other Voyager personnel responsible for leading the Research Program and the Development Program and (B) conducting such investigations and assessments, including where possible any relevant tests and studies, as are reasonably necessary to make such a determination. Any Subject Technology that specifically relates to Vectorized Alpha-Synuclein Antibodies or Alpha-Synuclein shall be deemed to be necessary for Program Activities unless the Parties agree otherwise in writing.

(i) If, after complying with Section 6.2.2(a) above, Voyager determines that the Subject Technology would reasonably be expected to be necessary (or such Subject Technology is otherwise deemed in accordance with the last sentence of Section 6.2.2(a) to be necessary) for the Program Activities, or if Voyager fails to comply with Section 6.2.2(a) above, then Voyager may enter into such Subject Technology Agreement and with respect to the Program Activities, such Subject Technology Agreement shall be consistent with the terms and conditions of this Agreement in all material respects and shall not in any way limit AbbVie's rights and interests or increase its obligations hereunder, except to the extent that such agreement

and any such inconsistency, limitation or obligation is agreed to in writing by AbbVie prior to execution.

- (ii) If, after complying with Section 6.2.2(a) above, Voyager determines that the Subject Technology is not reasonably expected to be necessary (and such Subject Technology is not otherwise deemed in accordance with the last sentence of Section 6.2.2(a) to be necessary) for the Program Activities, then (A) Voyager may enter into such Subject Technology Agreement on such terms and conditions as it determines, provided that the terms and conditions applicable to the Program Activities are no less favorable than the terms and conditions applicable to any other targets, programs or activities, and (B) unless such Subject Technology Agreement is consistent with the terms and conditions of this Agreement in all material respects and does not in any way limit AbbVie's rights and interests or increase its obligations hereunder, Voyager shall not use or incorporate any such Subject Technology in the Research Program or the Development Program or any Research Compound, Research Product, Selected Research Compound, Selected Research Product, Licensed Compound or Licensed Product (and any such Know-How or Patent Rights shall not be included in the Voyager Background IP, AbbVie Designated Antibody IP or Collaboration IP), unless and until such agreement and any such inconsistency, limitation or obligation is agreed to in writing by AbbVie.
- with respect to any Subject Technology pursuant to Section 6.2.2(a)(ii), Voyager or AbbVie determines that such Subject Technology is necessary for the Program Activities, then Voyager shall use Commercially Reasonable Efforts to amend such Subject Technology Agreement to be consistent with the terms and conditions of this Agreement in all material respects and to not in any way limit AbbVie's rights and interests or increase its obligations hereunder, except to the extent that such agreement and any such inconsistency, limitation or obligation is agreed to in writing by AbbVie. Voyager shall consult and coordinate with AbbVie with respect to Voyager's efforts to amend such Subject Technology Agreement under this Section 6.2.2(b) and shall consider in good faith AbbVie's recommendations with respect thereto. Voyager shall not use or incorporate any such Subject Technology in the Research Program or the Development Program or in any Research Compound, Research Product, Selected Research Compound, Selected Research Product, Licensed Compound or Licensed Product (and any such Know-How or Patent Rights shall not be included in the Voyager Background IP, AbbVie Designated Antibody IP or Collaboration IP), until such agreement is amended in accordance with the immediately preceding sentence or any such inconsistency, limitation or obligation is agreed to in writing by AbbVie, not to be unreasonably withheld, conditioned or delayed.
- (c) AbbVie's failure to agree to any inconsistency, limitation or obligation with respect to any Subject Technology for which agreement is required by AbbVie pursuant to this Section 6.2.2 (and the subsequent exclusion of any Subject Technology from the Voyager Background IP, AbbVie Designated Antibody IP or Collaboration IP) shall not be a factor in determining whether Voyager used Diligent Efforts or Commercially Reasonable Efforts, as applicable, with respect to its obligations set forth in Section 2.2.1, Section 2.2.2, Section 2.2.3, Section 3.2.1, Section 3.2.2 or Section 3.2.3.

The Parties agree that it would not be commercially reasonable for Voyager to acquire any Subject Technology (other than a Virus Capsid that is the subject of the [\*\*] as of the Effective Date) if, pursuant to the applicable Subject Technology Agreement, Voyager would [\*\*] a Licensed Product such that the [\*\*]. In such an event, Voyager shall not be obligated under this Agreement to enter into such Subject Technology Agreement; provided that (A) Voyager has used good faith efforts to negotiate any such Subject Technology Agreement to [\*\*] thereunder and (B) in the event Voyager identifies any Subject Technology that would be necessary or reasonably useful to Exploit a Licensed Product and Voyager is unable to [\*\*] in accordance with the foregoing, Voyager shall notify AbbVie thereof, and the Parties shall discuss in good faith whether the Parties desire to acquire such Subject Technology and, if so, the [\*\*] with respect thereto; and further provided that if the applicable Subject Technology Agreement Covers Virus Capsids (other than a Virus Capsid that is the subject of the [\*\*] as of the Effective Date) (a "Future Capsid Agreement"), [\*\*], in which case it shall not be considered commercially reasonable for Voyager to enter such Future Capsid Agreement and the Parties shall discuss in good faith whether the Parties desire to acquire such Virus Capsid(s) and, if so, the [\*\*] with respect thereto in accordance with the foregoing provisions of this Section 6.2.2(d). The Parties acknowledge that [\*\*] under a Subject Technology Agreement [\*\*] and, in such an event, Voyager shall not be obligated under this Agreement to enter into such Subject Technology Agreement if [\*\*] with respect to such Licensed Product [\*\*]; provided that (x) Voyager has used good faith efforts to negotiate any such Subject Technology Agreement to [\*\*] for such Licensed Product thereunder and (y) in the event Voyager identifies any Subject Technology that would be necessary or reasonably useful to Exploit a Licensed Product and Voyager is unable to [\*\*] in accordance with the foregoing, Voyager shall notify AbbVie thereof, and the Parties shall discuss in good faith whether the Parties desire to acquire such Subject Technology and, if so, [\*\*] with respect thereto; and <u>further provided</u> that, with respect to any Future Capsid Agreement, if [\*\*] with respect to such Licensed Product [\*\*], the Parties agree that it shall be commercially reasonable for Voyager to acquire such Virus Capsid [\*\*] that would result in Voyager

- 6.2.3 Amendments; Breaches; Terminations. After the Effective Date, (a) Voyager shall not enter into any subsequent agreement or understanding with any Third Party to an In-License Agreement that modifies, amends or terminates any such In-License Agreement, or waives any right or obligation thereunder, in any way that would adversely affect in any material respect AbbVie's rights or interests under this Agreement, including by increasing any of AbbVie's obligations, without AbbVie's prior written consent, not to be unreasonably withheld, conditioned or delayed and (b) Voyager shall not, and shall cause its Affiliates not to, commit any acts or permit the occurrence of any omissions that would cause breach or termination of any In-License Agreement. Without limiting the preceding sentence, Voyager shall provide to AbbVie for review, comment and, if applicable, approval a copy of all proposed modifications to, amendments of or waivers with respect to the In-License Agreements, regardless of whether AbbVie's approval is required with respect thereto, reasonably in advance of the execution thereof for AbbVie's review and comment and shall consider in good faith any comments provided by AbbVie.
- 6.3 <u>Sublicensing Rights.</u> AbbVie shall have the right to grant and authorize sublicenses under the rights granted to it under Section 6.1 to any of its Affiliates and Third Parties through multiple tiers (each such Third Party that is not a Distributor, a "<u>Sublicensee</u>"). AbbVie shall provide Voyager with a fully executed copy of any agreement (redacted as necessary to protect confidential or commercially sensitive information that is not necessary for Voyager to determine AbbVie's compliance with this Agreement or for Voyager to comply with the In-License Agreements) reflecting any such sublicense to a Sublicensee promptly after the execution thereof. If AbbVie, any of its Affiliates or any Sublicensee grants a sublicense, the terms and conditions of this Agreement that are applicable to Sublicensees shall apply to such Sublicensee to the same extent as they apply to AbbVie. AbbVie assumes full responsibility, and shall remain primarily responsible, for causing the performance of all obligations of each of its Affiliates and Sublicensees and will itself pay and account to Voyager for all payments due under this Agreement by reason of operation of any such sublicense. Each sublicense must be consistent with, and require the Sublicensee to meet, all applicable obligations and requirements of this Agreement.
- 6.4 <u>Licenses to Voyager</u>. Subject to the terms and conditions of this Agreement, AbbVie hereby grants to Voyager, and Voyager accepts:
- 6.4.1 a non-exclusive, royalty-free, non-transferable (except in accordance with Section 17.3), sublicenseable (only to its permitted subcontractors under Section 9.3) license under the AbbVie Background IP, the AbbVie Designated Antibody IP and AbbVie's interests in the Collaboration IP and Joint IP to Research, Develop, use, Manufacture and have Manufactured (a) the Research Compounds and Research Products during the Voyager Research Period as set forth in the Research Plan, and (b) the Selected Research Compounds and Selected Research Products during the Voyager Development Period as set forth in the Development Plan, in each case ((a) and (b)) in the Field in the Territory in accordance with this Agreement; and

- 6.4.2 subject to Section 6.1.1, Section 6.1.2 and ARTICLE 11, a non-exclusive, perpetual, irrevocable, royalty-free, transferable, sublicenseable (through multiple tiers) license under AbbVie's interests in the Collaboration IP and Joint IP for all purposes.
  - 6.5 [\*\*].
- 6.5.1 Without limiting the representations, warranties and covenants set forth in ARTICLE 14, Voyager acknowledges and agrees that the sublicenses and any other rights granted by AbbVie to Voyager in this Agreement, including with respect to prosecution, enforcement and defense rights as set forth in ARTICLE 12, are subject to the terms of the [\*\*], the scope of the licenses granted to AbbVie or the applicable Affiliate thereunder and the rights granted to or retained by [\*\*] and any other Third Party with rights thereunder. For clarity, any recoveries or amounts to be shared by the Parties as set forth in ARTICLE 12 shall be reduced by any payments with respect to such recoveries that are owed to [\*\*] pursuant to the [\*\*].
- 6.5.2 The Parties shall cooperate with each other in good faith to support each other in complying with AbbVie's obligations under the [\*\*]. Without limitation to the foregoing, (a) the Parties shall, from time to time, upon the reasonable request of either Party, discuss the terms of the [\*\*] and agree upon, to the extent reasonably possible, a consistent interpretation of the terms of the [\*\*] in order to, as fully as possible, allow AbbVie to comply with the terms of the [\*\*] and Voyager to receive its rights and benefits under this Agreement; (b) to the extent there is a conflict between any terms of this Agreement and any terms of the [\*\*], the terms of the [\*\*] shall control with respect to the relevant Know-How, Patent Rights or other rights granted to Voyager hereunder; and (c) although AbbVie is responsible for making certain payments under the [\*\*], Voyager and its Affiliates and (sub)licensees shall comply with any applicable reporting and other requirements under the [\*\*], and the provisions regarding currency conversion, international payments and late payments, and any other relevant definitions and provisions, of the [\*\*] shall apply to the calculation of the payments due under the [\*\*].
- 6.6 <u>No Other Rights</u>. Except as otherwise expressly provided in this Agreement, under no circumstances shall a Party, as a result of this Agreement, obtain any ownership interest, license right or other right in any Know-How, Patent Rights or other intellectual property rights of the other Party or any of its Affiliates, including items owned, controlled, developed or acquired by the other Party or any of its Affiliates, or provided by the other Party to the first Party at any time pursuant to this Agreement.
- 6.7 <u>Confirmatory Patent License</u>. (a) Voyager shall, if requested to do so by AbbVie, promptly enter into confirmatory license agreements in such form as may be reasonably requested by AbbVie for purposes of recording the licenses granted under this Agreement with such patent offices in the Territory as AbbVie considers appropriate, and (b) AbbVie shall, if requested to do so by Voyager, promptly enter into confirmatory license agreements in such form as may be reasonably requested by Voyager for purposes of recording the licenses granted under this Agreement with such patent offices in the Territory or Terminated Territory, as applicable, as Voyager considers appropriate. Until the execution of any such confirmatory licenses, so far as may be legally possible, Voyager and AbbVie shall have the same rights in respect of the Voyager Background Patent Rights,

AbbVie Background Patent Rights, AbbVie Designated Antibody Patent Rights, AbbVie Manufacturing Improvements, Collaboration Patent Rights and Joint Patent Rights, and be under the same obligations to each other with respect thereto, in all respects, to the extent set forth in this Agreement and subject to any conditions on such licenses (including the conditions on such licenses until the exercise of Development Option and the License Option), as if the said confirmatory licenses had been executed.

6.8 <u>Section 365(n) of the Bankruptcy Code</u>. All rights and licenses granted under or pursuant to this Agreement by a Party to the other, including those set forth in Section 6.1 and 6.4, are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code and any foreign counterpart thereto. The Parties acknowledge and agree that only the payments made under Section 10.3 shall constitute royalties within the meaning of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction.

# ARTICLE 7 POST-LICENSE OPTION EXERCISE ACTIVITIES

- 7.1 <u>Transition Plan.</u> On the License Option Effective Date, without additional consideration to Voyager (unless otherwise set forth in this ARTICLE 7) and within [\*\*] after the License Option Effective Date, the Parties shall agree in good faith to a plan ("<u>Transition Plan</u>") to transfer to AbbVie (or its designee) all Development activities relating to Licensed Compound(s) and Licensed Product(s) then being undertaken by Voyager as efficiently as possible; <u>provided</u>, <u>however</u>, that Voyager shall have no obligation to transfer any Development activities to the extent necessary for Voyager to fulfill its obligations under the Development Plan that are in effect after the License Option Effective Date, unless and until AbbVie agrees to assume, or otherwise relieves Voyager of, such obligations in writing or Voyager completes such Development activities. Voyager shall use Commercially Reasonable Efforts to transition all such activities to AbbVie and to do so in accordance with the Transition Plan.
- 7.2 <u>Voyager Transition Obligation Upon License Option Exercise</u>. On the License Option Effective Date, without limiting Section 7.1 and without additional consideration to Voyager (unless otherwise set forth in Section 8.1.2(b)):
- 7.2.1 Upon AbbVie's request, Voyager shall, subject to Section 7.4, assign to AbbVie any agreements (including any agreement with any Third Party manufacturer with respect to a Licensed Compound or Licensed Product) to the extent relating to the Research, Development or Manufacture of any Licensed Compound or Licensed Product to which Voyager or any of its Affiliates is a party; <u>provided</u> that to the extent any Research Compound, Research Product, Selected Research Compound or Selected Research Product is necessary for Voyager to fulfill its obligations under the Research Plan or Development Plan that are in effect after the License Option Effective Date, if such Research Compound, Research Product, Selected

Research Compound or Selected Research Product is supplied under an agreement assigned to AbbVie, AbbVie shall use Commercially Reasonable Efforts to promptly provide to Voyager such quantities of such Research Compound, Research Product, Selected Research Compound or Selected Research Product that are necessary for Voyager to fulfill such obligations, unless and until AbbVie agrees to assume, or otherwise relieves Voyager of, such obligations in writing or Voyager completes such Development activities;

- 7.2.2 Voyager shall transfer to AbbVie (a) copies of all data, reports, records, materials and other information arising out of the Research Program or the Development Program or any Manufacturing activities with respect thereto, including all non-clinical and clinical data relating to any Licensed Compound or Licensed Product, and all adverse event or other safety data resulting from the Research Program or the Development Program as well as any chemistry, manufacturing and controls (CMC) or other Manufacturing data generated in connection with the foregoing, and (b) the image file wrappers (as that term is understood under U.S. law but in no instance more comprehensive than a file wrapper submitted before the USPTO) relating to the prosecution, defense, maintenance, validity and enforceability of the Collaboration Patent Rights and the Joint Patent Rights, but excluding any privileged communications between counsel and Voyager related to such image file wrappers or other documents or materials;
- 7.2.3 Voyager and AbbVie shall duly execute the quality agreement negotiated by the Parties for each Licensed Product pursuant to the Development Plan;
- 7.2.4 Voyager shall provide AbbVie with a written summary of all of its inventory of all Licensed Compound(s) and Licensed Product(s) that were produced in accordance with the Development Plan, and Voyager shall, at AbbVie's election, promptly destroy such inventory or deliver such inventory to AbbVie DPP basis (as defined in Incoterms 2010) at a location designated by AbbVie. Voyager represents and warrants that, at the time of delivery, all clinical supply of Licensed Products (a) will have been Manufactured in accordance with applicable Law, including cGMPs, (b) will not be adulterated or misbranded under the FFDCA and may be introduced into interstate commerce pursuant to the FFDCA, (c) complies with the applicable specifications with respect thereto, and (d) complies with the applicable quality agreement as provided in Section 7.2.3; provided that if any such inventory does not satisfy the conditions set forth in clauses (a) through (d) above, the Parties shall meet and discuss in good faith the disposition of such inventory;
- 7.2.5 Voyager shall and hereby does assign to AbbVie all of its right, title, and interest in and to all Regulatory Filings (including all INDs) relating to any Licensed Product, and Voyager shall deliver such Regulatory Filings (and any documentation or correspondence, including conversation logs, relating to or supporting such Regulatory Filings) to AbbVie within [\*\*] after the License Option Effective Date; except that, to the extent the Voyager Development Period is in effect after the License Option Effective Date, Voyager shall retain its right, title, and interest in and to any INDs solely as necessary to perform its obligations under the Development Plan, in which case (a) Voyager and AbbVie shall retain their respective rights and obligations set forth in Section 9.2.1 with respect to such INDs, (b) Voyager shall and hereby does assign to AbbVie all of its right, title and interest in and to any such IND effective as of the date of delivery of the Final Development Report with respect to the Licensed Product that is the

subject of such IND (or to the extent earlier requested by AbbVie to the extent AbbVie agrees to assume Voyager's regulatory obligations with respect to such IND) and (c) Voyager shall promptly deliver such IND to AbbVie after the delivery of the Final Development Report with respect to the Licensed Product that is the subject of such IND (or such earlier request);

- 7.2.6 without limiting Section 7.2.2(b) and to the extent consistent with AbbVie's first right to Prosecute and Maintain the relevant Patent Rights under ARTICLE 12, Voyager shall assist and cooperate with AbbVie, as AbbVie may reasonably request in the transition of the Prosecution and Maintenance, enforcement and defense of the Collaboration Patent Rights and the Joint Patent Rights from Voyager to AbbVie; and
- 7.2.7 Voyager shall duly execute and deliver or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary under or as AbbVie may reasonably request in connection with or to carry out more effectively the purpose of or to better assure and confirm unto AbbVie its rights to Exploit the Licensed Compounds and Licensed Products in accordance with this Agreement.

#### 7.3 AbbVie Development and Commercialization.

- 7.3.1 <u>AbbVie Responsibilities</u>. From and after the License Option Effective Date, subject to the second sentence of Section 8.2 and any of Voyager's continuing responsibilities pursuant to Section 3.3.3(b), AbbVie shall be solely responsible for all Development, Manufacturing and Commercialization activities in connection with the Licensed Compound(s) and the Licensed Product(s) in the Field in the Territory, which activities shall be conducted in accordance with this Agreement.
- 7.3.2 <u>AbbVie Diligence</u>. From and after the License Option Effective Date, AbbVie shall use Commercially Reasonable Efforts to (a) Develop through to receipt of Regulatory Approval and (b) Commercialize, in each case ((a) and (b)) at least one (1) Licensed Product in each of the United States, Japan and each Major European Market, in each case for so long as such country is in the Territory.
- 7.3.3 <u>AbbVie Reports</u>. From and after the License Option Effective Date, AbbVie shall, within [\*\*] after the end of each Calendar Year, provide the JGC and Voyager with written progress reports on the status of the Development and Commercialization activities with respect to the Licensed Compounds and the Licensed Products in such Calendar Year.
- 7.4 <u>Allocation of Rights with Respect to Transferred Contracts</u>. To the extent that the assignment by Voyager of any agreement pursuant to Section 7.2.1 or Section 8.1.2(b) requires any notice to or consent of the relevant Third Party counterparty to such Agreement, or requires the separation of such agreement into an agreement that is retained by Voyager and an agreement that is assignable to (or entered into by) AbbVie, as applicable (a) Voyager shall use reasonable efforts to give such notice and (b) the Parties will reasonably cooperate to (i) obtain such consent or (ii) at the request and with the reasonable assistance of AbbVie, negotiate such

separation, in each case ((a) and (b)), as soon as practicable; <u>provided</u> that, with respect to any agreement to be assigned by Voyager pursuant to Section 7.2.1 (other than any such agreement that relates to the Manufacture of any Licensed Compound or Licensed Product), neither Voyager nor any of its Affiliates shall be required to make any payments or agree to any material undertakings in connection therewith. Until such notice is given, such consent is obtained or such separation is executed, (x) the Parties will reasonably cooperate to provide to AbbVie the benefits under such agreement to the extent applicable to the rights to be assigned to AbbVie and (y) subject to ARTICLE 15, AbbVie will be responsible for all of the losses, taxes, liabilities or obligations under such agreement to the extent applicable to the benefits provided to AbbVie under such agreement.

# ARTICLE 8 MANUFACTURING

#### 8.1 <u>Manufacturing Responsibilities Prior to License Option Exercise.</u>

8.1.1 <u>AbbVie Designated Antibody.</u> During the Voyager Research Period and the Voyager Development Period, AbbVie shall be solely responsible for (a) providing to Voyager the amino acid sequence for, and (b) the Manufacture and supply to Voyager of, AbbVie Designated Antibodies. AbbVie shall be responsible for establishing and maintaining proper quality assurance and quality control policies and procedures in connection with such Manufacturing activities. AbbVie shall comply, and shall require its Affiliates and Third Party subcontractors to comply, with all applicable Laws, including applicable local health, safety and environmental Laws, in the Manufacture of the AbbVie Designated Antibodies and shall only use Manufacturing facilities (including those of its Affiliates or Third Party subcontractors) that comply with all applicable Laws, including local health, safety and environmental Laws, at the time of such Manufacture. AbbVie shall solely bear all costs and expenses relating to the Manufacturing and supply of the AbbVie Designated Antibodies.

# 8.1.2 <u>Voyager's Responsibility</u>.

- (a) Subject to Section 8.1.1, unless the Parties otherwise agree, during the Voyager Research Period and the Voyager Development Period, Voyager shall Manufacture and supply all pre-clinical requirements of Research Compounds and Research Products and all pre-clinical and clinical requirements of Selected Research Compounds and Selected Research Products (with respect to clinical supply of Selected Research Compounds and Selected Research Products, that comply with the warranty set forth in Section 7.2.4 (other than clause (d) thereof)), and placebos or comparator products with respect thereto, and all components of the foregoing, to the extent necessary to perform its obligations under each of the Research Plan and Development Plan in accordance with the terms hereof and shall generate the necessary chemistry, manufacturing and controls (CMC) data required by applicable Law to be included or referenced in, or otherwise support, an IND with respect to each Selected Research Product.
- (b) Without limiting Section 9.3.2, with respect to any agreement that Voyager enters into with Third Party manufacturer(s) to supply Research Compounds, Research Products, Selected Research Compounds or Selected Research Products, (i) to the extent such

Agreement solely applies to the Research Period, Voyager shall use reasonable efforts to ensure, and (ii) to the extent such agreement applies to the Development Period or any period thereafter or to any Selected Research Compound or Selected Research Product, Voyager shall ensure, in each case (i) and (ii) that such agreement provides that (A) Voyager may freely assign such agreement to AbbVie upon the License Option Effective Date without further consideration, (B) Voyager may freely source supply of such Research Compounds (including Selected Research Compounds) or Research Products (including Selected Research Products) and the components of each of the foregoing from other suppliers in its sole discretion, and (C) upon request by AbbVie and at AbbVie's cost and expense, such Third Party manufacturer shall provide AbbVie with all reasonable assistance required in order to transfer to AbbVie any Manufacturing Process or related technology used in the Manufacture of such Research Compounds (including Selected Research Compounds) or Research Products (including Selected Research Products), including all materials, data, methods, processes, documentation and other Know-How related thereto.

- 8.2 <u>Manufacturing After License Option Exercise</u>. From and after the License Option Effective Date, AbbVie shall have the right to Manufacture the Licensed Compounds and Licensed Products in connection with AbbVie's Development and Commercialization activities hereunder. Upon written request by AbbVie to Voyager, the Parties shall negotiate in good faith either or both a clinical supply agreement or a commercial supply agreement for Voyager to supply AbbVie with any Licensed Compound or Licensed Product at a price not to exceed Voyager's fully burdened manufacturing cost plus [\*\*] percent ([\*\*]%). The Parties may also determine at the time to form a Working Group to address the Manufacturing activities to be conducted by or on behalf of each Party.
- Manufacturing Technology Transfer and Continued Improvement. Upon AbbVie's request after the License Option Effective Date, Voyager, at its sole cost and expense, shall (a) (i) promptly effect a full transfer to AbbVie or its designee (which designee may be an Affiliate or a Third Party manufacturer) of all Know-How relating to the processes for the Manufacture of each Licensed Product, including each Licensed Compound, that have been used by or on behalf of Voyager to Manufacture Selected Research Products, including Selected Research Compounds, for the Development Program and (ii) use Diligent Efforts to promptly effect a full transfer to AbbVie or its designee (which designee may be an Affiliate or a Third Party manufacturer) of all Know-How relating to any other Manufacturing process generated under or in connection with a Plan (each of the processes described in clause (i) and (ii), a "Manufacturing Process" and all such Know-How, "Manufacturing Process Know-How") and (b) provide reasonable assistance to AbbVie in implementing each Manufacturing Process at facilities designated by AbbVie (such transfer and implementation, as more fully described in this Section 8.3, the "Manufacturing Technology Transfer"), subject to AbbVie maintaining the confidentiality of any portion of the Manufacturing Process that Voyager deems to be a trade secret in accordance with ARTICLE 13. Voyager shall provide, shall cause its Affiliates to provide, and shall assist AbbVie in having Third Party manufacturers provide, all reasonable assistance requested by AbbVie to enable AbbVie (or its Affiliate or designated Third Party manufacturer, as applicable) to implement each Manufacturing Process at the facilities designated by AbbVie. If requested by AbbVie, such assistance shall include facilitating the entering into of agreements with applicable Third Party suppliers relating to the Licensed

Products, but Voyager does not guarantee that any such supplier shall enter into any such agreement. Without limitation of the foregoing, in connection with the Manufacturing Technology Transfer:

- 8.3.1 Voyager shall, and shall cause its Affiliates to, make available, and shall assist AbbVie in having Third Party manufacturers make available, to AbbVie (or its Affiliate or designated Third Party manufacturer, as applicable) from time to time as AbbVie may request, all Manufacturing Process Know-How and materials that have been used in, or generated under or in connection with, any Manufacturing Process, including such methods, processes and testing/characterization information, and all documentation constituting material support, performance advice, shop practice, standard operating procedures, specifications as to materials to be used and control methods, that are reasonably necessary or useful to enable AbbVie (or its Affiliate or designated Third Party manufacturer, as applicable) to use and practice any such Manufacturing Process;
- 8.3.2 Voyager shall assign to AbbVie all of its right, title and interest in and to, and shall deliver to AbbVie, all cell banks, including any uninfected working insect cell banks, all baculovirus infected insect cells expressing the transgene and baculovirus infected insect cells expressing the capsid, used or developed by or on behalf of Voyager or any of its Affiliates or Third Party manufacturers to Manufacture the Licensed Products or Licensed Compounds. Voyager shall maintain the master uninfected cell bank for each working cell bank delivered to AbbVie and, if any such working cell bank becomes contaminated or is no longer useable to Manufacture the Licensed Products or Licensed Compounds, then, upon AbbVie's reasonable request, Voyager shall provide replacement working cell banks using the applicable master uninfected cell bank, and AbbVie shall reimburse Voyager for the reasonable FTE Costs and Out-of-Pocket Costs incurred by Voyager in connection therewith;
- 8.3.3 Voyager shall cause all appropriate employees and consultants of Voyager and its Affiliates, and shall assist AbbVie in seeking to cause Voyager's Third Party manufacturers, to meet with employees or representatives of AbbVie (or its Affiliate or designated Third Party manufacturer, as applicable) at the applicable manufacturing facility at mutually convenient times to assist with the working up and use of each Manufacturing Process and with the training of the personnel of AbbVie (or its Affiliate or designated Third Party manufacturer, as applicable) to the extent reasonably necessary or useful to enable AbbVie (or its Affiliate or designated Third Party manufacturer, as applicable) to use and practice such Manufacturing Process;
- 8.3.4 Without limiting the generality of Section 8.3.3, Voyager shall cause all appropriate analytical and quality control laboratory employees and consultants of Voyager and its Affiliates as reasonably requested by AbbVie, and shall reasonably assist AbbVie in seeking to cause all appropriate analytical and quality control laboratory employees and consultants of Voyager's Third Party manufacturers, to meet with employees or representatives of AbbVie (or its Affiliate or designated Third Party manufacturer, as applicable) at the applicable manufacturing facility and make available all necessary equipment, at mutually convenient times reasonably agreed by the Parties, to support and execute the transfer of all applicable analytical methods and the validation thereof (including all Manufacturing Process Know-How, methods,

validation documents and other documentation, materials and sufficient supplies of all primary and other reference standards) relevant to each Manufacturing Process;

- 8.3.5 Voyager shall, and shall cause its Affiliates to, take such steps, and shall assist AbbVie in seeking to cause its Third Party manufacturers to take such steps, as are reasonably necessary or useful to assist AbbVie (or its Affiliate or designated Third Party manufacturer, as applicable) in obtaining any necessary licenses, permits or approvals from Regulatory Authorities with respect to each Manufacturing Process at the applicable facilities;
- 8.3.6 Voyager shall, and shall cause its Affiliates to, provide, and shall assist AbbVie in seeking to cause its Third Party manufacturers to provide, such other assistance as AbbVie (or its Affiliate or designated Third Party manufacturer, as applicable) may reasonably request to enable AbbVie (or its Affiliate or designated Third Party manufacturer, as applicable) to use and practice each Manufacturing Process and Voyager shall provide reasonable assistance to AbbVie (or its Affiliate or designated Third Party manufacturer, as applicable) otherwise to Manufacture the Licensed Products and the Licensed Compounds;
- 8.3.7 The Parties shall reasonably coordinate the activities with respect to the Manufacturing Technology Transfer to not unreasonably interfere with other activities of either Party. Voyager's obligation to pay the costs and expenses associated with the transfer of each Manufacturing Process as set forth in this Section 8.3 is limited to the transfer to a single facility designated by AbbVie (which facility may differ for each Manufacturing Process, if necessary) and to the extent AbbVie designates additional facilities with respect to a single Manufacturing Process, AbbVie shall reimburse Voyager for the reasonable FTE Costs and Out-of-Pocket Costs incurred by Voyager with respect to the transfer to such additional facilities. Subject to Voyager's performance of its obligations set forth in this Section 8.3, Voyager provides no representation, warranty or guarantee that the Manufacturing Technology Transfer will be successful or that AbbVie will be capable of Manufacturing or having Manufactured any Research Compound or Research Product;
- 8.3.8 Voyager shall promptly disclose to AbbVie (a) all modifications, enhancements and improvements to each Manufacturing Process transferred to AbbVie pursuant to this Section 8.3 and (b) any other Manufacturing process, in each case ((a) and (b)) conceived, discovered, developed or otherwise made or acquired (whether by license, option, acquisition or otherwise) or otherwise Controlled by or on behalf of Voyager or any of its Affiliates that is necessary or reasonably useful to Manufacture the Licensed Products ((a) and (b) together with the Patent Rights Covering the foregoing, "Voyager Manufacturing Improvements"). At AbbVie's request, Voyager shall provide AbbVie with reasonable assistance to enable AbbVie (or its Affiliate or designated Third Party manufacturer, as applicable) to implement such modifications, enhancements and improvements, and AbbVie shall reimburse Voyager for the reasonable FTE Costs and Out-of-Pocket Costs incurred by Voyager with respect to such assistance; and
- 8.3.9 At AbbVie's request, Voyager shall provide AbbVie with reasonable assistance to scale-up any Manufacturing Process for a Selected Research Product in order to produce sufficient quantities of such Selected Research Product for Phase 2 Clinical Trials, Phase 3 Clinical Trials or Commercialization, and AbbVie shall reimburse Voyager for the

reasonable FTE Costs and Out-of-Pocket Costs incurred by Voyager with respect to such assistance.

Notwithstanding anything to the contrary in this Agreement, (a) Voyager shall have no obligations to transfer to AbbVie any Know-How related to Manufacturing until after the License Option Effective Date and then only in accordance with this Section 8.3, (b) Voyager shall not, without AbbVie's prior written consent, perform any of its obligations set forth in this Agreement (including any obligation to develop a Manufacturing Process under a Plan) under or in connection with the [\*\*], unless and until [\*\*] (as such term is defined in the [\*\*]) that relate to Vectorization Technology, including the method of making any compound or product owned or in-licensed by Voyager, (c) Voyager represents and warrants that, as of the Effective Date, no Patent Rights, materials, Know-How or other intellectual property rights have been created or conceived under or in connection with the [\*\*] that are necessary or reasonably useful to conduct the Research Program or the Development Program or that would reasonably be expected to be necessary or useful to Exploit any Research Compounds, Research Products, Selected Research Compounds, Selected Research Products, Licensed Compounds or Licensed Products and (d) Voyager shall not use or incorporate any [\*\*] or [\*\*] (as each such term is defined in the [\*\*]) (or any invention Covered by either of the foregoing) in the Research Program or the Development Program or any Research Compound, Research Product, Selected Research Compound, Selected Research Product, Licensed Compound or Licensed Product unless and until Voyager obtains the right to grant AbbVie a sublicense under such Institution Patent Right or Joint Patent Right, as applicable.

#### 8.4 <u>AbbVie Manufacturing Improvements</u>.

8.4.1 Subject to Section 6.1.1, Section 8.4.2 and Section 8.4.3, AbbVie hereby grants to Voyager a non-exclusive, perpetual, irrevocable, royalty-free, transferable, non-sublicenseable (except in accordance with the following proviso) license under all modifications, enhancements and improvements to the Manufacturing Process(es) made under this Agreement during the Term and any Patent Rights that claim any such modifications, enhancements or improvements to the extent such modifications, enhancements, improvements or Patent Rights, as applicable, are Controlled by AbbVie (collectively, "AbbVie Manufacturing Improvements") for all Manufacturing purposes other than Manufacturing any Licensed Compound, Licensed Product or, to the extent that Voyager is subject to Section 11.1, Section 11.2 or Section 11.3, Vectorized Alpha-Synuclein Antibody; provided, however, that Voyager shall not practice or use any AbbVie Manufacturing Improvements for the benefit of any Affiliate or Third Party, or grant any Affiliate or Third Party a sublicense under any AbbVie Manufacturing Improvements, in either case, unless Voyager has the right to grant AbbVie a (sub)license (with the right to sublicense through multiple tiers) with respect to all modifications, enhancements and improvements to the Manufacturing Process(es) or other Manufacturing process with respect to Vectorization Technology transferred by Voyager to such Affiliate or Third Party conceived, discovered, developed or otherwise made or acquired (whether by license, option, acquisition or otherwise) or otherwise controlled by such Affiliate or Third Party, as applicable.

8.4.2 To the extent that any AbbVie Manufacturing Improvement is in-licensed by AbbVie or any of its Affiliates, (a) AbbVie shall provide a copy of the relevant in-license

agreement to Voyager, and any license to Voyager under such AbbVie Manufacturing Improvements pursuant to Section 8.4.1 shall be subject to the terms and conditions of such in-license, (b) Voyager shall (i) make any payments (including royalties, milestones, and other amounts) payable by AbbVie to Third Parties under any Third Party agreements with respect to the AbbVie Manufacturing Improvements that are the subject of the license granted by AbbVie to Voyager pursuant to Section 8.4.1, by making such payments directly to AbbVie and, in each instance, Voyager shall make the requisite payments to AbbVie and provide the necessary reporting information to AbbVie in sufficient time to enable AbbVie to comply with its obligations under such Third Party agreements and (ii) not, and shall cause its Affiliates and (sub)licensees not to, take or fail to take any action if doing so (or not doing so) would cause AbbVie to be in breach of any such Third Party agreement and (c) AbbVie shall be responsible for paying or providing to any such Third Party any payments or reports made or provided by Voyager under this Section 8.4.2.

8.4.3 Voyager may terminate its license under all or any portion of any AbbVie Manufacturing Improvements at any time by providing written notice to AbbVie and upon AbbVie's receipt of such notice the applicable Know-How or Patent Rights shall be excluded from AbbVie Manufacturing Improvements and from the licenses granted to Voyager pursuant to Section 8.4.1.

# ARTICLE 9 GENERAL PROVISIONS RELATING TO ACTIVITIES

9.1 <u>Compliance</u>. All Research, Development, Manufacturing and Commercialization activities to be conducted by a Party under this Agreement shall be conducted in compliance with applicable Laws, including all applicable cGMP requirements, good laboratory practice requirements and good clinical practice requirements.

#### 9.2 <u>Regulatory Activities</u>.

#### 9.2.1 INDs and Related Communications.

- (a) Prior to the License Option Effective Date (or after the License Option Effective Date, to the extent the Voyager Development Period is in effect, unless and until AbbVie agrees to assume, or otherwise relieves Voyager of, the regulatory obligations set forth in this Section 9.2.1 in writing or Voyager completes such regulatory obligations), Voyager shall have the sole right and responsibility to prepare, obtain and maintain all INDs necessary to perform its obligations under the Development Plan, and to conduct communications with the applicable Regulatory Authorities with respect to such INDs; provided that the form and content of all such INDs (including any material amendments and supplements thereto) and communications shall be subject to the review and approval of AbbVie prior to their submission to the applicable Regulatory Authorities, such approval not to be unreasonably withheld, conditioned or delayed.
- (b) Except as provided in Section 9.2.1(c), Voyager shall provide access to drafts of such INDs and communications to AbbVie via the access methods (such as

secure databases) mutually agreed by the Parties, for AbbVie's review and comment at least [\*\*] (or, with respect to Voyager's final draft of any IND, at least [\*\*] and with respect to such communications, such shorter period of time as is necessary under the circumstances but in no event less than [\*\*] (or with respect to any such communication concerning a serious adverse event, no less than [\*\*])) prior to submission of such IND or communication to the applicable Regulatory Authority. Voyager shall, and shall cause its Affiliates to, reasonably incorporate any comments of AbbVie (and after the License Option Effective Date, shall incorporate any such comments of AbbVie) into such INDs and communications if received by Voyager within [\*\*] (or, with respect to the final draft of any IND, [\*\*] and with respect to such communications, such shorter period of time as is necessary under the circumstances but in no event less than [\*\*] (or with respect to any such communication concerning a serious adverse event, no less than [\*\*])) after Voyager has provided access to AbbVie.

(c) Notwithstanding the foregoing, with respect to material amendments and material supplements to such INDs, Voyager shall provide access to drafts of any such material amendment or material supplement to AbbVie via the access methods (such as secure databases) mutually agreed by the Parties, for AbbVie's review and comment at least [\*\*] prior to submission. Voyager shall, and shall cause its Affiliates to, reasonably incorporate any comments of AbbVie (and after the License Option Effective Date, shall incorporate any such comments of AbbVie) into such material amendments and material supplements if received by Voyager within [\*\*] after Voyager has provided access to AbbVie. With respect to immaterial amendments and immaterial supplements to such INDs, AbbVie shall not have the right to review and approve any such immaterial amendment or immaterial supplement (*e.g.*, an amendment to provide additional information about an investigator). Voyager shall provide copies of any immaterial amendments or immaterial supplements to such INDs to AbbVie contemporaneously with filing.

For clarity, this Section 9.2.1 shall not in any way prohibit Voyager from complying with its reporting requirements pursuant to applicable Law, including with respect to adverse event reporting.

- 9.2.2 Voyager shall provide AbbVie with prior written notice, to the extent Voyager has advance knowledge, of any scheduled meeting, conference, or discussion (including any advisory committee meeting) with a Regulatory Authority in the Territory relating to a Selected Research Product, within [\*\*] after Voyager or its Affiliate first receives notice of the scheduling of such meeting, conference, or discussion (or within such shorter period as may be necessary in order to give AbbVie a reasonable opportunity to attend such meeting, conference, or discussion). AbbVie shall have the right to have one (1) or, to the extent reasonable, more of its employees or agents attend and participate in all such meetings, conferences, and discussions.
- 9.2.3 From and after the License Option Effective Date, AbbVie shall, as between the Parties, have the sole right to prepare, obtain and maintain all INDs (except to the extent the Voyager Development Period is in effect after the License Option Effective Date, in which case Voyager and AbbVie shall retain their respective rights and obligations set forth in Section 9.2.1 with respect to such INDs, unless and until AbbVie agrees to assume, or otherwise relieves Voyager of, the regulatory obligations set forth in Section 9.2.1 in writing or Voyager completes such regulatory obligations), Regulatory Approval Applications (including the setting

of the overall regulatory strategy therefor), other Regulatory Approvals, Pricing Approvals and other submissions and to conduct communications with the Regulatory Authorities and Governmental Authorities in the Territory for the Licensed Products. Voyager shall, at AbbVie's request, support AbbVie, as may be reasonably necessary, in obtaining Regulatory Approvals and Pricing Approvals for the Licensed Products and in the activities in support thereof, including providing all documents or other materials in the possession or control of Voyager or any of its Affiliates as may be necessary or reasonably useful for AbbVie or any of its Affiliates or its or their Sublicensees to obtain Regulatory Approvals or Pricing Approvals for the Licensed Products; provided that (a) Voyager shall provide up to [\*\*] FTE-hours of such support per Calendar Year at its cost and (b) unless otherwise agreed to by the Parties, Voyager shall not be required to provide more than [\*\*] FTE-hours of such support per Calendar Year.

9.2.4 From and after the License Option Effective Date, all Regulatory Filings (including all Regulatory Approvals) and Pricing Approvals in the Territory with respect to the Licensed Products shall be owned by, and shall be the sole property and held in the name of, AbbVie or its designated Affiliate, Sublicensee or designee, except as otherwise provided in Section 7.2.5.

# 9.3 Subcontracting.

- 9.3.1 Subject to Section 14.3.1, AbbVie shall have the right to engage Affiliates or Third Party subcontractors (including by appointing one (1) or more contract sales forces, co-promotion partners or Distributors) to perform any of its Development, Manufacturing or Commercialization activities under this Agreement.
- 9.3.2 Subject to Section 14.3.1, Voyager shall have the right to subcontract its Research, Development and Manufacturing activities under this Agreement to any Affiliate or Third Party subcontractor to the extent expressly provided for in a Plan or with the approval of AbbVie, not to be unreasonably withheld, conditioned or delayed; <u>provided</u> that approval of AbbVie is not needed for any subcontracting to an Affiliate of Voyager existing as of the Effective Date or to any of the subcontractors set forth on <u>Schedule 9.3.2</u>.
- 9.3.3 Any Affiliate or Third Party subcontractor to be engaged by a Party to perform a Party's obligations set forth in this Agreement shall meet the qualifications typically required by such Party for the performance of work similar in scope and complexity to the subcontracted activity. Any Party engaging an Affiliate or Third Party subcontractor hereunder shall remain principally responsible and obligated for such activities.
- 9.4 Records and Audits. Each Party shall, and shall require its Affiliates and shall use commercially reasonable efforts to require its permitted subcontractors to, maintain materially complete, current and accurate hard or electronic (as applicable) copies of records of all work conducted pursuant to its Research, Development, Manufacturing and Commercialization activities under this Agreement, and all results, data, developments and Know-How made in conducting such activities. Such records shall accurately reflect all such work done and results achieved in sufficient detail to verify compliance with its obligations under this Agreement and shall be in good scientific manner appropriate for applicable patent and regulatory purposes. With respect to Voyager and its

Affiliates, Voyager shall ensure, and with respect to permitted subcontractors, Voyager shall use commercially reasonable efforts to ensure, that physical embodiments of data from activities under this Agreement (e.g., laboratory notebooks) record only Research and Development activities performed pursuant to this Agreement and not include or be commingled with records of activities outside the scope of this Agreement. AbbVie shall have the right, during normal business hours and upon reasonable notice but not more frequently than [\*\*], to inspect all records of Voyager maintained pursuant to this Section 9.4; provided that AbbVie shall maintain any Voyager Confidential Information in such records in confidence in accordance with ARTICLE 13.

# ARTICLE 10 INITIAL FEE; MILESTONES AND ROYALTIES; PAYMENTS

- 10.1 <u>Upfront Fee</u>. In consideration for the Development Option granted to AbbVie hereunder, AbbVie shall pay Voyager a one-time, non-refundable, non-creditable upfront payment of Sixty-Five Million Dollars (\$65,000,0000) (the "<u>Initial Fee</u>") within fifteen (15) Business Days after the Effective Date.
- Milestone Payments. In partial consideration for the rights and licenses granted to AbbVie hereunder, with respect to each Licensed Compound, except as otherwise provided in (a) Section 10.2.1(c), (b) Section 10.2.1(a) with respect to the Milestone Event set forth in Section 10.2.1(a)(i) and (c) Section 10.2.2(c), and subject to Section 16.5.1, within [\*\*] after the first achievement during the Term of a milestone event (each, a "Milestone Event") set forth below by or on behalf of AbbVie, any of its Affiliates or any Sublicensee with respect to a Licensed Product that contains or is comprised of such Licensed Compound, AbbVie shall make a one-time, non-refundable and non-creditable milestone payment to Voyager in the amount below corresponding to such Milestone Event (each in Section 10.2.1 and Section 10.2.2, a "Regulatory Milestone Payment", and in Section 10.2.3, a "Commercial Milestone Payment", and collectively, "Milestone Payments").
- 10.2.1 <u>Regulatory Milestone Payments for Each Licensed Compound for a Parkinson's Disease Indication.</u>

# (a) <u>Regulatory Milestone Payments</u>.

| Milestone Event   | Regulatory Milestone Payment |
|---|------------------------------|
| (i) [**] (There are no Regulatory Milestone Payments payable with respect to this Milestone Event with respect to any additional Licensed Compounds or Licensed Products) | [**]                         |

| Milestone Event | Regulatory Milestone Payment |
|-----------------|------------------------------|
| (ii) [**]       | [**]                         |
| (iii) [**]      | [**]                         |
| (iv) [**]       | [**]                         |
| (v) [**]        | [**]                         |

The Milestone Payment in Section 10.2.1(a)(i) is payable only once. Each other Regulatory Milestone Payment set forth in Section 10.2.1(a) is payable only once for each Licensed Compound. Only one Regulatory Milestone Payment is payable for each Milestone Event for a Licensed Compound, even if multiple Licensed Products that contain or are comprised of such Licensed Compound achieve such Milestone Event. Only one Milestone Payment is payable for each Milestone Event for a Licensed Product, irrespective of the number of Licensed Compounds contained by such Licensed Product. By way of example and not limitation, if a Licensed Product containing or comprised of Licensed Compound x achieves the Milestone Event in Section 10.2.1(a)(ii), then no additional Milestone Payment shall be due if a different Licensed Product containing or comprised of Licensed Compound x achieves such Milestone Event.

(b) <u>Skipped Milestones</u>. In the event that the Milestone Event in Section 10.2.1(a)(ii) is first achieved prior to the Milestone Event in Section 10.2.1(a)(i) with respect to any Licensed Compound, then the Milestone Payment for Section 10.2.1(a)(i) shall not be paid for the first Regulatory Milestone Payment associated with the achievement of the Milestone Event in Section 10.2.1(a)(ii) and no further Regulatory Milestone Payments shall be due for any achievement of the Milestone Event in Section 10.2.1(a)(i). On a Licensed Compound-by-Licensed Compound basis, in the event that a Milestone Event in Section 10.2.1(a)(iii), Section 10.2.1(a)(iv) or Section 10.2.1(a)(v) is achieved with respect to a Licensed Product containing or comprised of a Licensed Compound prior to the Milestone Event in Section 10.2.1(a)(ii) with respect to a Licensed Product containing or comprised of such Licensed Compound, then the Regulatory Milestone Payment associated with such achieved

Milestone Event and the Regulatory Milestone Payment associated with the Milestone Event in Section 10.2.1(a)(ii) shall be paid concurrently for such Licensed Compound.

(c) <u>Failed Product</u>. If a Regulatory Milestone Payment under Section 10.2.1(a) is made for the achievement of a Milestone Event in a Parkinson's Disease Indication by a Licensed Product containing or comprised of a particular Licensed Compound, and, thereafter, the Development and Commercialization of such Licensed Compound (and all Licensed Products containing or comprised of such Licensed Compound) ceases, then the Regulatory Milestone Payment with respect to such Milestone Event shall not be paid again the next time a Licensed Product containing or comprised of a different Licensed Compound achieves such Milestone Event for a Parkinson's Disease Indication; <u>provided</u> that if AbbVie or any of its Affiliates or Sublicensees reinitiates the Development or Commercialization of any Licensed Product containing or comprised of such first Licensed Compound, then such unpaid Regulatory Milestone Payment shall be paid within [\*\*] if the next Milestone Event occurs for such reinitiated Licensed Product.

10.2.2 <u>Regulatory Milestone Payments for Each Licensed Compound in a Non-Parkinson's Disease Indication</u>. As used herein, a "<u>Non-Parkinson's Disease Indication</u>" is an Indication other than a Parkinson's Disease Indication.

#### (a) Regulatory Milestone Payments.

| Milestone Event | Regulatory Milestone Payment |
|-----------------|------------------------------|
| (i) [**]        | [**]                         |
| (ii) [**]       | [**]                         |
| (iii) [**]      | [**]                         |
| (iv) [**]       | [**]                         |
| (v) [**]        | [**]                         |

| Milestone Event | Regulatory Milestone Payment |
|-----------------|------------------------------|
| (vi) [**]       | [**]                         |
| (vii) [**]      | [**]                         |
| (viii) [**]     | [**]                         |

Each Regulatory Milestone Payment set forth in Section 10.2.2(a) is payable only once for each Licensed Compound (e.g., if a [\*\*]). Only one Regulatory Milestone Payment is payable for each Milestone Event for a Licensed Compound, even if multiple Licensed Products that contain or are comprised of such Licensed Compound achieve such Milestone Event. Only one Milestone Payment is payable for each Milestone Event for a Licensed Product, irrespective of the number of Licensed Compounds contained by such Licensed Product. By way of example and not limitation, if a Licensed Product containing or comprised of Licensed Compound x achieves the Milestone Event in Section 10.2.2(a)(ii), then no additional Milestone Payment shall be due if a different Licensed Product containing or comprised of Licensed Compound x achieves such Milestone Event.

(b) <u>Skipped Milestones</u>. On a Licensed Compound-by-Licensed Compound basis, (i) if a Milestone Event in Section 10.2.2(a)(iii), Section 10.2.2(a)(v) or Section 10.2.2(a)(vii) is achieved with respect to a Licensed Product that contains or is comprised of a Licensed Compound prior to the Milestone Event in Section 10.2.2(a)(i) with respect to a Licensed Product that contains or is comprised of such Licensed Compound, then the Regulatory Milestone Payment associated with such achieved Milestone Event and the Regulatory Milestone Payment associated with the Milestone Event in Section 10.2.2(a)(i) shall be paid concurrently for such Licensed Compound, and (ii) if a Milestone Event in Section 10.2.2(a)(iv), Section 10.2.2(a)(vi) or Section 10.2.2(a)(viii) is achieved with respect to a Licensed Product containing or comprised of a Licensed Compound prior to the Milestone Event in Section 10.2.2(a)(ii) with respect to a Licensed Product containing or comprised of such Licensed Compound, then the Regulatory Milestone Payment associated with such achieved Milestone Event and the Regulatory Milestone Payment associated with the Milestone Event in Section 10.2.2(a)(ii) shall be paid concurrently for such Licensed Compound.

(c) <u>Failed Product</u>. If a Regulatory Milestone Payment under Section 10.2.2(a) is made for the achievement of a Milestone Event in a particular Non-Parkinson's Disease Indication by a Licensed Product containing or comprised of a particular Licensed

Compound, and, thereafter, the Development and Commercialization of such Licensed Compound (and all Licensed Products containing or comprised of such Licensed Compound) ceases, then the Regulatory Milestone Payment with respect to such Milestone Event shall not be paid again the next time a Licensed Product containing or comprised of a different Licensed Compound achieves such Milestone Event for the same Non-Parkinson's Disease Indication; provided that if AbbVie or any of its Affiliates or Sublicensees reinitiates the Development or Commercialization of any Licensed Product containing or comprised of such first Licensed Compound, then such unpaid Regulatory Milestone Payment shall be paid within [\*\*] if the next Milestone Event occurs for such reinitiated Licensed Product.

#### 10.2.3 Commercial Milestones for Licensed Products for all Indications.

| Milestone Event   | Commercial Milestone<br>Payment                 |
|---|---|
| (a) Aggregate Territory-wide Annual Net Sales of all Licensed Products for all Indications greater than or equal to [**] Dollars (\$[**]) | [**] Dollars (\$[**])                           |
| (b) Aggregate Territory-wide Annual Net Sales of all Licensed Products for all Indications greater than or equal to [**] Dollars (\$[**]) | [**] Dollars (\$[**])                           |
| (c) Aggregate Territory-wide Annual Net Sales of all Licensed Products for all Indications greater than or equal to [**] Dollars (\$[**]) | [**] Dollars (\$[**])                           |
| (d) Aggregate Territory-wide Annual Net Sales of all Licensed Products for all Indications greater than or equal to [**] Dollars (\$[**]) | [**] Dollars (\$[**])                           |
| Total for all Licensed Products   | Five Hundred Million<br>Dollars (\$500,000,000) |

Each Commercial Milestone Payment set forth in Section 10.2.3 is payable only once.

10.2.4 <u>Milestone Achievement and Notice</u>. Subject to Section 16.5.1, each Milestone Payment shall be deemed earned as of the achievement of the corresponding Milestone Event. AbbVie shall promptly notify Voyager in writing in the event that any Milestone Event has been achieved.

#### 10.3 Royalties.

10.3.1 In further consideration of the licenses and other rights granted to AbbVie, with respect to each Licensed Compound, AbbVie shall pay to Voyager a royalty on Annual Net Sales of Licensed Products that contain or are comprised of such Licensed Compound at the following rates:

| Annual Net Sales of all Licensed Products that contain or are comprised of such Licensed Compound  | Royalty Rate         |
|--|----------------------|
| (a) For that portion of Annual Net Sales with respect to such Licensed Compound less than [**] Dollars (\$[**])  | [**] Percent ([**]%) |
| (b) For that portion of Annual Net Sales with respect to such Licensed Compound greater than or equal to [**] Dollars (\$[**]) and less than [**] Dollars (\$[**]) | [**] Percent ([**]%) |
| (c) For that portion of Annual Net Sales with respect to such Licensed Compound greater than or equal to [**] Dollars (\$[**])                                     | [**] Percent ([**]%) |

10.3.2 <u>Calculation of Royalties</u>. With respect to each Licensed Compound, royalties on Annual Net Sales shall be paid at the rate applicable to the portion of Net Sales of Licensed Products containing or comprised of such Licensed Compound within each of the Net Sales tiers during such Calendar Year; <u>provided</u> that if a Licensed Product contains or is comprised of more than one (1) Licensed Compound, then royalties shall only be payable once with respect to such Licensed Product. For example, if, during a Calendar Year, Annual Net Sales of a Licensed Product are equal to \$[\*\*] then the royalties payable by AbbVie with respect to such Licensed Product would be calculated by adding [\*\*].

Royalty Term. On a country-by-country and Licensed Product-by-Licensed Product basis, royalty payments in the Territory shall commence upon the First Commercial Sale of such Licensed Product in such country and shall terminate upon the end of the Term or, if earlier, the later of: (a) subject to the last sentence of Section 12.2.2(b), the expiration, invalidation or abandonment date of the last Voyager Background Patent Rights, AbbVie Designated Antibody Patent Rights, Joint Patent Rights and Collaboration Patent Rights in such country that includes a Valid Claim that claims (i) the composition of matter of such Licensed Product or (ii) (A) a method of treatment or other therapeutic use of such Licensed Product for any Indication for which Regulatory Approval has been received for such Licensed Product in such country or (B) a method of making such Licensed Product that claims the Manufacturing Process or any other process provided by Voyager in accordance with Section 8.3 that is used in the Manufacture of such Licensed Product for commercial sales, in either case ((A) or (B)), only for so long as no Biosimilar Product for such Licensed Product has launched in such country; (b) ten (10) years from First Commercial Sale of such Licensed Product in such country; and (c) expiration of Regulatory Exclusivity for such Licensed Product in such country (the applicable "Royalty Term").

- 10.5 <u>Royalty Adjustments</u>. Notwithstanding Section 10.3.1, but subject to Section 10.5.4 and the last sentence of Section 12.2.2(b):
- 10.5.1 <u>Valid Claim Expiration</u>. From and after the date on which a Licensed Product is sold in a particular country and during the applicable Royalty Term is not Covered by a Valid Claim of Voyager Background Patent Rights, AbbVie Designated Antibody Patent Rights, Joint Patent Rights or Collaboration Patent Rights that claims (a) the composition of matter of such Licensed Product in such country or (b)(i) a method of treatment or other therapeutic use of such Licensed Product for any Indication for which Regulatory Approval has been received for such Licensed Product in such country or (ii) a method of making such Licensed Product that claims the Manufacturing Process or any other process provided by Voyager in accordance with Section 8.3 that is used in the Manufacture of such Licensed Product for commercial sales, in either case ((i) or (ii)), only for so long as no Biosimilar Product for such Licensed Product has launched in such country, then the royalty rate for such Licensed Product with respect to such country shall be reduced by [\*\*] percent ([\*\*]%) from the applicable rate(s) set forth in Section 10.3.1 (as adjusted by Section 10.5.3).
- 10.5.2 <u>Biosimilar Products</u>. If, in any country in the Territory during the Royalty Term in such country for a Licensed Product, a Biosimilar Product with respect to such Licensed Product is launched in such country, then, starting with any Calendar Quarter in which the Net Sales of such Licensed Product in such country is at least [\*\*] percent ([\*\*]%) less than the Net Sales of such Licensed Product in such country in the last full Calendar Quarter immediately prior to such Biosimilar Product's launch in such country, the royalty rate for such Licensed Product with respect to such country shall thereafter be reduced by [\*\*] percent ([\*\*]%) from the applicable rate(s) set forth in Section 10.3.1 (as adjusted by Section 10.5.3).
- 10.5.3 Stacking. If AbbVie or any of its Affiliates determines in good faith that, in order to avoid infringement or misappropriation of any Third Party Right, it is reasonably necessary or reasonably useful to obtain a license from a Third Party in order for AbbVie, its Affiliates and Sublicensees to Exploit a Licensed Product in the Field in a country in the Territory, and AbbVie or any of its Affiliates actually enters into any such license after the License Option Effective Date, AbbVie shall be entitled to deduct from any of AbbVie's royalty payments under Section 10.3 for such Licensed Product in such country in a Calendar Quarter [\*\*] percent ([\*\*]%) of the royalties, milestones and other license fees actually paid by AbbVie or any of its Affiliates to such Third Party with respect to such license ("Third Party Payments") to the extent applicable to such Licensed Product in such country during such Calendar Quarter; provided, however, that (a) AbbVie shall be entitled to deduct [\*\*] percent ([\*\*]%) of Third Party Payments that arise as a result of or in connection with any breach by Voyager of its representations and warranties under Section 8.3 or Section 14.2 or its covenants in Section 14.3 or Section 14.4; and (b) AbbVie shall not be entitled to deduct any amounts payable by AbbVie or any of its Affiliates to (i) [\*\*] under the [\*\*] or any Third Party under any other agreement through which AbbVie has licensed or otherwise acquired rights to any [\*\*] Antibodies or their use as of the Effective Date or (ii) Third Parties under any agreement pursuant to which AbbVie licenses or otherwise acquires rights to any AbbVie Designated Antibody or its use that exists at the time AbbVie adds such AbbVie Designated Antibody to this Agreement pursuant to Section 2.1.3 (whether entered into before or after the Effective Date). In no event shall the deductions

made pursuant to this Section 10.5.3 reduce by more than [\*\*] percent ([\*\*]%) the royalties that would otherwise be owed under Section 10.3.1 (as adjusted by Section 10.5.1 or Section 10.5.2) in any Calendar Quarter. Credits for reductions pursuant to this Section 10.5.3 not exhausted in any Calendar Quarter may be carried into future Calendar Quarters, subject the preceding sentence.

- 10.5.4 <u>Mechanics of Adjustments</u>. Any reductions set forth in Section 10.5 shall be applied to the royalty rate payable to Voyager under Section 10.3.1 in the order in which the event triggering such reduction occurs; <u>provided</u> that the adjustments made pursuant to Section 10.5 shall not reduce by more than [\*\*] percent ([\*\*]%) the royalties that would otherwise be owed under Section 10.3.1. Any adjustments pursuant to Section 10.5 shall apply only to the relevant Licensed Product in the relevant country and shall be allocated pro rata across each of the royalty tiers in the relevant Calendar Quarter.
- 10.6 <u>Estimated Sales Levels</u>. Voyager acknowledges and agrees that the sales levels set forth in Section 10.3.1 and Section 10.2.3 shall not be construed as representing an estimate or projection of anticipated sales of the Licensed Products, or implying any level of diligence or Commercially Reasonable Efforts, in the Territory and that the sales levels set forth in such Section are merely intended to define AbbVie's royalty and milestone obligations in the event such sales levels are achieved.
- 10.7 <u>Reports; Payment of Royalty.</u> During the Term, following the First Commercial Sale of any Licensed Product in any country in the Territory, AbbVie shall furnish to Voyager a written report within [\*\*] after the end of each Calendar Quarter showing, on a Licensed Product-by-Licensed Product and country-by-country basis, the Net Sales of each Licensed Product in each country of the Territory and the royalties payable under this Agreement. Royalties with respect to Net Sales of Licensed Products shall be due and payable on the date such royalty report is due.

#### 10.8 Financial Records.

- 10.8.1 Voyager shall, and shall cause its Affiliates to, keep full, clear and accurate records pertaining to Research Costs and Voyager Development Costs incurred in the Voyager Research Period or Voyager Development Period, for a minimum period of [\*\*] after such costs are incurred pursuant to this Agreement, in sufficient detail to enable AbbVie to (a) verify reports provided (or required to be provided) by Voyager under Section 2.2.3(a) or Section 3.2.3(a), as applicable and (b) calculate and verify any Substitution True-Up Amount hereunder.
- 10.8.2 AbbVie shall, and shall cause its Affiliates to, keep full, clear and accurate records pertaining to Net Sales for a minimum period of [\*\*] after the relevant payment is owed pursuant to this Agreement, in sufficient detail to enable royalties and compensation payable to Voyager hereunder to be calculated and verified.

### 10.9 Audit; Audit Dispute.

10.9.1 Upon not less than [\*\*]' prior written notice, each Party shall, and shall require its Affiliates to, permit the records maintained pursuant to Section 10.8 to be audited by an independent accounting firm selected by the other Party and reasonably acceptable to the

audited Party, at reasonable times and upon reasonable notice, for the sole purpose of verifying reports provided (or required to be provided) by AbbVie under Section 10.7 or by Voyager under Section 2.2.3(a) or Section 3.2.3(a), as applicable, or the Substitution True-Up Amount. Such audit shall not (a) be conducted for any Calendar Quarter more than [\*\*] after the end of such Calendar Quarter, (b) be performed more frequently than [\*\*] period, or (c) be repeated for any Calendar Quarter; provided, however, that nothing herein shall prevent Voyager from adding together the Net Sales for any Calendar Quarter in a Calendar Year, even if audited in separate audits, for purposes of determining AbbVie's compliance with the royalty payment obligations. Such audit shall be conducted under appropriate confidentiality provisions. Upon completion of the audit, the independent accounting firm shall notify the audited Party and the auditing Party in writing of the results of such audit, but shall not share the underlying records with the auditing Party.

10.9.2 Such audit is to be made at the expense of the auditing Party, except if the results of the audit reveal a variance of more than [\*\*] percent ([\*\*]%) or [\*\*] Dollars (\$[\*\*]), whichever is greater, in any Calendar Quarter, in which case the reasonable fees and expenses for such audit shall be paid by the audited Party. Notwithstanding the foregoing, the auditing Party shall have no obligation to reimburse the audited Party for costs and expenses incurred by the audited Party, its employees or agents in cooperating with the auditing Party in such audit. Unless disputed pursuant to Section 10.9.3, if such audit concludes that (a) additional amounts were owed by AbbVie, AbbVie shall pay the additional amounts, with interest from the date originally due as provided in Section 10.12, (b) excess payments were made by AbbVie, Voyager shall reimburse such excess payments, or (c) additional amounts were owed by Voyager, Voyager shall pay the additional amounts, in each case ((a), (b) and (c)), within [\*\*] after the date on which such audit is completed.

10.9.3 In the event of a dispute with respect to any audit under this Section 10.9, Voyager and AbbVie shall work in good faith to resolve the dispute. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within [\*\*], the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "Auditor"). The decision of the Auditor shall be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in such manner as the Auditor shall determine. Not later than [\*\*] after such decision and in accordance with such decision, the underpaying Party shall pay the additional amounts, with interest from the date originally due as provided in Section 10.12, or the overpaid Party shall reimburse the excess payments, as applicable.

10.10 Methods of Payments. All payments due from one Party to the other Party under this Agreement shall be paid in Dollars by wire transfer to a bank in the United States designated in writing by the payee. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), a Party shall convert any amount expressed in a foreign currency into Dollar equivalents using its, its Affiliate's or (sub)licensee's/Sublicensee's standard conversion methodology consistent with the Accounting Standards and shall, along with the relevant report or payment, report to the payee the amount payable (or Net Sales in) the applicable foreign currency as well as its Dollar

equivalent, along with information regarding the currency conversion methodology used sufficient for the payee to calculate such conversion itself.

#### 10.11 <u>Taxes</u>.

10.11.1 <u>Income Taxes</u>. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the activities of the Parties under this Agreement.

### 10.11.2 <u>Withholding Taxes</u>.

- If any sum due to be paid to either Party hereunder is or would otherwise be subject to any withholding or similar tax, the Parties shall cooperate with each other and use their commercially reasonable efforts to do all such acts and things and to sign all such documents as will enable them to secure any available exemption from, reduction in, or refund of such tax. In the event there is no applicable exemption from such withholding or similar tax, with due regard to any reduction described in the preceding sentence, the payor shall remit the amount owed on account of such withholding or similar tax to the appropriate Governmental Authority, deduct the amount so remitted from the amount otherwise due to the payee hereunder and secure and send to payee the best available evidence of the payment of such withholding or similar tax; provided that if an assignment of this Agreement by the payor pursuant to Section 17.3 results in an increase in the amount of such withholding or similar tax, the payor shall pay the recipient such additional amounts ("Additional Amounts") as are necessary to ensure receipt by the recipient of the amount the recipient would have received had such assignment not been made; provided, however, that the payor will have no obligation to pay any Additional Amounts pursuant to this Section 10.11.2 (i) to the extent that the recipient is able to claim a refund of such additional amounts, (ii) if the recipient has the ability to offset such withheld amounts against other tax liabilities of the recipient, or (iii) if such increased withholding tax would not have been imposed but for (A) the assignment by the recipient pursuant to Section 17.3 of its rights under this Agreement, the assignment or transfer of any interest in the recipient, or any redomiciliation of the recipient, or (B) the failure by the recipient to comply with the requirements of this Section 10.11.2.
- (b) In the event that a Governmental Authority retroactively determines that a payment made by a Party to the other Party pursuant to this Agreement should have been subject to withholding or similar (or to additional withholding or similar) taxes, and such Party (the "Withholding Party") remits such withholding or similar taxes to the Government Authority, including any interest and penalties that may be imposed thereon (together with the tax so remitted, the "Later Amount"), the Withholding Party will have the right, upon written notice to the other Party, to either (x) offset the Later Amount against future payment obligations of the Withholding Party under this Agreement or (y) invoice the other Party for the Later Amount (which shall be payable by the other Party within [\*\*] of its receipt of such invoice).
- (c) Any amounts properly deducted and remitted by the payor pursuant to this Section 10.11.2 shall be treated as having been paid by the payor to the payer for purposes of this Agreement.

- (d) Neither Party shall have any obligation to seek a refund of any withholding or similar tax imposed by a Governmental Authority upon any sum payable to such Party hereunder.
- 10.11.3 <u>Indirect Taxes</u>. All payments under this Agreement are exclusive of value added taxes, sales taxes, consumption taxes and other similar taxes (the "<u>Indirect Taxes</u>"). If any Indirect Taxes are chargeable in respect of any payment under this Agreement, the paying Party shall pay such Indirect Taxes at the applicable rate in respect of such payment following receipt, where applicable, of an Indirect Taxes invoice in the appropriate form issued by the receiving Party in respect of those payments. The Parties shall issue invoices for all amounts payable under this Agreement consistent with Indirect Tax requirements and irrespective of whether the sums may be netted for settlement purposes. If the Indirect Taxes originally paid or otherwise borne by the paying Party are in whole or in part subsequently determined not to have been chargeable, the receiving Party shall take all reasonable steps to receive a refund of these undue Indirect Taxes from the applicable Governmental Authority or other fiscal authority and any amount of undue Indirect Taxes repaid by such authority to the receiving Party will be transferred to the paying Party within [\*\*] of receipt by the receiving Party.
- 10.12 <u>Late Payments</u>. Any undisputed amount owed by one Party to the other Party under this Agreement that is not paid on or before the date such payment is due shall bear interest at a rate per annum equal to the lesser of (a) the higher of (i) [\*\*] percent ([\*\*]%) or (ii) [\*\*] basis points above the London Interbank Offered Rate, as adjusted from time to time on the first London business day of each month; <u>provided</u>, <u>however</u>, that if such rate is unavailable, then clause (ii) shall be [\*\*] basis points above the effective federal funds rate published by the Federal Reserve Bank of New York, as adjusted from time to time on the first New York business day of each month, and (b) the highest rate allowed by applicable Law, in each case ((a) or (b)), compounded monthly, such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest.
  - 10.13 Financial Obligations under In-License Agreements and any AbbVie Agreements.
- 10.13.1 AbbVie shall be solely responsible for all payments owed to (a) Third Parties under the [\*\*] and (b) subject to Section 10.5.3, any agreement between AbbVie or any of its Affiliates, on the one hand, and a Third Party on the other hand, that Covers (i) any AbbVie Designated Antibody or any Exploitation thereof or (ii) any Licensed Compound or Licensed Product or the Exploitation of any of the foregoing.
- 10.13.2 Voyager shall be responsible for all payments owed to Third Parties under the In-License Agreements; [\*\*]

# ARTICLE 11 EXCLUSIVITY

- 11.1 <u>Vectorized Alpha-Synuclein Antibody Exclusivity</u>. During the Term (subject to any extension pursuant to Section 16.4.1(b) with respect to Voyager and any exception set forth in Section 16.3, if applicable) neither Party or, subject to Section 17.4, any of its Affiliates, shall (a) directly or indirectly, alone or in collaboration with any Affiliate or Third Party, Research, Develop, Manufacture, Commercialize or otherwise Exploit any Vectorized Alpha-Synuclein Antibody, other than (i) Voyager's activities (itself or through subcontractors in accordance with Section 9.3.2) with respect to the Research Compounds and Research Products during the Voyager Research Period, (ii) Voyager's activities (itself or through subcontractors in accordance with Section 9.3.2) with respect to the Selected Research Compounds and Selected Research Products during the Voyager Development Period, (iii) Voyager's activities (itself or through subcontractors in accordance with Section 9.3.2) to support the transition of the Exploitation of the Licensed Compounds and Licensed Products to AbbVie or its designee in accordance with Section 7.1, Section 7.2 or Section 8.3, or (iv) AbbVie's activities (itself or through its Affiliates and Sublicensees) with respect to the Licensed Compounds and Licensed Products during the remainder of the Term after the License Option Effective Date, or (b) grant any Affiliate or Third Party any right or license to do so.
- 11.2 <u>AbbVie Designated Antibody Exclusivity.</u> During the Term (subject to any extension pursuant to Section 16.4.1(b) with respect to Voyager, if applicable), Voyager shall not (a) directly or indirectly, alone or in collaboration with any Affiliate or Third Party, Research, Develop, Manufacture, Commercialize or otherwise Exploit any AbbVie Designated Antibody, other than (i) Voyager's activities (itself or through subcontractors in accordance with Section 9.3.2) with respect to the Research Compounds and Research Products during the Voyager Research Period, (ii) Voyager's activities (itself or through subcontractors in accordance with Section 9.3.2) with respect to the Selected Research Compounds and Selected Research Products during the Voyager Development Period, or (iii) Voyager's activities (itself or through subcontractors in accordance with Section 9.3.2) to support the transition of the Exploitation of the Licensed Compounds and Licensed Products to AbbVie or its designee in accordance with Section 7.1, Section 7.2 or Section 8.3, or (b) grant any Affiliate or Third Party any right or license to do so.
- 11.3 <u>Failure to Deliver Final Reports; Infeasibility Terminations</u>. If (a) AbbVie terminates this Agreement pursuant to Section 16.2.1 for Voyager's breach of Section 2.3.2 or Section 3.3.2 or

(b) this Agreement is terminated in its entirety pursuant to Section 16.2.4, in either case ((a) or (b)), Voyager and its Affiliates shall not, directly or indirectly, alone or in collaboration with any Affiliate or Third Party, Research, Develop, Manufacture, Commercialize or otherwise Exploit any Vectorized Alpha-Synuclein Antibody until the date that is eighteen (18) months after the effective date of such termination; provided, however, that, with respect to a termination pursuant to Section 16.2.4, if at any time during such eighteen (18)-month period, Voyager desires to resume any Research or Development activities with respect to a Research Compound, Research Product, Selected Research Compound or Selected Research Product (or any Vectorized Alpha-Synuclein Antibody that Encodes any AbbVie Designated Antibody (including Derivatives of an AbbVie Designated Antibody) as such Research Compound, Research Product, Selected Research Compound or Selected Research Product), Voyager shall notify AbbVie of such desire, and, upon AbbVie's election, this Agreement shall resume with respect to such Research Compound, Research Product, Selected Research Compound or Selected Research Product (or such Vectorized Alpha-Synuclein Antibody).

# 11.4 Exception for Basic Research.

11.4.1 Notwithstanding Section 11.1, AbbVie and any of its Affiliates shall be free, itself, or with, through or for an Affiliate, to conduct internal, scientific Research with respect to the biological mechanism of action, pharmacology, structure-activity relationship (SAR) or the like for any Research Compound or Research Product that Encodes any AbbVie Designated Antibody. For clarity, AbbVie and its Affiliates shall be free to Exploit AbbVie Designated Antibodies that are not Vectorized Alpha-Synuclein Antibodies outside of this Agreement.

### ARTICLE 12 OWNERSHIP OF INTELLECTUAL PROPERTY RIGHTS

#### 12.1 Ownership of Intellectual Property; Disclosure.

12.1.1 Ownership. Subject to Section 12.1.2 and Section 14.3.1, and the license grants and other rights herein, as between the Parties, (a) all right, title and interest in and to all Know-How conceived, discovered, developed or otherwise made solely by or on behalf of Voyager (or its Affiliates or its or their (sub)licensees) in the course of activities conducted under this Agreement, and any and all Patent Rights and other intellectual property rights with respect thereto, shall be owned by Voyager; (b) all right, title and interest in and to all Know-How conceived, discovered, developed or otherwise made solely by or on behalf of AbbVie (or its Affiliates or its or their Sublicensees) in the course of activities conducted under this Agreement, and any and all Patent Rights and other intellectual property rights with respect thereto, shall be owned by AbbVie; and (c) all right, title and interest in and to all Know-How conceived, discovered, developed or otherwise made jointly by or on behalf of AbbVie (or its Affiliates or its or their Sublicensees) and by or on behalf of Voyager (or its Affiliates or its or their (sub)licensees) in the course of activities conducted under this Agreement ("Joint Know-How") and any and all Patent Rights and other intellectual property rights with respect to the Joint Know-How ("Joint Patent Rights" and, together with the Joint Know-How, "Joint IP") shall be

owned jointly by AbbVie and Voyager. For the purpose of this ARTICLE 12, AbbVie, its Affiliates and its or their Sublicensees shall not be considered a (sub)licensee of Voyager or its Affiliates and Voyager, its Affiliates and its or their (sub)licensees shall not be considered a Sublicensee of AbbVie or its Affiliates. Subject to the license grants in Section 6.1 and Section 6.4, as applicable, and the exclusivity obligations set forth in ARTICLE 11, (i) each Party shall have the right to practice, grant licenses under, and transfer any Joint IP, (ii) neither Party shall have any obligation to account to the other for profits or to obtain any approval of the other Party to license or Exploit any Joint IP by reason of joint ownership thereof, and (iii) each Party hereby waives any right it may have under the laws of any jurisdiction to require any such consent or accounting.

# 12.1.2 <u>Exceptions</u>.

- (a) <u>Vectorization IP</u>. Notwithstanding Section 12.1.1, subject to Section 6.1 and Section 14.3.1, as between the Parties, Voyager shall exclusively own all right, title and interest in and to any and all Vectorization IP, in each case regardless of which Party or its Affiliates or (sub)licensees/Sublicensees developed such Vectorization IP or whether such Vectorization IP was jointly developed by or on behalf of the Parties or their Affiliates or (sub)licensees/Sublicensees. For clarity, AbbVie shall not have any rights in or to any Vectorization IP, except pursuant to the license grants in Section 6.1.
- (b) <u>AbbVie Designated Antibody IP</u>. Notwithstanding Section 12.1.1, subject to Section 6.4 and Section 14.3.1, as between the Parties, AbbVie shall exclusively own all right, title and interest in and to any and all AbbVie Designated Antibody IP, regardless of which Party or its Affiliates or (sub)licensees/Sublicensees developed such AbbVie Designated Antibody IP or whether such AbbVie Designated Antibody IP was jointly developed by or on behalf of the Parties or their Affiliates or (sub)licensees/Sublicensees. For clarity, Voyager shall not have any rights in or to any AbbVie Designated Antibody IP, except pursuant to the license grants in Section 6.4.1.
- (c) <u>Collaboration IP</u>. Notwithstanding Section 12.1.1, as between the Parties, subject to Section 6.1 and Section 6.4, as applicable, and Section 14.3.1, the Parties shall each own an equal, undivided interest in any and all Collaboration IP, regardless of which Party or its employees or agents developed or acquired such Collaboration IP or whether such Collaboration IP was jointly developed by the Parties. Further, to the extent any Collaboration IP is in-licensed by a Party, such Party shall grant a sublicense and such other rights to the other Party so as to effect, as nearly as possible, that each Party shall have an equal, undivided right in and to such inlicensed Collaboration IP. Subject to the license grants in Section 6.1 and Section 6.4, as applicable, and the exclusivity obligations set forth in ARTICLE 11, (i) each Party shall have the right to practice, grant licenses under, and transfer (except with respect to any obligations to the licensor of any in-licensed Collaboration IP pursuant to the terms of the applicable in-license or sublicense with respect thereto and subject to this Agreement) any Collaboration IP, (ii) neither Party shall have any obligation to account to the other for profits or to obtain any approval of the other Party to license or Exploit any Collaboration IP by reason of joint ownership thereof, and (iii) each Party hereby waives any right it may have under the laws of any jurisdiction to require any such consent or accounting.

12.1.3 <u>United States Law.</u> The determination of whether Know-How is conceived, discovered, developed or otherwise made by a Party or its Affiliates or (sub)licensees/Sublicensees for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with United States patent law and other applicable Law in the United States without regard to conflict of laws, irrespective of where or when such conception, discovery, development or making occurs. Each Party shall, and does hereby, assign, and, subject to Section 14.3.1, shall cause its Affiliates and its and their (sub)licensees/Sublicensees to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Know-How as well as any intellectual property rights with respect thereto, as is necessary to fully effect (a) the sole ownership provided for in Section 12.1.1(a), Section 12.1.1(b), Section 12.1.2(a), and Section 12.1.2(b), or (b) the joint ownership provided for in Section 12.1.1(c) and Section 12.1.2(c), as applicable.

#### 12.1.4 <u>Disclosure of IP</u>.

(a) During the Voyager Research Period and Voyager Development Period each Party shall, and shall cause its Affiliates and (sub)licensees/Sublicensees to, promptly disclose in writing to the other Party the development, making, conception or reduction to practice or acquisition of any Collaboration Know-How by or on behalf of such Party or any of its Affiliates or (sub)licensees/Sublicensees.

# (b) During the Term:

- (i) AbbVie shall, and shall cause its Affiliates and its and their licensees and Sublicensees to, promptly disclose to Voyager in writing the development, making, conception or reduction to practice or acquisition of any Vectorization Know-How (prior to the Cut-Off Date) or AbbVie Manufacturing Improvements by or on behalf of AbbVie or any of its Affiliates or Sublicensees;
- (ii) each Party shall, and shall cause its Affiliates and (sub)licensees/Sublicensees to, promptly disclose in writing to the other Party the development, making, conception or reduction to practice or acquisition of any Joint Know-How by or on behalf of such Party or any of its Affiliates or (sub)licensees/Sublicensees; and
- (iii) in addition to and without limiting its obligation to disclose set forth in Section 8.3.8, Voyager shall, and shall cause its Affiliates and (sub)licensees to, promptly disclose in writing to AbbVie the development, making, conception or reduction to practice or acquisition of any AbbVie Designated Antibody Know-How.
- 12.1.5 <u>Control of Intellectual Property.</u> Subject to Section 6.2, neither Party shall enter into or amend any agreement with a Third Party, or include in any such agreement or amendment any restrictive provisions, with an intent to limit its Control of, or to not Control, any Know-How, Patent Right or other intellectual property right that would be subject to the license grants in Section 6.1 or Section 6.4 in the absence of such agreement, amendment or restrictive provisions. Further, when entering into any agreement or amendment with a Third Party relating to any Know-How, Patent Rights or other intellectual property rights that, if Controlled by a

Party, would be subject to the license grants in Section 6.1 or Section 6.4, each Party shall use good faith efforts to obtain Control of such Know-How, Patent Rights and other intellectual property rights.

#### 12.2 Patent Prosecution and Maintenance.

Voyager Background Patent Rights. As between the Parties, Voyager shall have the sole right, but not the obligation, at its sole cost and expense, using counsel of its choice, to Prosecute and Maintain the Voyager Background Patent Rights (other than the Voyager Background LP Patent Rights) worldwide and to conduct any opposition, re-issuance, reexamination request, nullity action, interference, or other similar post-grant proceedings and any appeals therefrom (each, a "Defense Proceeding") relating thereto (except that in connection with any actions subject to Section 12.3.2, the Party with responsibility for such action pursuant to Section 12.3.2 shall have responsibility for such Defense Proceedings). Without limiting the foregoing, Voyager shall (a) provide AbbVie with copies of the text of the applications for any Voyager Background VA Patent Right (other than the Voyager Background LP Patent Rights) or the Exploitation thereof sufficiently in advance of (and shall use reasonable efforts to provide such text no less than [\*\*] prior to) submitting such applications so as to allow for a reasonable opportunity for AbbVie to review and comment thereon (and shall use reasonable efforts to permit review for no less than [\*\*]); (b) keep AbbVie advised of the status of all material communications, actual and prospective filings or submissions regarding any such Voyager Background Patent Right, and give AbbVie copies of any such material communications, filings, responses and submissions proposed to be sent to any patent authority, court or other tribunal sufficiently in advance of submitting such communications, filings and submissions (and shall use reasonable efforts to provide such copies no less than [\*\*] prior) so as to allow for a reasonable opportunity for AbbVie to review and comment thereon (and shall use reasonable efforts to permit review for no less than [\*\*]); (c) provide AbbVie with a copy of each filing made to and material document received from a patent authority, court or other tribunal regarding any such Voyager Background Patent Right reasonably promptly after making such filing or receiving such material document, including a copy of each application as filed together with notice of its filing date and application number; and (d) consider in good faith and reasonably incorporate AbbVie's comments on the material communications, filings, responses and submissions for any such Voyager Background Patent Right.

#### 12.2.2 <u>Voyager Background LP Patent Rights; Collaboration Patent Rights; Joint Patent Rights.</u>

(a) Subject to Section 12.2.2(b), as between the Parties, (i) prior to the License Option Effective Date, Voyager shall have the first right, but not the obligation, at its sole cost and expense, using counsel reasonably satisfactory to AbbVie, to Prosecute and Maintain the Voyager Background LP Patent Rights, Collaboration Patent Rights and Joint Patent Rights worldwide and to conduct any Defense Proceeding relating thereto (except that in connection with any actions subject to Section 12.3.2, the Party with responsibility for such action pursuant to Section 12.3.2 shall have responsibility for such Defense Proceedings), and (ii) from and after the License Option Effective Date, (A) AbbVie shall have the first right, but not the obligation, at its sole cost and expense, using counsel of its choice, to Prosecute and

Maintain the Voyager Background LP Patent Rights, Collaboration Patent Rights (if specifically related to a Licensed Compound or Licensed Product) and Joint Patent Rights (if specifically related to a Licensed Compound or Licensed Product) worldwide and to conduct any Defense Proceeding relating thereto (except that in connection with any actions subject to Section 12.3.2, the Party with responsibility for such action pursuant to Section 12.3.2 shall have responsibility for such Defense Proceedings), and (B) Voyager shall have the first right, but not the obligation, at its sole cost and expense, using counsel of its choice, to Prosecute and Maintain the Collaboration Patent Rights (other than Collaboration Patent Rights that are specifically related to a Licensed Compound or Licensed Product) and Joint Patent Rights (other than Joint Patent Rights that are specifically related to a Licensed Compound or Licensed Product) and to conduct any Defense Proceeding relating thereto (except that in connection with any actions subject to Section 12.3.2, the Party with responsibility for such action pursuant to Section 12.3.2 shall have responsibility for such Defense Proceedings).

- The Party with the first right to Prosecute and Maintain and conduct any Defense Proceedings with respect to any Voyager Background LP Patent Right, Collaboration Patent Right or Joint Patent Right (the "First Party") shall notify the other Party as to any decision not to file, to abandon, to cease Prosecution and Maintenance of, or not to continue to pay the expenses of Prosecution and Maintenance of, or not to continue the conduct of any Defense Proceeding with respect to, such Voyager Background LP Patent Right, Collaboration Patent Right or Joint Patent Right at least [\*\*] prior to any filing or payment due date, or any other due date that requires action, in connection with such Voyager Background LP Patent Right, Collaboration Patent Right or Joint Patent Right. Thereafter, such other Party may, upon written notice to the First Party (and, with respect to Voyager's option to assume control, with AbbVie's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed), at such other Party's sole cost and expense, control the Prosecution and Maintenance of, or conduct any Defense Proceeding with respect to, such Voyager Background LP Patent Right, Collaboration Patent Right or Joint Patent Right. Any Voyager Background LP Patent Right, Collaboration Patent Right or Joint Patent Right for which, prior to the License Option Effective Date, AbbVie controls the Prosecution and Maintenance or any Defense Proceeding pursuant to this Section 12.2.2(b) shall not be deemed to be a Voyager Background Patent Right, Collaboration Patent Right or Joint Patent Right, as applicable, for purposes of Section 10.4 and Section 10.5.1.
- (c) Without limiting the foregoing, the Party Prosecuting and Maintaining any Voyager Background LP Patent Right, Collaboration Patent Right or Joint Patent Right (the "Prosecuting Party") shall (i) provide the non-Prosecuting Party with copies of the text of the applications for any such Voyager Background LP Patent Right, Collaboration Patent Right or Joint Patent Right sufficiently in advance of (and shall use reasonable efforts to provide such copies no less than [\*\*] prior to) submitting such applications so as to allow for a reasonable opportunity for the non-Prosecuting Party to review and comment thereon (and shall use reasonable efforts to permit review for no less than [\*\*]); (ii) keep the non-Prosecuting Party advised of the status of all material communications, actual and prospective filings or submissions regarding any such Voyager Background LP Patent Right, Collaboration Patent Right or Joint Patent Right, and give the non-Prosecuting Party copies of any such material communications, filings, responses and submissions proposed to be sent to any patent authority, court or other tribunal sufficiently in advance of (and shall use reasonable efforts to provide such

copies no less than [\*\*] prior to) submitting such communications, filings and submissions so as to allow for a reasonable opportunity for the non-Prosecuting Party to review and comment thereon (and shall use reasonable efforts to permit review for no less than [\*\*]); (iii) provide the non-Prosecuting Party with a copy of each filing made to and material document received from a patent authority, court or other tribunal regarding any such Voyager Background LP Patent Right, Collaboration Patent Right or Joint Patent Right reasonably promptly after making such filing or receiving such material document, including a copy of each application as filed together with notice of its filing date and application number; and (iv) consider in good faith and reasonably incorporate the non-Prosecuting Party's comments on the material communications, filings, responses and submissions for any such Voyager Background LP Patent Right, Collaboration Patent Right or Joint Patent Right.

- 12.2.3 <u>AbbVie Background Patent Rights; AbbVie Designated Antibody Patent Rights.</u> As between the Parties, AbbVie shall have the sole right, but not the obligation, at its sole cost and expense, using counsel of its choice, to Prosecute and Maintain the AbbVie Background Patent Rights and the AbbVie Designated Antibody Patent Rights worldwide and to conduct Defense Proceedings relating thereto.
- 12.2.4 <u>UPC Opt-Out and Opt-In</u>. The Parties shall coordinate in good faith and agree on any decision regarding whether or not to elect Opt-Out or Opt-In with respect to any Voyager Background LP Patent Right, AbbVie Designated Antibody Patent Right, Collaboration Patent Right or Joint Patent Right; <u>provided</u> that after the License Option Effective Date, AbbVie shall have final say regarding any such Opt-Out or Opt-In.
- 12.2.5 <u>Cooperation</u>. With respect to the Voyager Background LP Patent Rights, AbbVie Designated Antibody Patent Rights, Collaboration Patent Rights and Joint Patent Rights, the non-Prosecuting Party shall, and shall cause its Affiliates to, reasonably cooperate with and assist the Prosecuting Party in connection with the Prosecuting Party's Prosecution and Maintenance activities and conduct of Defense Proceedings under this Section 12.2 upon the reasonable request of the Prosecuting Party, including by (a) offering its comments (if any) promptly, (b) making scientists, employees, scientific records and other relevant documents and evidence reasonably available to the Prosecuting Party and (c) executing all such documents and instruments and the performing such acts as may be reasonably necessary in order to permit the other Party to continue any Prosecution or Maintenance of, or Defense Proceedings with respect to, such Patent Rights; <u>provided</u> that, in each case, each Party shall bear its costs and expenses incurred in connection therewith.
- 12.2.6 <u>Patent Term Extension</u>. Notwithstanding anything to the contrary in Section 12.2, with respect to each Licensed Compound or Licensed Product, AbbVie shall have the sole right to make decisions regarding, and AbbVie shall have the sole right to apply for, patent term extensions in the Territory, including in the United States with respect to extensions pursuant to 35 U.S.C. § 156 *et. seq.* and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable, for Voyager Background LP Patent Rights, AbbVie Background Patent Rights, AbbVie Designated Antibody Patent Rights, Collaboration Patent Rights and Joint Patent Rights, in each case including whether or not to so apply; <u>provided</u> that, AbbVie shall consult with Voyager to determine the course of action with respect

to such filings with respect to the Voyager Background LP Patent Rights, Collaboration Patent Rights and Joint Patent Rights. Voyager shall provide prompt and reasonable assistance, as requested by AbbVie, including by taking such action as is required under any applicable Law, to obtain such extension or supplementary protection certificate. Voyager shall not make any decisions regarding, or apply for, patent term extensions in the Territory, including in the United States with respect to extensions pursuant to 35 U.S.C. § 156 *et. seq.* and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable, for Voyager Background Patent Rights with respect to a Licensed Product without AbbVie's prior written consent, such consent not to be unreasonably conditioned, withheld or delayed. For clarity, neither Party shall apply for a patent term extension in the Territory for Voyager Background VA Patent Rights, AbbVie Background Patent Rights, AbbVie Designated Antibody Patent Rights, Collaboration Patent Rights or Joint Patent Rights prior to the License Option Effective Date.

12.2.7 <u>Patent Listings.</u> As between the Parties, with respect to each Licensed Compound or Licensed Product, AbbVie shall have the sole right to make all filings with Regulatory Authorities in the Territory with respect to the AbbVie Background Patent Rights and AbbVie Designated Antibody Patent Rights, in each case including as required or allowed in the United States or other jurisdictions. From and after the License Option Effective Date, AbbVie shall have the sole right to make all filings with Regulatory Authorities in the Territory with respect to the Voyager Background Patent Rights, Collaboration Patent Rights and Joint Patent Rights with respect to each Licensed Product, in each case including as required or allowed in the United States or other jurisdictions.

#### 12.3 <u>Enforcement and Defense</u>.

12.3.1 <u>Notice</u>. Each Party shall promptly notify the other Party in writing of any knowledge it acquires of any actual or potential infringement of (a) any Voyager Background Patent Right or AbbVie Background Patent Right by any Competitive Product, and (b) any AbbVie Designated Antibody Patent Right, Collaboration Patent Right or Joint Patent Right by any pharmaceutical product, in each case ((a) and (b)) by a Third Party in any jurisdiction in the Territory.

#### 12.3.2 Actions.

- (a) <u>AbbVie Background Patent Rights; AbbVie Designated Antibody Patent Rights</u>. If any AbbVie Background Patent Right or AbbVie Designated Antibody Patent Right is infringed by a Third Party in any country in the Territory, then, as between the Parties, AbbVie shall have the sole right, but not the obligation, to institute, prosecute, and control any infringement with respect to the AbbVie Background Patent Rights and AbbVie Designated Antibody Patent Rights, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at AbbVie's sole cost and expense, using counsel of its own choice.
- (b) <u>Voyager Background Patent Rights (other than Voyager Background VA Patent Rights)</u>. If any Voyager Background Patent Right (other than a Voyager Background VA Patent Right) is infringed by a Third Party in any country in the Territory, then,

as between the Parties, Voyager shall have the first right, but not the obligation, to institute, prosecute, and control any infringement with respect to such Voyager Background Patent Right, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at Voyager's sole cost and expense, using counsel of its own choice. AbbVie shall have the right to join as a party to such claim, suit or proceeding in the Territory and participate with its own counsel at its sole cost and expense; provided that Voyager shall retain control of the prosecution of such claim, suit or proceeding, including the response to any defense or defense of any counterclaim raised in connection therewith. If Voyager or its designee does not bring an infringement action pursuant to this Section 12.3.2(b) with respect to an infringement by a Third Party's Exploitation of a Competitive Product within [\*\*] after receipt of notice of the existence of such an infringement (or in cases where there is a relevant statutory period during which an infringement action must be commenced or in which any material rights may be lost that would expire on or prior to the [\*\*] after the expiration of such [\*\*] period and of which AbbVie has notified Voyager promptly after it becomes aware, [\*\*] prior to the expiration of such relevant statutory period) then (i) Voyager shall so notify AbbVie and (ii) upon written notice to Voyager (and with Voyager's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed), AbbVie may thereafter institute, prosecute, and control such infringement action at its sole cost and expense.

Voyager Background VA Patent Rights; Collaboration Patent Rights. If any Voyager (c) Background VA Patent Right or Collaboration Patent Right is infringed by a Third Party in any country in the Territory, then, as between the Parties, (i) prior to the License Option Effective Date, Voyager shall have the first right, but not the obligation, to institute, prosecute, and control any infringement with respect to the Voyager Background VA Patent Rights and Collaboration Patent Rights, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at Voyager's sole cost and expense, using counsel of its own choice, and (ii) from and after the License Option Effective Date, (A) AbbVie shall have the first right, but not the obligation, to institute, prosecute, and control any infringement with respect to the Voyager Background VA Patent Rights (with respect to an infringement by a Third Party's Exploitation of a Competitive Product) and the Collaboration Patent Rights, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at AbbVie's sole cost and expense, using counsel of its own choice, and (B) Voyager shall have the first right, but not the obligation, to institute, prosecute, and control any infringement with respect to the Voyager Background VA Patent Rights (other than with respect to an infringement by a Third Party's Exploitation of a Competitive Product), including as a defense or counterclaim in connection with any Third Party Infringement Claim, at Voyager's sole cost and expense, using counsel of its own choice. The non-controlling Party shall have the right to join as a party to such claim, suit or proceeding in the Territory and participate with its own counsel at its sole cost and expense; provided that the controlling Party shall retain control of the prosecution of such claim, suit or proceeding, including the response to any defense or defense of any counterclaim raised in connection therewith. If the controlling Party or its designee does not bring an infringement action pursuant to this Section 12.3.2(c) within [\*\*] after receipt of notice of the existence of an infringement (or in cases where there is a relevant statutory period during which an infringement action must be commenced or in which any material rights may be lost that would expire on or prior to the [\*\*] after the expiration of such [\*\*] period and of which the noncontrolling Party has notified the controlling Party promptly after it becomes aware, [\*\*] prior to the expiration of such relevant statutory period), then (x) the

controlling Party shall so notify the non-controlling Party and (y) upon written notice to the controlling Party (and, with respect to Voyager's option to assume control, with AbbVie's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed), the non-controlling Party may thereafter institute, prosecute, and control such infringement action at its sole cost and expense.

#### (d) <u>Joint Patent Rights</u>.

- From and after the License Option Effective Date, if any Joint Patent Right is (i) infringed by a Third Party's Exploitation of a Competitive Product in any country in the Territory, then, as between the Parties, AbbVie shall have the first right, but not the obligation, to institute, prosecute, and control any such infringement with respect to the Joint Patent Rights, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at AbbVie's sole cost and expense, using counsel of its own choice. Voyager shall have the right to join as a party to such claim, suit or proceeding in the Territory and participate with its own counsel at its sole cost and expense; provided that AbbVie shall retain control of the prosecution of such claim, suit or proceeding, including the response to any defense or defense of any counterclaim raised in connection therewith. If AbbVie or its designee does not bring an infringement action pursuant to this Section 12.3.2(d) with respect to an infringement by a Third Party's Exploitation of a Competitive Product within [\*\*] after receipt of notice of the existence of an infringement (or in cases where there is a relevant statutory period during which an infringement action must be commenced or in which any material rights may be lost that would expire on or prior to the [\*\*] after the expiration of such [\*\*] period and of which Voyager has notified AbbVie promptly after it becomes aware, [\*\*] prior to the expiration of such relevant statutory period) then (i) AbbVie shall so notify Voyager and (ii) upon written notice to AbbVie (and with AbbVie's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed), Voyager may thereafter institute, prosecute, and control such infringement action at its sole cost and expense.
- (ii) If (A) from and after the License Option Effective Date, any Joint Patent Right is infringed by a Third Party's Exploitation of a product other than a Competitive Product or (B) prior to the License Option Effective Date, any Joint Patent Right is infringed by a Third Party's Exploitation of any product, in either case ((A) or (B)) in any country in the Territory, then the Parties shall meet to discuss in good faith the allocation of enforcement rights and recoveries with respect to such Joint Patent promptly after either Party provides notice to the other Party with respect to such infringement in accordance with Section 12.3.1.
- (e) The Party initiating the suit shall have the sole and exclusive right to elect counsel for any suit initiated by it pursuant to Section 12.3.2(a), (b), (c) or (d); provided that, with respect to a Voyager Background Patent Right, Collaboration Patent Right or Joint Patent Right, such counsel is reasonably acceptable to the other Party.
- 12.3.3 <u>Cooperation</u>. Each Party agrees to cooperate fully in any infringement action under Section 12.3.2 that is controlled by the other Party, including executing legal papers and cooperating in the prosecution as may be reasonably requested by the controlling Party, furnishing a power of attorney solely for such purpose or joining in, or being named as a

necessary party to, such action, providing access to relevant documents and other evidence and by making available its employees as well as the inventors, applicable records and documents (including laboratory notebooks) with respect to the relevant Patent Rights; provided that, except with respect to Voyager Background VA Patent Rights, Collaboration Patent Rights and Joint Patent Rights, the controlling Party shall reimburse such other Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith. Unless otherwise set forth herein, the Party entitled to bring any infringement action in accordance with this Section 12.3 shall have the right to settle such action; provided that neither Party shall have the right to settle any infringement action under this Section 12.3.3 in a manner that imposes any costs or liability on or involves any admission by, the other Party, without the express written consent of such other Party (which consent shall not be unreasonably withheld, conditioned or delayed); provided, further, that the foregoing limitation shall not be deemed to require the consent of such other Party in connection with a settlement of infringement that would or may result in reduced payments hereunder. In connection with any activities with respect to an infringement action prosecuted by a Party pursuant to this Section 12.3 involving Patent Rights Controlled by or licensed under Section 6.1 or Section 6.4 to the other Party, the Party controlling such action shall (a) consult with the other Party as to the strategy for the prosecution of such claim, suit or proceeding, (b) consider in good faith any comments from the other Party with respect thereto and (c) keep the other Party reasonably informed of any material steps taken and provide copies of all material documents filed, in connection with such action or the settlement thereof.

12.3.4 Recovery. Unless otherwise agreed by the Parties in writing, the amount of any recovery from a proceeding brought under Section 12.3.2 (whether by way of settlement or otherwise) shall first be applied to the internal and out-of-pocket costs and expenses of the Parties with respect to such action (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses), and any remaining recovery amount shall be (a) allocated first to the Inbound Licensor pursuant to the applicable In-License Agreement (or to the licensor under any in-license agreement entered into by AbbVie or any of Affiliates applicable to the Exploitation of a Licensed Compound or Licensed Product), if applicable, provided that the Party subject to the relevant In-License Agreement/in-license agreement shall provide the other Party with reasonable documentation of such allocation and (b) thereafter be retained by the Party that has exercised its right to bring the enforcement action; provided, however, that to the extent that any award or settlement (whether by judgment or otherwise) with respect to a Voyager Background Patent Right, AbbVie Designated Antibody Patent Right, Collaboration Patent Right or Joint Patent Right (with respect to Joint Patent Rights, solely in an action concerning a Competitive Product) is attributable to loss of sales or profits with respect to a Licensed Product, such amount shall be (x) paid to or retained by AbbVie, (y) for purposes of Section 10.3, treated as "Net Sales" in the Calendar Year in which the money is actually received and (z) for purposes of Section 10.2.3, treated as "Net Sales" and allocated among the Calendar Year(s) to which such recovery relates, in accordance with the applicable judgment or settlement and allocated on a straight line basis over the Calendar Years to which such recovery relates.

12.3.5 <u>Invalidity or Unenforceability Defense or Actions</u>. With respect to any defense or declaratory judgment actions relating to or other attack upon validity or enforceability of a Voyager Background Patent Right, AbbVie Background Patent Right,

AbbVie Designated Antibody Patent Right, Collaboration Patent Right or Joint Patent Right, excluding any Prosecution or Maintenance, any Defense Proceeding (which shall be governed by Section 12.2) and any such action or attack in connection with any counterclaim brought in actions subject to Section 12.3.2, each Party shall promptly notify the other Party in writing of any such alleged or threatened action or attack. As between the Parties, (a) Voyager shall have the sole right, but not the obligation, to defend (including the right to settle) any such claim relating to the Voyager Background Patent Rights (other than the Voyager Background VA Patent Rights), (b) AbbVie shall have the sole right, but not the obligation, to defend (including the right to settle) any such claim relating to the AbbVie Background Patent Rights and the AbbVie Designated Antibody Patent Rights, and (c) (i) prior to the License Option Effective Date, Voyager shall have the first right, but not the obligation, to defend (including the right to settle) any such claim relating to the Voyager Background VA Patent Rights, Collaboration Patent Rights or Joint Patent Rights, and (ii) from and after the License Option Effective Date, AbbVie shall have the first right, but not the obligation, to defend (including the right to settle) any such claim relating to the Voyager Background VA Patent Rights, Collaboration Patent Rights or Joint Patent Right, in each case ((a), (b) and (c)), at its sole cost and expense in the Territory and using counsel of its own choice. With respect to any Voyager Background VA Patent Rights, Collaboration Patent Right or Joint Patent Right, (a) the non-defending Party shall have the right, at its sole cost and expense, to join any such defense with counsel of its choice, and (b) if the Party with the first right to defend a Patent Right or its designee declines to assume the defense of, or otherwise fails to initiate and maintain the defense of, any such Patent Right, then the other Party shall have the right, but not the obligation, upon written notice to the defending Party (and, with respect to Voyager's option to assume the defense, with AbbVie's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed) to assume the defense thereof at its sole cost and expense. Each Party shall, and shall cause its Affiliates to, render such reasonable assistance as the defending Party may reasonably request from time to time with respect to actions brought pursuant to this Section 12.3.5, including executing legal papers and cooperating in the defense, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making available its employees as well as the inventors, applicable records and documents (including laboratory notebooks) with respect to the relevant Patent Rights; provided that, except with respect to Voyager Background VA Patent Rights, Collaboration Patent Rights and Joint Patent Rights, the defending Party shall reimburse such other Party for its reasonable and verifiable outof-pocket costs and expenses incurred in connection therewith. In connection with any activities with respect to a defense, claim or counterclaim relating to the Voyager Background VA Patent Rights, AbbVie Designated Antibody Patent Rights, Collaboration Patent Rights or Joint Patent Rights pursuant to this Section 12.3.5, the defending Party shall (i) consult with the other Party as to the strategy for such activities, (ii) consider in good faith any comments from the other Party and (iii) keep the other Party reasonably informed of any material steps taken and provide copies of all material documents filed, in connection with such defense, claim or counterclaim.

# 12.4 Biosimilar Applicants.

12.4.1 Notwithstanding the foregoing, AbbVie shall have the sole right to prosecute and manage any litigation with respect to Biosimilar Products to the extent applicable to any AbbVie Background Patent Rights, AbbVie Designated Antibody Patent Rights, Voyager

Background VA Patent Rights, Collaboration Patent Rights or Joint Patent Rights, in accordance with this Section 12.4, but subject to the expense reimbursement and settlement approval provisions of Section 12.3.3 and the recovery provisions of Section 12.3.4, as applicable. If either Party receives notice or a copy of an application submitted to the FDA or its foreign counterpart for a Biosimilar Product for which a Licensed Product is a "reference product," as such term is used in the BPCI Act (a "Biosimilar Application"), whether or not such notice or copy is provided under any applicable Laws, or otherwise becomes aware that such a Biosimilar Application has been submitted to a Regulatory Authority for Regulatory Approval (such as in an instance described in Section 351(1)(9)(C) of the PHSA), the remainder of this Section 12.4.1 shall apply. If either Party receives such notice or communication or any equivalent or similar communication or notice in the United States, such Party shall, within [\*\*], notify and provide the other Party copies of such notice or communication to the extent permitted by applicable Law. AbbVie shall carry out the rights and responsibilities of the "reference product sponsor," as defined in Section 351(1)(1)(A) of the PHSA, for purposes of such Biosimilar Application, in consultation with Voyager to the extent requested by AbbVie and permitted under applicable Law. If requested by AbbVie, Voyager shall seek to obtain access to such Biosimilar Application and related confidential information, including in accordance with Section 351(1)(1)(B)(iii) of the PHSA, if applicable.

- 12.4.2 If permitted pursuant to applicable Law, upon AbbVie's request, Voyager shall assist AbbVie in identifying and listing any AbbVie Background Patent Rights, AbbVie Designated Antibody Patent Rights, Voyager Background Patent Rights, Collaboration Patent Rights or Joint Patent Rights as required pursuant to Section 351(l)(1)(3)(A) or Section 351(l)(7) of the PHSA, in negotiating with the filer of the Biosimilar Application pursuant to Section 351(l)(4) of the PHSA, and in selecting patents for and conducting litigation pursuant to Section 351(l)(5) and Section 351(l)(6) of the PHSA, to the extent applicable, and shall cooperate with AbbVie in responding to relevant communications with respect to such lists from the filer of the Biosimilar Application. Upon AbbVie's request, Voyager shall assist in seeking an injunction against any commercial marketing by the filer of a Biosimilar Application as permitted pursuant to Section 351(l)(8)(B) of the PHSA or in filing an action for infringement against the filer of such Biosimilar Application.
- 12.4.3 Neither Party shall have the right to settle any litigation under this Section 12.4 in a manner that imposes any costs or liability on or involves any admission by, the other Party, without the express written consent of such other Party (which consent shall not be unreasonably withheld, conditioned or delayed); provided that the foregoing limitation shall not be deemed to require the consent of such other Party in connection with a settlement that would or may result in reduced payments hereunder.

## 12.5 <u>Infringement Claimed by Third Parties</u>.

12.5.1 If a Third Party commences, or threatens to commence, any proceeding against a Party alleging infringement of such Third Party's intellectual property by the Exploitation by a Party, its Affiliates, subcontractors, Sublicensees, Distributors or customers of (a) any Research Compound or Research Product, which Exploitation occurred during the Voyager Research Period, (b) any Selected Research Compound or Selected Research Product,

which Exploitation occurred during the Voyager Development Period or (c) any Licensed Compound or Licensed Product (each of (a)-(c), a "<u>Third Party Infringement Claim</u>"), including any defense or counterclaim in connection with an infringement action initiated pursuant to Section 12.3.2, the Party first becoming aware of such alleged infringement shall promptly notify the other Party thereof in writing.

Without limiting the right of the Party against whom a Third Party Infringement Claim is filed to seek indemnification for such Third Party Infringement Claim covered pursuant to ARTICLE 15 as between the Parties, notwithstanding any right of the Indemnifying Party to control as set forth in Section 15.3, (a) prior to the License Option Effective Date, Voyager shall have the first right, but not the obligation, at its sole cost and expense, using counsel of its own choice, to control the defense and settlement of any Third Party Infringement Claim, and (b) from and after the License Option Effective Date, AbbVie shall have the first right, but not the obligation, at its sole cost and expense, using counsel of its own choice, to control the defense and settlement of any Third Party Infringement Claim, except in each case ((a) and (b)) to the extent such Third Party Infringement Claim relates to an AbbVie Designated Antibody, in which case AbbVie shall have the sole right (except that, to the extent that such Third Party Infringement Claim is brought against Voyager, AbbVie shall have the first right), but not the obligation, at its sole cost and expense, using counsel of its own choice, to control the defense and settlement of such Third Party Infringement Claim. The non-controlling Party may participate in any such claim, suit or proceeding with counsel of its choice at its sole cost and expense. If the Party with the first right to control such Third Party Infringement Claim or its designee elects (in a written communication submitted to the non-controlling Party within a reasonable amount of time after notice of the alleged patent infringement) not to defend or control the defense of, or otherwise fails to initiate and maintain the defense of, any such claim, suit or proceeding, within such time periods so that the non-controlling Party is not prejudiced by any delays, the non-controlling Party may conduct and control the defense of any such claim, suit or proceeding at its sole cost and expense, except, with respect to Voyager as the non-controlling Party, to the extent such Third Party Infringement Claim relates to an AbbVie Designated Antibody and is not brought against Voyager. Where a Party controls such an action, the other Party shall, and shall cause its Affiliates to, assist and cooperate with the controlling Party, as such controlling Party may reasonably request from time to time, in connection with its activities set forth in this Section 12.5, including executing legal papers and cooperating in the defense, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and, in the case of Voyager, making available its employees as well as inventors, applicable records and documents (including laboratory notebooks) with respect to the relevant Patent Rights; provided that the controlling Party shall reimburse such other Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith. Each Party shall keep the other Party reasonably informed of all material developments in connection with any such claim, suit or proceeding. Each Party agrees to provide the other Party with copies of all material pleadings filed in such action and to allow the other Party reasonable opportunity to participate in the defense of the claims.

### 12.6 Marking.

12.6.1 <u>Licensed Product Marking</u>. AbbVie shall, and shall cause its Affiliates and Sublicensees to, mark each Licensed Product in such a manner to conform with the patent laws and practice of any country in which such Licensed Product is Manufactured or sold or to which such Licensed Product is shipped consistent with AbbVie's marking practices with respect to its other patented pharmaceutical products in such country.

### 12.7 Product Trademarks.

- Ownership of Product Trademarks. As between the Parties, AbbVie shall have the sole 12.7.1 right to determine the Trademarks used in connection with any Licensed Product anywhere in the world (the "Product Trademarks") and, as between the Parties, shall own all worldwide right, title and interest in and to any such Product Trademarks. AbbVie shall not select as a Product Trademark any Trademark, corporate name or corporate logo of Voyager or any of its Affiliates that, prior to the time of AbbVie's use or AbbVie's first filing of any trademark application for such Trademark in connection with any Licensed Product, is the subject of a registration or a pending application that is owned by Voyager or any of its Affiliates or that has been used in commerce by Voyager or any of its Affiliates (any such Trademark, a "Voyager Trademark"); provided that if AbbVie notifies Voyager that AbbVie has filed or is planning to file a potential Product Trademark and (a) within [\*\*] after receipt of such notice, Voyager notifies AbbVie that such potential Product Trademark is a Voyager Trademark and AbbVie thereafter ceases any registration or use of such potential Product Trademark or (b) Voyager fails to provide such notice to AbbVie within such [\*\*]-period, then AbbVie shall not be in breach of this Section 12.7.1 with respect to its use of such Product Trademark. Voyager shall not, and shall cause its Affiliates not to, (a) use in their respective businesses, any Trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any of the Product Trademarks and (b) knowingly do any act that endangers, destroys, or similarly affects, in any material respect, the value of the goodwill pertaining to the Product Trademarks. Voyager shall not, and shall cause its Affiliates not to, attack, dispute or contest the validity of or ownership of any Product Trademarks anywhere in the Territory or any registrations issued or issuing with respect thereto. All costs and expenses of registering, prosecuting, and maintaining the Product Trademarks shall be borne solely by AbbVie. Voyager shall provide all assistance and documents reasonably requested by AbbVie in support of its prosecution, registration, and maintenance of the Product Trademarks.
- 12.7.2 <u>Enforcement of Product Trademarks</u>. As between the Parties, AbbVie shall have the sole right to take such action as AbbVie deems necessary against a Third Party based on any alleged, threatened, or actual infringement, dilution, misappropriation, or other violation of, or unfair trade practices or any other like offense relating to, the Product Trademarks by a Third Party in the Territory. AbbVie shall bear the costs and expenses relating to any enforcement action commenced pursuant to this Section 12.7.2 and any settlements and judgments with respect thereto, and shall retain any damages or other amounts collected in connection therewith.
- 12.7.3 <u>Third Party Claims</u>. As between the Parties, AbbVie shall have the sole right to defend against (including the right to settle) any alleged, threatened, or actual claim

by a Third Party that the use or registration of the Product Trademarks in the Territory infringes, dilutes, misappropriates, or otherwise violates any Trademark or other right of that Third Party or constitutes unfair trade practices or any other like offense, or any other claims as may be brought by a Third Party against a Party in connection with the use of the Product Trademarks with respect to a Licensed Product in the Territory. AbbVie shall bear the costs and expenses relating to any defense commenced pursuant to this Section 12.7.3 and any settlements and judgments with respect thereto and shall retain any damages or other amounts collected in connection therewith.

12.7.4 <u>Notice and Cooperation</u>. Voyager shall, and shall cause its Affiliates to, (a) provide prompt written notice of any actual or threatened infringement of the Product Trademarks in the Territory and of any actual or threatened claim that the use of the Product Trademarks in the Territory violates the rights of any Third Party, to the extent known to Voyager or such Affiliate, and (b) assist and cooperate with AbbVie, as AbbVie may reasonably request from time to time, in connection with its activities set forth in this Section 12.7, including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours; <u>provided</u> that AbbVie shall reimburse Voyager for its and its Affiliates' reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith.

## 12.8 Third Party Agreements.

- 12.8.1 The provisions of this ARTICLE 12 are subject to the Third Party agreement terms specifically set forth in <u>Schedule 12.8</u>.
- 12.8.2 Without limiting the foregoing, (a) at all times during the Term, without AbbVie's prior written consent, such consent not be unreasonably conditioned, withheld or delayed, Voyager shall maintain patent protection on, and shall not abandon or otherwise forfeit, any [\*\*] (as such term is defined in the [\*\*]) that is also a Voyager Background Patent Right, (b) Voyager shall consult with AbbVie prior to permitting [\*\*] to enforce or defend, solely to extent permitted under Section 15.4.2.1 and Section 15.4.2.2 of the [\*\*], any [\*\*] (as such term is defined in the [\*\*]) that is also a Voyager Background Patent Right, and Voyager shall consider in good faith any comments or concerns of AbbVie with respect thereto, (c) at all times during the Term, without AbbVie's prior written consent, such consent not be unreasonably conditioned, withheld or delayed, Voyager shall maintain patent protection on, and shall not abandon or otherwise forfeit, any [\*\*] (as such term is defined in the [\*\*]) that is also a Voyager Background Patent Right, and (d) Voyager shall consult with AbbVie prior to refusing to enforce or defend, solely to extent permitted under Section 10.3.2(c) and Section 10.3.3 of the [\*\*], any [\*\*] (as such term is defined in the [\*\*]) that is also a Voyager Background Patent Right, and Voyager shall consider in good faith any comments or concerns of AbbVie with respect thereto.
- 12.8.3 Voyager shall not use in the Research Program or Development Program or otherwise incorporate into a Research Compound, Research Product, Selected Research Compound, Selected Research Product, Licensed Compound or Licensed Product any

vector, Virus Capsid or other invention that is the subject of a claim within the [\*\*] as such term is defined in the [\*\*].

# ARTICLE 13 CONFIDENTIALITY

- Confidentiality; Exceptions. At all times during the Term, except as otherwise set forth in Section 16.4, and for a period of [\*\*] following termination or expiration of this Agreement in its entirety (and thereafter with respect to any Confidential Information that either Party specifically identifies to the other Party in writing that constitutes a trade secret under applicable Law for so long as such Confidential Information constitutes a trade secret under applicable Law), except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that the receiving Party (the "Receiving Party") shall, and shall cause its Affiliates, and its and each of its Affiliate's respective officers, directors, employees and agents, to, keep confidential and not publish or otherwise disclose to a Third Party or use, directly or indirectly, for any purpose other than as provided for in this Agreement, any technical, business or other information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) that is disclosed to it or any of its Affiliates by or on behalf of the other Party (the "Disclosing Party"), whether prior to (pursuant to the Existing Confidentiality Agreement, as described in Section 13.2), on or after the Effective Date, including the terms of this Agreement (subject to Section 13.5); Voyager Background Know-How, AbbVie Background Know-How, AbbVie Designated Antibody Know-How, Collaboration Know-How, Joint Know-How, Manufacturing Process Know-How and any other Know-How with respect to an AbbVie Designated Antibody, Research Compound or any Research Product, any Research, Development, Commercialization or Manufacture of any Licensed Product developed by or on behalf of the Disclosing Party or its Affiliates or its or their (sub)licensees/Sublicensees; and the scientific, regulatory or business affairs or other activities of either Party (collectively, "Confidential Information"). Notwithstanding the foregoing, Confidential Information constituting (a) Collaboration Know-How and Joint Know-How shall (i) prior to the License Option Effective Date, be deemed Confidential Information of both Parties (and both Parties shall be deemed the Receiving Party and the Disclosing Party with respect thereto) and (ii) from and after the License Option Effective Date, be deemed the Confidential Information of AbbVie (and AbbVie shall be deemed the Disclosing Party, and Voyager shall be deemed the Receiving Party, with respect thereto), (b) Vectorization Know-How shall be deemed the Confidential Information of Voyager (and Voyager shall be deemed the Disclosing Party, and AbbVie shall be deemed the Receiving Party, with respect thereto), (c) AbbVie Designated Antibody Know-How shall be deemed the Confidential Information of AbbVie (and AbbVie shall be deemed the Disclosing Party, and Voyager shall be deemed the Receiving Party, with respect thereto), and (d) the terms of this Agreement shall be deemed to be the Confidential Information of both Parties (and both Parties shall be deemed the Receiving Party and the Disclosing Party with respect thereto).
- 13.2 <u>Exceptions to Confidential Information</u>. Notwithstanding Section 13.1, the confidentiality and non-use obligations under this ARTICLE 13 shall not apply to the extent that it can be established by the Receiving Party that such Confidential Information:

- 13.2.1 was in the lawful knowledge and possession of the Receiving Party prior to the time it was first disclosed to the Receiving Party by the Disclosing Party, or was otherwise developed independently by the Receiving Party without reference to any of the Disclosing Party's Confidential Information, in each case as evidenced by written records kept in the ordinary course of business or other documentary proof; <u>provided</u> that the foregoing exception shall not apply with respect to Vectorization Know-How, AbbVie Designated Antibody Know-How, Collaboration Know-How or Joint Know-How;
- 13.2.2 was generally available to the public or otherwise part of the public domain at the time of its first disclosure to the Receiving Party by the Disclosing Party;
- 13.2.3 became generally available to the public or otherwise part of the public domain by public use, publication, general knowledge or the like after its disclosure to the Receiving Party by the Disclosing Party and other than through any act or omission of the Receiving Party in breach of this Agreement or the Existing Confidentiality Agreement; or
- 13.2.4 was disclosed to the Receiving Party by a Third Party who had no obligation to the Disclosing Party or to any Third Party not to disclose such information to others.

Specific aspects or details of Confidential Information shall not be deemed to be generally available to the public or otherwise part of the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information that is generally available to the public or otherwise part of the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information shall not be considered to be generally available to the public or otherwise part of the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are generally available to the public or otherwise part of the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

For the avoidance of doubt, any information disclosed by a Party or any of its Affiliates to the other Party or any of its Affiliates prior to the Effective Date pursuant to the Mutual Confidentiality Agreement between Voyager and AbbVie dated August 11, 2016 (as amended from time to time, the "Existing Confidentiality Agreement"), that was considered Confidential Information (as defined in the Existing Confidentiality Agreement) and was not subject to Section 5(a), 5(b), 5(c) or 5(d) of the Existing Confidentiality Agreement as of the Effective Date of this Agreement shall be Confidential Information of such Disclosing Party, subject to the provisions of Sections 13.1, 13.2.1, 13.2.2, 13.2.3 and 13.2.4.

- 13.3 <u>Authorized Disclosure</u>. A Receiving Party may use and disclose Confidential Information of the Disclosing Party as follows:
- 13.3.1 to the extent required to those of its employees and agents who reasonably need to know such Confidential Information in order to advise or assist the Receiving Party in connection with the performance of its obligations or exercise of its rights granted or

reserved in this Agreement and under appropriate confidentiality provisions no less protective of the Disclosing Party than those set forth in this Agreement;

- Authority of competent jurisdiction or, based on the advice of the Receiving Party's legal counsel, as otherwise required by Law, including pursuant to the rules or regulations of securities regulators or of a securities exchange on which the securities of the Disclosing Party or any of its Affiliates are listed (or to which an application for listing has been submitted); provided, however, that if a Receiving Party is required to make any such disclosure of a Disclosing Party's Confidential Information, the Receiving Party shall, to the extent consistent with applicable Law, give reasonable advance notice to the Disclosing Party of such disclosure requirement and give the Disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information that are the subject of such order or required to be disclosed be held in confidence by such court or Governmental Authority or, if disclosed, be used only for the purposes for which the order was issued or such disclosure was required by applicable Law; and provided, further, that the Confidential Information disclosed in response to such court or governmental order or as required by Law shall be limited to only the Confidential Information legally required to be disclosed;
- 13.3.3 in communication with existing or prospective investors, lenders, professional advisors, acquirers, merger partners, subcontractors, licensees or Inbound Licensors on a need to know basis, in each case under appropriate confidentiality provisions substantially equivalent to those of this Agreement; provided that, in the event of any disclosure of the terms of this Agreement to a Third Party who is a prospective investor, lender, professional advisor, acquirer, merger partner, subcontractor, licensee or Inbound Licensor and not already an existing investor, lender, professional advisor, acquirer, merger partner, subcontractor, licensee or Inbound Licensor, (a) this Agreement shall only be initially disclosed to such Third Party and its advisors in the redacted form that has been filed with the United States Securities and Exchange Commission and (b) after negotiations with any such Third Party have progressed so that the Disclosing Party reasonably and in good faith believes it will execute a definitive agreement with such Third Party within [\*\*], this Agreement may be disclosed in an unredacted form to such Third Party and its advisors as and to the extent relevant to such Third Party (which shall be redacted for information that is not relevant);
- 13.3.4 made by or on behalf of the Receiving Party to a patent authority as may be reasonably necessary or useful for purposes of preparing, obtaining, Prosecuting and Maintaining, defending or enforcing a Patent Right under this Agreement; <u>provided</u>, <u>however</u>, that reasonable measures shall be taken to assure confidential treatment of such Confidential Information, to the extent such protection is available; or
  - 13.3.5 to the extent mutually agreed to in writing by the Parties.
- 13.4 <u>Additional Permitted Disclosures and Use by AbbVie</u>. AbbVie and its Affiliates and its and their Sublicensees may disclose and use Confidential Information of Voyager as may be necessary or useful in connection with (a) any filing, application or request for Regulatory

Approval or Pricing Approval by or on behalf of AbbVie or any of its Affiliates or its or their Sublicensees (provided, however, that AbbVie shall take reasonable measures to assure confidential treatment of such Confidential Information, to the extent such protection is available) and (b) the Research, Development, Commercialization, Manufacture or other Exploitation of Licensed Compounds or Licensed Products, including to existing or potential Distributors, Sublicensees, collaboration partners, and co-promotion partners; provided that any (i) disclosure of Manufacturing Process Know-How and (ii) disclosure pursuant to clause (b) of this Section 13.4 of Confidential Information of Voyager that does not specifically relate to a Licensed Product or the components thereof shall be made under appropriate confidentiality provisions no less protective of Voyager than those set forth in this Agreement.

- 13.5 <u>Use of Names</u>. Except as otherwise permitted herein, neither Party shall mention or otherwise use the name, logo or Trademark of the other Party or, to the extent such first Party is aware that a Person is any of the following, any of its Affiliates or any of its or their (sub)licensees/Sublicensees (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material or other form of publicity without the prior written approval of such other Party or such Person in each instance. The restrictions imposed by this Section 13.5 shall not prohibit (a) AbbVie from making any disclosure identifying Voyager as the manufacturer of any Licensed Product, if applicable, the innovator of the Vectorization Technology, licensor of the Licensed Compounds or Licensed Products or a counterparty to this Agreement, and (b) either Party from making any disclosure identifying the other Party, any of its Affiliates or any of its or their (sub)licensees/Sublicensee that is required by applicable Law or pursuant to the rules or regulations of securities regulators or of a securities exchange on which the securities of the Disclosing Party or any of its Affiliates are listed (or to which an application for listing has been submitted).
- <u>Press Release</u>; <u>Disclosure of Agreement</u>. On or within [\*\*] after the Effective Date, the Parties shall jointly issue a public announcement of the execution of this Agreement in the form attached hereto as Schedule 13.6. Subject to Section 13.7, neither Party may issue any subsequent press release or other public disclosure regarding this Agreement or its terms or the Parties' activities hereunder, or any results or data arising hereunder, except (a) with the other Party's prior written consent, or (b) for any disclosure that is, based on the advice of the Disclosing Party's counsel, reasonably necessary to comply with applicable Law or the rules or regulations of securities regulators or of a securities exchange on which the securities of such Party or any of its Affiliates are listed (or to which an application for listing has been submitted). Each Party shall provide to the other Party a copy of any public announcement regarding this Agreement or the subject matter hereof (including any filing with the United States Securities and Exchange Commission (or any securities exchange on which the securities of such Party or any of its Affiliates are listed (or to which an application for listing has been submitted), including Nasdaq)) reasonably prior to (and in no event less than [\*\*] prior to) its scheduled release. Each Party shall have the right to review and recommend changes to any such announcement, which changes shall be considered in good faith; provided that, except as otherwise reasonably necessary to comply with applicable Law or the rules or regulations of securities regulators or of a securities exchange on which the securities of the Party making the announcement (or any of its Affiliates) are listed (or to which an application for listing has been submitted), the Party whose announcement has been reviewed

shall, except to the extent permitted to be disclosed pursuant to Section 13.2, remove any Confidential Information of the reviewing Party that the reviewing Party reasonably deems to be inappropriate for disclosure. Notwithstanding the foregoing, to the extent information regarding (y) this Agreement or its terms or (z) the Parties' activities hereunder, or any results or data arising therefrom, has already been publicly disclosed, each Party (other than a Party that had caused such information to become publicly disclosed in breach of this ARTICLE 13) may subsequently disclose substantially the same information to the public without the consent of the other Party and without prior notice, and, with respect to clause (z), to the extent that any Third Party would be able to make such disclosure; provided that such information remains accurate as of such time and provided the frequency and form of such disclosure are reasonable.

<u>Publications</u>. Subject to the remainder of this Section 13.7 and subject to Section 17.4, (a) neither Party nor its Affiliates shall make any publication or public disclosure regarding a Research Compound, Research Product, Selected Research Compound, Selected Research Product, Licensed Compound, Licensed Product, or the Exploitation activities conducted by either Party under this Agreement, and (b) Voyager shall not make any publication or public disclosure regarding an AbbVie Designated Antibody, in each case ((a) and (b)), without the prior written consent of the other Party, except as expressly permitted in Section 13.3, Section 13.4 or Section 13.6; provided that from and after the License Option Effective Date, AbbVie shall be free to publish or publicly disclose the results of and information specifically related to any Licensed Compound or Licensed Product or the components thereof. The Party that desires to publish in accordance with the immediately preceding sentence shall provide the other Party with a copy of any proposed abstract, manuscript, or presentation no less than [\*\*] prior to its intended submission for publication. The reviewing Party shall respond in writing promptly and in no event later than [\*\*] after receipt of the proposed publication, which may include one (1) or more of the following: (i) comments on the proposed material, which the publishing Party shall consider in good faith, (ii) a specific statement of concern based upon the need to seek patent protection or block publication if a Party reasonably determines that the proposed disclosure contains or describes intellectual property that should be maintained as a trade secret to protect (A) with respect to either Party as the disclosing Party, a Research Compound, Selected Research Compound, Research Product, Selected Research Product, Licensed Compound or Licensed Product, any Exploitation activities conducted under this Agreement or the Vectorization Technology and (B) with respect to Voyager as the disclosing Party, an AbbVie Designated Antibody, or (iii) an identification of the reviewing Party's Confidential Information that is contained in the material reviewed, which, if requested by the reviewing Party, except to the extent permitted to be disclosed pursuant to Section 13.2, Section 13.3, Section 13.4 or Section 13.6, shall be removed by the publishing Party. In the event of concern over patent protection, the publishing Party agrees not to submit such publication or to make such presentation that contains such information until the reviewing Party is given a reasonable period of time, and in no event more than [\*\*], to seek patent protection for any material in such publication or presentation that it believes is patentable. In the event of concern over whether maintaining a trade secret would be a priority, the Parties shall meet to discuss in good faith the content of the proposed publication or presentation as it relates to such trade secret, including whether the publishing Party should abandon such proposed publication or presentation in order to maintain the disclosed information as a trade secret and, if such trade secret is Vectorization Technology (except to the extent such information specifically relates to a Licensed Compound or Licensed Product or the components

thereof), the publishing Party shall remove such trade secret from such proposed publication or presentation unless otherwise agreed by the Parties.

# ARTICLE 14 REPRESENTATIONS AND WARRANTIES

- 14.1 <u>Representations and Warranties of Both Parties</u>. Each Party hereby represents and warrants to the other Party, as of the Effective Date:
- 14.1.1 such Party is duly organized, validly existing and in good standing under the Laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;
- 14.1.2 such Party has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;
- 14.1.3 this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);
- 14.1.4 the execution, delivery and performance of this Agreement by such Party do not conflict with and do not violate: (a) such Party's charter documents, bylaws or other organizational documents; (b) except as set forth on Schedule 14.1.4, in any material respect, any agreement or any provision or obligation thereof, or any instrument or understanding, oral or written, to which it is a party or by which it is bound; (c) any applicable Law; or (d) any order, writ, judgment, injunction decree, determination or award of any court, governmental body or administrative or other agency having jurisdiction over such Party;
- 14.1.5 Except as set forth on <u>Schedule 14.1.5</u>, it is not under any obligation, contractual or otherwise, to any Person that, to its Knowledge, would materially impede the diligent and complete fulfillment of its obligations hereunder;
- 14.1.6 no government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any applicable Laws currently in effect, is or will be necessary for, or in connection with, the transaction contemplated by this Agreement or for the performance by it of its obligations under this Agreement, except as may be required to obtain HSR Clearance, to conduct Clinical Trials, to conduct Manufacturing activities under this Agreement, or to seek or obtain Regulatory Approvals or Pricing Approvals; and
- 14.1.7 neither Party nor any of its Affiliates has been debarred or is subject to debarment and neither it nor any of its Affiliates will use in any capacity, in connection with the activities to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCA or who is the subject of a conviction described in such section. Each

Party agrees to inform the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its or its Affiliates' knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing services hereunder.

- Representations, Warranties and Covenants, as applicable, of Voyager. Voyager hereby represents, warrants and covenants to AbbVie, as of (a) the Effective Date, except as set forth in Schedule 14.2 attached hereto, (b) the date(s) on which AbbVie exercises a Development Option (or, in the event AbbVie does not exercise a Development Option with respect to a Research Compound, the end of the Development Option Period for such Research Compound) with respect to a Selected Research Compound and Selected Research Product, except as set forth in Schedule 14.2 attached hereto or the corresponding section of the Schedule 14.2 delivered as part of any Final Research Report(s) delivered prior to such date with respect to (i) such Selected Research Compound and Selected Research Product or (ii) any other Research Compound and corresponding Research Product for which Voyager has previously delivered a Final Research Report but for which AbbVie has not yet exercised its Development Option, and (c) the date on which AbbVie exercises the License Option (or, in the event AbbVie does not exercise the License Option, the end of the License Option Period), except as set forth in Schedule 14.2 attached hereto or the corresponding section of the Schedule 14.2 delivered as part of any Final Research Report(s) or Final Development Report(s) delivered prior to such date; provided, however, that (x) for purposes of determining the accuracy of the representations and warranties of Voyager as of each date set forth in each of (a), (b) and (c) above, the representations and warranties shall be deemed qualified only by such exceptions as are disclosed in <u>Schedule</u> 14.2 delivered as of such date and any prior version thereof, and (y) an exception made by Voyager in an updated <u>Schedule 14.2</u> may not cure a deficiency in a prior version of <u>Schedule 14.2</u>:
- 14.2.1 Voyager is entitled to grant the licenses specified herein. Except with respect to the Existing In-License Agreements as set forth on Schedule 14.2.1 and any Future Voyager In-License Agreements to the extent agreed by AbbVie pursuant to Section 6.2.2, (a) Voyager Controls all Subject IP, (b) neither Voyager nor any of its Affiliates has entered into any agreement, whether written or oral, that assigns, transfers, licenses, conveys, encumbers or otherwise grants any Third Party any rights or interest in, to or under (including by granting a covenant not to sue with respect to) Voyager's right, title or interest in or to the Subject IP in a manner that would limit AbbVie's rights under this Agreement with respect to the Subject IP (e.g., by granting a covenant not to sue or a non-exclusive license with respect thereto) or that is otherwise inconsistent with the rights granted to AbbVie under this Agreement and (c) except to the extent agreed by AbbVie pursuant to Section 6.2.2(a) or Section 6.2.2(b), the rights and obligations of the Parties hereunder are fully consistent with, and are not limited in any material respect by, the In-License Agreements, including such that the rights granted to AbbVie hereunder to intellectual property licensed pursuant to an In-License Agreement are no more restricted than the analogous rights granted to AbbVie hereunder with respect to intellectual property rights wholly owned (and not out-licensed) by Voyager or its Affiliates;

- 14.2.2 Except with respect to the Sequence of an AbbVie Designated Antibody that may be Encoded thereby (with respect to which Voyager is making no representation or warranty under this Section 14.2.2), (a) the conduct of the Research Program and the Development Program and (b) to the Knowledge of Voyager, (i) the Exploitation of the Research Compounds, Research Products, Selected Research Compounds, Selected Research Products, Licensed Compounds and Licensed Products pursuant to this Agreement and (ii) the Exploitation of the Vectorization Technology in connection with the foregoing ((a) and (b)) have not, do not and will not infringe any Patent Rights or misappropriate any materials, Know-How or other intellectual property of any Third Party;
- 14.2.3 The Research, Development, Manufacture or Commercialization of the Research Compounds, Research Products, Selected Research Compounds, Selected Research Products, Licensed Compounds or Licensed Products as contemplated herein will not be subject to any license or agreement (other than the In-License Agreements) to which Voyager or any of its Affiliates is a party;
- 14.2.4 All Voyager Background Patent Rights existing as of such date (collectively, the "Existing Patent Rights") are listed on Schedule 14.2.4 and identified as Voyager Managed Patent Rights or Third Party Managed Patent Rights. All Existing Patent Rights that are issued patents are, and all Existing Patent Rights that are patent applications, upon issuance, will be, to Voyager's Knowledge, not invalid and not unenforceable, in whole or in part. All Voyager Managed Patents, and, to Voyager's Knowledge, all Third Party Managed Patent Rights are filed and maintained properly and correctly and all applicable fees have been paid on or before any final due date for payment. The pending applications included in Voyager Managed Patent Rights and, to Voyager's Knowledge, the pending applications included in Third Party Managed Patent Rights, are being diligently prosecuted in the respective patent offices in the Territory in accordance with applicable Law. With respect to Voyager Managed Patent Rights, Voyager and its Affiliates have presented or are presenting all relevant references, documents and information of which it and the inventors, to the extent such inventors are or were employees of Voyager or any of its Affiliates, are aware to the relevant patent examiner at the relevant patent office. Schedule 14.2.4 indicates whether each Existing Patent Right is owned exclusively by Voyager or any of its Affiliates, is owned jointly by Voyager or any of its Affiliates, on the one hand, and one (1) or more Third Parties, on the other hand, or is licensed to Voyager by a Third Party. For each Existing Patent Right that is owned, but not owned exclusively, by Voyager or any of its Affiliates, or that is licensed to Voyager, Schedule 14.2.4 identifies (v) with respect to each such Existing Patent Right that is a Voyager Managed Patent Right, the Third Party owner(s) and, if applicable, the In-License Agreement pursuant to which Voyager Controls such Existing Patent Right, and (z) with respect to each such Existing Patent Right that is a Third Party Managed Patent Right, the Third Party owner(s) and, if applicable, the In-License Agreement pursuant to which Voyager Controls such Existing Patent Right. For each Existing Patent Right that is licensed, but not exclusively licensed, to Voyager, Schedule 14.2.4 indicates whether such license is non-exclusive or co-exclusive;
- 14.2.5 Complete and correct copies of (a) the image file wrappers (IFW), as that term is understood under U.S. Law but in no instance more comprehensive than a file wrapper submitted before the USPTO, relating to the prosecution, defense, maintenance, validity and enforceability of the Voyager Managed Patent Rights and (b) all Existing In-License

- All of the Existing In-License Agreements and Future Voyager In-License Agreements are listed on Schedule 14.2.6, and (a) the licenses granted to Voyager or its Affiliates in the In-License Agreements are in full force and effect and, by their terms, are sublicenseable to AbbVie as contemplated by this Agreement, (b) to Voyager's Knowledge, there are no challenges to or violation of the rights granted to Voyager or its Affiliates thereunder by any Third Party, (c) Voyager or its Affiliate, if applicable, is not in breach under any of the In-License Agreements that would reasonably be expected to give the counterparty to any such In-License Agreement the right to terminate or otherwise alter (in any way materially adverse to AbbVie) Voyager's or its Affiliates' rights or obligations under the In-License Agreement, nor, to Voyager's Knowledge, is any counterparty thereto in breach of any In-License Agreement, (d) neither Voyager nor any of its Affiliates has received any written notice of breach under any of the In-License Agreements from the counterparty thereto, (e) to Voyager's Knowledge, no facts or circumstances exist that would reasonably be expected to give rise to any such challenge, violation or breach and (f) the execution and performance of this Agreement does not constitute a material breach of any such In-License Agreement;
- 14.2.7 Neither Voyager nor any of its Affiliates has entered into any agreement, whether written or oral, that (a) assigns, transfers, licenses, conveys or otherwise encumbers (including by granting a covenant not to sue with respect to) Voyager's right, title or interest in or to, or (b) grants any Third Party any rights to or under (including rights of reference) or access to in a manner that would materially adversely impact AbbVie's rights under this Agreement, in each case ((a) and (b)), any Regulatory Filings owned by, in the possession of or under the control of Voyager or any of its Affiliates or that Voyager or its Affiliates otherwise has rights to, in each case with respect to any Research Compound, Research Product, Selected Research Compound, Selected Research Product, Licensed Compound or Licensed Product, as applicable ("Voyager Regulatory Filings");
- 14.2.8 No claim or litigation has been brought or asserted by a Third Party in writing (and Voyager has no Knowledge of any claim, whether or not brought or asserted by a Third Party in writing) alleging that (a) the issued patents in the Existing Patent Rights, or the Voyager Background Patent Rights are invalid or unenforceable, or the patent applications in the Existing Patent Rights, or the Voyager Background Patent Rights will, upon issuance, be invalid or unenforceable or (b) the conception, development, reduction to practice, disclosing, copying, making, assigning or licensing of (i) the Voyager Regulatory Filings, (ii) the Vectorization Technology, the Existing Patent Rights, the Voyager Background Know-How, the Voyager Background Patent Rights, and (iii) the Exploitation of the Vectorization Technology, the Research Compounds, Research Products, Selected Research Compounds, Selected Research Products, Licensed Compounds and Licensed Products as contemplated herein, infringes or would infringe any Patent Rights of any Person or misappropriates or would misappropriate any Know-How of any Person;
- 14.2.9 Except as described in the In-License Agreements, there are no amounts that will be required to be paid to a Third Party as a result of (a) the Exploitation of the Vectorization Technology in Voyager's conduct of the Research Program or the Development

Program or (b) the Exploitation of any Research Compound, Research Product, Selected Research Compound, Selected Research Product, Licensed Compound or Licensed Product as contemplated by this Agreement, in each case ((a) and (b)), that arise out of any agreement to which Voyager or any of its Affiliates is a party;

- 14.2.10 To Voyager's Knowledge, no Person is infringing or threatening to infringe, or misappropriating or threatening to misappropriate, the Existing Patent Rights, the Voyager Background Know-How, the Vectorization Technology or any Voyager Regulatory Filings, in each case in a manner that would affect AbbVie's rights under this Agreement;
- 14.2.11 Each of the Voyager Managed Patent Rights and, to Voyager's Knowledge, each of the Third Party Managed Patent Rights, properly identifies, or when issued will identify, each and every inventor of the claims thereof as determined in accordance with the Laws of the jurisdiction in which such Existing Patent Right is issued or such application is pending;
- 14.2.12 (a) There are no pending, and to Voyager's Knowledge, there are no alleged or threatened, (i) inter partes reviews, post-grant reviews, interferences, re-examinations or oppositions involving the Voyager Managed Patent Rights that are in or before any patent authority (or other Governmental Authority performing similar functions) or (ii) any inventorship challenges involving the Voyager Managed Patent Rights that are in or before any patent authority or other Governmental Authority, and (b) to Voyager's Knowledge, there are no pending, alleged or threatened (i) inter partes reviews, post-grant reviews, interferences, re-examinations or oppositions involving the Third Party Managed Patent Rights that are in or before any patent authority (or other Governmental Authority performing similar functions) or (ii) any inventorship challenges involving the Third Party Managed Patent Rights that are in or before any patent authority;
- 14.2.13 With respect to the Patent Rights licensed to AbbVie under Section 6.1, except to the extent any such Patent Right is in-licensed by Voyager or any of Voyager's Affiliates, all named inventors of such Patent Rights have properly assigned to Voyager (or to an Affiliate or Third Party that assigned to Voyager) each such inventor's entire right, title and interest in and to all such Patent Rights, except with respect to any Patent Right that is co-owned by Voyager or any of its Affiliates and a Third Party because the inventions Covered by such Patent Right were invented jointly by or on behalf of Voyager or any of its Affiliates, on the one hand, and such Third Party, on the other hand, in which case each such named inventor who is an employee, agent or consultant of (a) Voyager or any of its Affiliates has properly assigned such inventor's entire right, title and interest in and to such Patent Right to Voyager or its applicable Affiliate and (b) such Third Party, to Voyager's Knowledge, has properly assigned such inventor's entire right, title and interest in and to such Patent Right to such Third Party. All current and former officers, employees, agents and consultants of Voyager or any of its Affiliates who are inventors of or have otherwise contributed in a material manner to the creation or development of any Subject IP or who are or will be performing any activities with respect to the Research Program or the Development Program have executed and delivered to Voyager or such Affiliate an assignment or other agreement regarding the protection of proprietary information and the assignment to Voyager or such Affiliate of any Subject IP. To Voyager's Knowledge, no current officer, employee, agent or consultant of Voyager or any of its Affiliates is in violation of

any term of any assignment or other agreement regarding the protection of Patents or other intellectual property or proprietary information of Voyager or such Affiliate;

- 14.2.14 To Voyager's Knowledge, the inventions claimed by the Existing Patent Rights (a) were not conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof and (b) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(e) and (c) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§ 200-212, as amended, as well as any regulations promulgated pursuant thereto, including in 37 C.F.R. part 401;
- 14.2.15 Voyager has made available to AbbVie (a) all Voyager Regulatory Filings (and any documentation or correspondence, including conversation logs, relating to or supporting such Regulatory Filings), and (b) all Voyager Background Know-How regarding the safety or efficacy of any Research Compounds and Research Products that are the subject of the applicable Final Research Report, or any Selected Research Compounds or Selected Research Products that are the subject of the applicable Final Development Report being delivered by Voyager, in each case ((a) and (b)) in Voyager's possession or Control;
- 14.2.16 Voyager and its Affiliates have generated, prepared, maintained and retained all Voyager Regulatory Filings that are required to be maintained or retained pursuant to and in accordance with good laboratory and clinical practice and applicable Law and all such information is complete and correct and what it purports to be, in each case in all material respects;
- 14.2.17 Voyager and its Affiliates have conducted, and its and their respective contractors and consultants have conducted, all Development of the Research Compounds, Research Products, Selected Research Compounds, Selected Research Products, Licensed Compounds and Licensed Products, including any and all preclinical and clinical studies related to the Research Compounds, Research Products, Selected Research Compounds, Selected Research Products, Licensed Compounds and the Licensed Products, in accordance with good laboratory and clinical practice, to the extent applicable, and all applicable Law, in each case in all material respects;
- 14.2.18 Neither Voyager nor any of its Affiliates, nor any of its or their respective officers, employees or agents, has (a) committed an act, (b) made a statement or (c) failed to act or make a statement that, in any case ((a), (b) and (c)), that (x) would be or create an untrue statement of material fact or fraudulent statement to the FDA or any other Governmental Authority with respect to the Exploitation of the Research Compounds, Research Products, Selected Research Compounds, Selected Research Products, Licensed Compounds or the Licensed Products or (y) could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory;

- 14.2.19 Each Final Research Report and Final Development Report is complete and correct in all material respects;
  - 14.2.20 All information, concepts and constructs included in the [\*\*]; and
- 14.2.21 Voyager has not, and without AbbVie's prior written consent Voyager shall not, agree to include Alpha-Synuclein as a Target on the Potential Target List (as such terms are defined in the [\*\*]) under the [\*\*].

provided that, notwithstanding the foregoing, (a) the representations and warranties made by Voyager as of the Effective Date do not include representations and warranties with respect to Research Compounds, Research Products, Selected Research Compounds, Selected Research Products, Licensed Compounds or Licensed Products, and (b) the representations and warranties made by Voyager as of the date on which AbbVie exercises a Development Option (or, in the event AbbVie does not exercise a Development Option with respect to a Research Compound, the end of the Development Option Period for such Research Compound) do not include representations and warranties with respect to (i) any Selected Research Compounds, Selected Research Products, Licensed Compounds and Licensed Products, (ii) any Research Compound for which Voyager has not delivered a Final Research Report.

# 14.3 <u>Mutual Covenants</u>. Each Party hereby covenants to the other Party that:

- Research activities, Development activities, Manufacturing activities or regulatory activities for such Party under this Agreement and who conceive, discover, develop or otherwise make any Know-How or Patent Rights by or on behalf of such Party or its Affiliates or its or their (sub)licensees/Sublicensees in connection with this Agreement to be under an obligation to assign (or, to the extent such Party is unable to cause such Person to agree to such assignment obligation, to use Commercially Reasonable Efforts to obtain an exclusive license or, to the extent such Party is unable to cause such Person to agree to such exclusive license despite such Party's using Commercially Reasonable Efforts to negotiate such exclusive license, to use Commercially Reasonable Efforts to obtain a non-exclusive license under) their rights in any Know-How or Patent Rights resulting therefrom to such Party, except where applicable Law requires otherwise and except in the case of governmental, not-for-profit and public institutions that have standard policies against such an assignment (in which case a suitable license, or right to obtain such a license, shall be obtained);
- 14.3.2 in performing its obligations or exercising its rights under this Agreement, such Party, its Affiliates, and its and their (sub)licensees/Sublicensees, shall comply with applicable Law in all material respects; and
- 14.3.3 such Party will not grant any license relating to the Voyager Background IP, Collaboration IP or Joint IP (if such Party is Voyager) or the AbbVie Background IP, AbbVie Designated Antibody IP, Collaboration IP or Joint IP (if such Party is

Additional Covenants of Voyager. From and after the Effective Date, Voyager shall not, and shall cause its Affiliates not to, (a) misappropriate any Know-How of a Third Party in connection with the Research of the Research Compounds and Research Products or Development of the Selected Research Compounds, Selected Research Products, Licensed Compounds and Licensed Products, (b) subject to Section 6.2, enter into any agreement, whether written or oral, with respect to, any Research Compounds, Research Products, Selected Research Compounds, Selected Research Products, Licensed Compounds or Licensed Products that is inconsistent with or otherwise diminishes the rights and licenses granted to AbbVie and its Affiliates hereunder or otherwise assign, transfer, license, convey or otherwise encumber (including by granting any covenant not to sue with respect to) any Research Compound, Research Product, Selected Research Compound, Selected Research Product, Licensed Compound or Licensed Product, (c) use any funds from the federal government of the United States or any agency thereof to fund, directly or indirectly, any Research or Development activities hereunder, in whole or in part or (d) until the exercise of the License Option, otherwise commit any act or permit the occurrence of any omission that would cause any of the representations and warranties of Section 14.2.1, Section 14.2.2, Section 14.2.3, Section 14.2.4, Section 14.2.5, Section 14.2.6, Section 14.2.7, Section 14.2.9, Section 14.2.11, Section 14.2.13, Section 14.2.15, Section 14.2.16, Section 14.2.17 or Section 14.2.18 to be untrue or materially misleading as of the date such representations and warranties are made hereunder absent any disclosures set forth on Schedule 14.2 that are delivered as part of any Final Research Report or Final Development Report.

# 14.5 <u>Additional Representations and Warranties with respect to the AbbVie Designated Antibody.</u>

14.5.1 AbbVie hereby represents and warrants to Voyager, with respect to the AbbVie Designated Antibodies, that (a) AbbVie had the right to provide samples of the AbbVie Designated Antibodies to Voyager and (b) to AbbVie's Knowledge, Voyager's Exploitation of the AbbVie Designated Antibodies in performing its activities under the Research Program and the Development Program, as applicable, will not infringe or misappropriate any AbbVie Affiliate's or Third Party's intellectual property rights.

### 14.6 Data Privacy and Security.

14.6.1 For purposes of this Section 14.6, "<u>Data Subject</u>", "<u>Personal Data</u>", and "<u>Processing</u>" will be construed in accordance with the EU General Data Protection Regulation 2016/679. AbbVie and Voyager agree that, for purposes of Data Protection Laws, each of AbbVie and Voyager are independent data controllers. For all Personal Data collected, Processed, hosted, or transmitted in performance of this Agreement by or on behalf of Voyager, including the conduct of the Phase 1 Clinical Trials and the preparation and transmission of the Final Development Report(s), Voyager shall, with respect to such Personal Data:

- (a) Process the Personal Data in accordance with Data Protection Laws and only for purposes compatible with this Agreement, except to the extent AbbVie or Voyager has obtained consent from the relevant Data Subject with respect to any new purpose for Processing or such purpose is otherwise compliant with Data Protection Laws;
  - (b) comply at all times in all material respects with the applicable Data Protection Laws;
- (c) to the extent permitted by applicable Law, notify AbbVie, as soon as practicable and in any event prior to making the relevant disclosure, if it is obliged to make a disclosure of the Personal Data under any statutory requirement, other than a disclosure otherwise required or permitted under this Agreement;
- (d) make timely notification to, and obtain any necessary authorizations from, any relevant data protection regulator where required under applicable Data Protection Laws with respect to its collection and other Processing of Personal Data in order to comply with its obligations under this Agreement;
- (e) at all times, act in a manner so as to minimize, to the extent permissible under Law, any prohibition or restriction that (i) prevents or materially restricts it from disclosing or transferring the Personal Data to AbbVie as required under this Agreement; or (ii) prevents or restricts either Party from Processing such Personal Data as envisaged under this Agreement. If Voyager becomes aware of any circumstances that it believes, acting reasonably, may give rise to such a prohibition or material restriction, it shall promptly notify AbbVie of the same and take all reasonable steps, including following AbbVie's reasonable instructions and as otherwise set forth in Section 14.6.2, to ensure that it reasonably minimizes any impact on its performance of its obligations under this Section 14.6:
- (f) ensure that all fair Processing or informed consent notices that are required by applicable Data Protection Laws have been obtained and are maintained and are sufficient in scope to enable Voyager to Process the Personal Data as required in order to comply with its obligation under this Agreement (including the transfer of all applicable Personal Data to AbbVie), in each case, in accordance with the Data Protection Laws;
- (g) implement and maintain reasonable administrative, technical, and physical safeguards designed to (i) maintain the security and confidentiality of the Personal Data; (ii) protect against reasonably anticipated threats or hazards to the security or integrity of the Personal Data; and (iii) protect against unauthorized access to or use of Personal Data; and
- (h) to the extent permitted by applicable Law, notify AbbVie promptly, and in any event within [\*\*] of receipt of (i) any correspondence from a data protection regulator in relation to the Processing of Personal Data related to this Agreement, or (ii) a written request or notice from a data subject exercising his rights under the Data Protection Laws, including to access, rectify or delete his Personal Data in relation to the Personal Data Processed under this Agreement.
- 14.6.2 <u>Data Export</u>. In the event Voyager needs to transfer Personal Data collected, Processed, hosted, or transmitted in performance of this Agreement that relates to

individuals who reside in any country in the EEA to an entity in a Third Country, unless such transfer is to a country that the European Commission has decided from time to time ensures an adequate level of protection in accordance with European Data Protection Laws, Voyager shall, to the extent that appropriate safeguards are required by applicable Data Protection Laws with respect to such transfer, enter into then-applicable standard contractual clauses or other required agreements under applicable Law with the relevant data importer or comply with other appropriate safeguards under applicable Law (including pursuant to an approved transfer mechanism under European Data Protection Laws (such as the EU Standard Contractual Clauses)); provided that, if requested by either Party, the Parties shall use good faith efforts to enter into an agreement containing EU Standard Contractual Clauses to permit such transfer in accordance with this Section 14.6.2. The Parties agree that if such standard contractual clauses are invalidated or amended in any way, the Parties will negotiate with such data importer a reasonable change, or otherwise comply with appropriate safeguards as required to ensure that such EEA Personal Data transfers continue to be conducted in accordance with applicable Data Protection Laws.

- 14.6.3 <u>Security Breach Notification</u>. Voyager shall promptly and without unreasonable delay notify AbbVie upon learning of any actual or suspected misappropriation or unauthorized access to, or disclosure or use of, Personal Data collected, Processed, hosted, or transmitted by Voyager in performance of this Agreement (a "<u>Data Breach</u>"). Voyager shall promptly investigate each Data Breach that it becomes aware of or has reason to suspect may have occurred and, in the case of an actual Data Breach, shall reasonably cooperate with AbbVie in connection with any independent investigation that AbbVie may desire to conduct with respect to such Data Breach. Voyager shall reasonably cooperate with AbbVie in identifying any reasonable steps that should be implemented to limit, stop or otherwise remedy any actual or suspected Data Breach.
- 14.7 <u>Disclaimer</u>. Except as otherwise expressly set forth in this Agreement, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY THAT ANY PATENT RIGHTS ARE VALID OR ENFORCEABLE, AND EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.
- 14.8 Anti-Bribery and Anti-Corruption Compliance. Each Party represents, warrants, and covenants to the other Party in connection with this Agreement that such first Party and its Affiliates (a) have complied and will comply with all applicable laws, rules, regulations and industry codes governing bribery, money laundering, and other corrupt practices and behavior (including, as applicable, the U.S. Foreign Corrupt Practices Act and UK Bribery Act), and (b) will not, directly or indirectly, offer, give, pay, promise to pay, or authorize the payment of any bribes, kickbacks, influence payments, or other unlawful or improper inducements to any Person in whatever form (including gifts, travel, entertainment, contributions, or anything else of value). AbbVie may terminate this Agreement in its entirety immediately on five (5) Business Days' written notice to Voyager in the event that AbbVie receives any information which it in good faith determines, in its sole discretion, to be evidence of an actual, alleged or potential breach by

Voyager or its Affiliates of any representation, warranty, or covenant provided in this Section 14.8; <u>provided</u> that, to the extent permitted by applicable Law and the instructions of any applicable Governmental Authority, such notice shall set forth AbbVie's basis for such termination and AbbVie shall discuss such basis with Voyager in good faith during such five (5) Business Day-period. In the event of such termination, AbbVie shall have no liability to Voyager for any charges, fees, reimbursements, or other compensation or claims under this Agreement, including for services previously performed, other than any payment obligation to Voyager that has accrued prior to such termination, including any payment obligations under ARTICLE 10.

# ARTICLE 15 INDEMNIFICATION; INSURANCE

- 15.1 <u>Indemnification by AbbVie</u>. Subject to Section 15.3, AbbVie shall indemnify, hold harmless and defend Voyager and its Affiliates, and its or their respective directors, officers, employees, and agents, from and against any and all liabilities, damages, losses, costs and expenses, including the reasonable fees of attorneys and other professional advisors (collectively, "<u>Losses</u>"), to the extent arising out of or resulting from any suits, investigations, claims, actions, proceedings or demands of Third Parties ("<u>Third Party Claims</u>") arising from or occurring as a result of:
- 15.1.1 the negligence, recklessness or willful misconduct of AbbVie, any of its Affiliates or any Sublicensee, or its or their respective directors, officers, employees, or agents, in connection with performance by or on behalf of AbbVie of AbbVie's obligations or exercise of AbbVie's rights under this Agreement;
- 15.1.2 any breach of this Agreement, including any representation or warranty or covenant, by AbbVie; or
- 15.1.3 the Exploitation conducted by or on behalf of AbbVie, any of its Affiliates or any Sublicensees of any Licensed Compound or Licensed Product (excluding Research, or Development or Manufacturing carried out by Voyager hereunder), including (a) any product liability, personal injury, property damage or other damage, and (b) infringement of any Patent Rights or other intellectual property rights of any Third Party, except any such infringement that arises from or relates to the Exploitation of any Vectorization Technology or any Voyager Background IP related to Vectorization Technology;

<u>except</u>, in each case (Section 15.1.1, Section 15.1.2 and Section 15.1.3), to the extent that Voyager has an obligation to indemnify AbbVie for Losses pursuant to Section 15.2, as to which Losses each Party shall indemnify the other to the extent of their respective liability for such Losses.

15.2 <u>Indemnification by Voyager</u>. Subject to Section 15.3, Voyager shall indemnify, hold harmless and defend AbbVie and its Affiliates, and its or their respective directors, officers, employees and agents, from and against any and all Losses to the extent arising out of or resulting from any Third Party Claims arising from or occurring as a result of:

- 15.2.1 the negligence, recklessness or willful misconduct of Voyager or any of its Affiliates or subcontractors, or its or their respective directors, officers, employees, or agents, in connection with performance by or on behalf of Voyager of Voyager's obligations or exercise of Voyager's rights under this Agreement;
- 15.2.2 any breach of this Agreement, including any representation or warranty or covenant, by Voyager;
- 15.2.3 (a) the Research or Manufacturing of Research Compounds or Research Products conducted by or on behalf of Voyager prior to the Effective Date or during the Voyager Research Period or (b) the Development or Manufacturing of Selected Research Compounds or Selected Research Products conducted by or on behalf of Voyager prior to the Effective Date or during the Voyager Development Period (in each case of (a) and (b), excluding any activities carried out by AbbVie or its Affiliate under a Plan), including (i) any product liability, personal injury, property damage or other damage, and (ii) infringement of any Patent Rights or other intellectual property rights of any Third Party; or
- 15.2.4 the infringement of any Patent Rights or other intellectual property rights of any Third Party by the Exploitation conducted by or on behalf of AbbVie, any of its Affiliates or any Sublicensees of any Licensed Product in or for the Territory that arises from or relates to any Vectorization Technology or Voyager Background IP related to Vectorization Technology;

<u>except</u>, in each case (Section 15.2.1, Section 15.2.2, Section 15.2.3 and Section 15.2.4), to the extent that AbbVie has an obligation to indemnify Voyager for Losses pursuant to Section 15.1.1, as to which Losses each Party shall indemnify the other to the extent of their respective liability for such Losses.

## 15.3 Procedure.

- 15.3.1 <u>Notice</u>. All indemnification claims in respect of a Party, its Affiliates, or its or their respective directors, officers, employees and agents (each, an "<u>Indemnitee</u>") shall be made solely by such Party (the "<u>Indemnified Party</u>"). The Indemnified Party shall give prompt written notification (an "<u>Indemnification Claim Notice</u>") to the Party from whom indemnification is sought (the "<u>Indemnifying Party</u>") of the commencement of any Third Party Claim for which indemnification may be sought or, if earlier, upon the assertion of any such Third Party Claim (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Third Party Claim as provided in this Section 15.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except that in no event shall the Indemnifying Party be liable for any Losses that result from any delay in providing such notice). The Indemnified Party shall furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Third Party Claims, including any Losses with respect thereto.
- 15.3.2 <u>Control of Defense</u>. Subject to Section 12.3.5 and Section 12.5.2, within [\*\*] after receipt of an Indemnification Claim Notice, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Third Party Claim with counsel reasonably selected by the Indemnifying Party. The assumption of the

defense of a Third Party Claim by the Indemnifying Party shall not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify the Indemnified Party or its Indemnitees in respect of such Third Party Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against the Indemnified Party's or its Indemnitees' claim for indemnification. In the event the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party or any of its Indemnitees in connection with the Third Party Claim. If the Indemnifying Party assumes the defense of a Third Party Claim, except as provided in Section 15.3.3, the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party or any of its Indemnitees in connection with the analysis, defense or settlement of such Third Party Claim unless specifically requested in writing by the Indemnifying Party. In the event that it is ultimately determined that the Indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party or its Indemnitees from and against the Third Party Claim, the Indemnified Party shall reimburse the Indemnifying Party for any and all reasonable and verifiable Losses incurred by the Indemnifying Party in its defense of the Third Party Claim. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense and, without limiting the Indemnifying Party's indemnification obligations, the Indemnifying Party shall reimburse the Indemnified Party for all reasonable and verifiable Losses incurred by the Indemnified Party in defending any Third Party Claim on a Calendar Quarter basis, within [\*\*] after receipt of any invoice therefor from the Indemnified Party.

- 15.3.3 <u>Right to Participate in Defense</u>. The Party not controlling such defense of any such Third Party Claim may, at its sole cost and expense, participate therein and may employ counsel of its choice for such purpose; <u>provided</u>, <u>however</u>, that, the Indemnifying Party shall pay such costs and expenses of the Indemnified Party if (a) the employment thereof has been specifically authorized in writing by the Indemnifying Party, (b) the Indemnifying Party has failed to assume the defense and employ counsel and the Indemnified Party controls the defense in accordance with Section 15.3.2 or (c) the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such Third Party Claim such that the representation by the same counsel of both Parties and any respective Indemnitees is prohibited under applicable Law, ethical rules or equitable principles.
- 15.3.4 <u>Settlement.</u> With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the applicable Indemnitee's becoming subject to injunctive or other relief or otherwise adversely affecting the business of the applicable Indemnitee in any manner and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify the applicable Indemnitee hereunder, the Indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all Losses in connection with Third Party Claims, (a) the Party controlling the defense (whether or not the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 15.3.2) shall not consent to the entry of any judgment, agree to any settlement or otherwise dispose of such Loss that would result in the other Party or its Affiliates (or Indemnitees, if applicable) becoming subject to injunctive or other relief or otherwise adversely

affecting the business of the other Party or any of its Affiliates (or Indemnitees, if applicable) in any manner without the prior written consent of the other Party, which consent shall not be unreasonably withheld, delayed or conditioned, and (b) the Party not controlling the defense shall not consent to the entry of any judgment, agree to any settlement or otherwise dispose of such Loss without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed.

15.3.5 <u>Cooperation</u>. The Party controlling such defense shall keep the other Party advised of the status of such Third Party Claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto. The Party not controlling the defense of any Third Party Claim shall, and if the Indemnifying Party controls such defense, the Indemnified Party shall cause each Indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party and, if applicable, the Indemnified Party (if it is controlling the defense), to, and reasonable retention by the other Party and the Indemnitees of, records and information that are reasonably relevant to such Third Party Claim and making Indemnitees and other employees and agents, as applicable, available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable and verifiable out-of-pocket expenses in connection therewith.

### 15.4 <u>Insurance</u>.

15.4.1 Voyager's Insurance Obligations. Voyager shall maintain, at its cost, insurance against liability and other risks associated with its activities and obligations under this Agreement, including (a) any insurance policy that is required by any applicable Law that may govern or have jurisdiction over any provision of this Agreement, (b) Clinical Trial Insurance with a minimum limit of [\*\*] Dollars (\$[\*\*]) in the aggregate (which policy shall be maintained in compliance with any and all local requirements in any territory in which Clinical Trials are conducted), and (c) Network Liability/Cyber Liability Insurance with a minimum limit of [\*\*] Dollars (\$[\*\*]) in the aggregate (which policy shall specifically cover (i) breaches of security, (ii) breaches of privacy, (iii) violation of federal, state, or foreign security or privacy laws or regulations, including investigative and notification costs, (iv) data theft, damage, destruction, deletion, or corruption, including unauthorized access, unauthorized use, identity theft, theft of personally identifiable information, personal health information or confidential corporate information, transmission of a computer virus or other type of malicious code and (v) participation in a denial of service attack on a Third Party). All such insurance (x) shall be primary insurance with respect to Voyager's participation under this Agreement, (y) shall be issued by a recognized insurer rated by A.M. Bests "A-IX" (or its equivalent), and (z) with respect to the coverage described in clause (b), shall list AbbVie as an additional insured thereunder. Voyager shall furnish to AbbVie certificates evidencing such insurance within [\*\*] after the Effective Date and following each renewal or replacement period. The foregoing policies of Voyager shall be primary to any liability insurance carried by AbbVie, which AbbVie insurance shall be excess and non-contributory for claims and losses arising out of the performance by Voyager of any of its obligations under this Agreement. Such policies shall remain in effect throughout the Term and shall not be canceled, not renewed or materially changed without the prior authorization of the AbbVie. Maintenance of such insurance coverage shall not relieve Voyager of any responsibility under this Agreement for damages in excess of insurance limits or otherwise.

- 15.4.2 <u>AbbVie's Insurance Obligations</u>. AbbVie hereby represents and warrants to Voyager that it is self-insured against liability and other risks associated with its and its Affiliates' and any Sublicensees' activities and obligations under this Agreement, including Clinical Trials (sponsored by AbbVie in any territory or jurisdiction where such coverage is required), the Exploitation of Licensed Products and AbbVie's indemnification obligations hereunder, in such amounts and on such terms as are (a) reasonably, normal and customary for large pharmaceutical companies in the pharmaceutical industry for the activities to be conducted by it under this Agreement, and (b) otherwise required by applicable Law. AbbVie shall furnish to Voyager evidence of such self-insurance upon request.
- 15.5 <u>Limitation of Liability</u>. EXCEPT (A) FOR A BREACH OF ARTICLE 11 OR ARTICLE 13, OR (B) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY FOR CLAIMS THAT ARE SUBJECT TO INDEMNIFICATION UNDER THIS ARTICLE 15, NEITHER VOYAGER NOR ABBVIE, NOR ANY OF THEIR RESPECTIVE AFFILIATES, LICENSORS, LICENSEES, (SUB)LICENSEES/ SUBLICENSEES OR SUBCONTRACTORS, SHALL BE LIABLE TO THE OTHER PARTY, ITS AFFILIATES OR SUBLICENSEES FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES OR LOST PROFITS OR ROYALTIES, LOST DATA OR COST OF PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY OR CONTRIBUTION, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE.

# ARTICLE 16 TERM AND TERMINATION

16.1 Term. This Agreement shall commence as of the Effective Date and, unless terminated earlier, this Agreement shall continue in full force and effect until the first to occur of: (a) the expiration of the Development Option Period, if AbbVie does not exercise the Development Option; (b) the expiration of the License Option Period, if AbbVie exercises the Development Option but does not exercise the License Option; and (c) the expiration of the last to expire Royalty Term with respect to all Licensed Products in all countries (the "Term"). Following the expiration of the Royalty Term for a Licensed Product in a country, the grants in Section 6.1 shall become unrestricted, fully-paid, royalty-free, perpetual and irrevocable for such Licensed Product in such royalty-free, perpetual and irrevocable in their entirety.

### 16.2 <u>Termination</u>.

### 16.2.1 <u>Termination for Cause</u>.

- (a) This Agreement may be terminated at any time upon written notice by either Party if the other Party is in material breach of its obligations hereunder and has not cured such breach within [\*\*] in the case of a payment breach, or within [\*\*] in the case of all other breaches, after the date on which the non-breaching Party provided written notice to the breaching Party of such breach in accordance with Section 17.7, which notice shall reference this Section 16.2.1 and shall specify the non-breaching Party's intent to terminate this Agreement if such breach is not cured (such period, the "Cure Period"); provided that (i) if such breach (other than a payment breach) cannot be cured within the Cure Period, such termination shall not become effective so long as the breaching Party commences actions to cure such breach within the Cure Period and thereafter diligently continues such actions, (ii) with respect to any alleged breach by AbbVie of its diligence obligations set forth in Section 7.3.2, Voyager shall first provide written notice thereof to AbbVie and the Executive Officers shall meet, by phone or in person, within [\*\*] after delivery of such notice to AbbVie to discuss in good faith such alleged breach, which discussions (unless AbbVie's Executive Officer fails to participate in such discussion) must occur before Voyager may issue any notice of termination with respect to such alleged breach (for clarity, neither Party may unilaterally extend such [\*\*] period and the Cure Period shall not commence prior to the conclusion or termination by either Party of such good faith discussions and the subsequent issuance of a notice of termination by Voyager) and (iii) if either Party initiates a dispute resolution procedure under Section 17.2 at any time during the Cure Period to resolve the dispute regarding the material breach for which termination is being sought and is diligently pursuing such procedure, the Cure Period set forth in this Section 16.2.1(a) shall be tolled and the termination shall become effective only if such breach remains uncured for [\*\*] after the final resolution of the dispute through such dispute resolution procedure (or, with respect to a breach other than a payment breach, if such breach cannot be cured within such [\*\*]-period, the termination shall become effective only if the breaching Party has not commenced actions to cure such breach within the [\*\*]-period or thereafter fails to diligently continue such actions). It is understood that termination pursuant to this Section 16.2.1 shall be available as a remedy of last resort and may be invoked only in the case where the breach is not reasonably expected to be remedied by the payment of money damages or other available relief (e.g., an injunction).
- (b) Notwithstanding clause (a), if the material breach and failure to cure contemplated by clause (a) is with respect to AbbVie's diligence obligations under Section 7.3.2 with respect to the United States, one (1) or more Major European Markets or Japan, but not the United States, all of the Major European Markets and Japan, Voyager shall not have the right to terminate this Agreement in its entirety, but shall have the right to terminate this Agreement solely with respect to such country(ies), and this Agreement shall remain in full force and effect with respect to all other countries.
- 16.2.2 <u>Challenges of Patent Rights</u>. If, during the Term, AbbVie or any of its Affiliates (a) commences or participates as a party in any claim, demand, action or proceeding before any administrative or regulatory body (including any patent opposition, re-examination or invalidation proceeding), or otherwise asserts any claim, challenging the validity or

any of its Affiliates or Sublicensees under this Agreement, Collaboration Patent Right or Joint Patent Right, or any claim thereof, or (b) actively assists any Person in bringing, prosecuting or participating in any claim, demand, action or proceeding before any administrative or regulatory body (including any patent opposition, re-examination or invalidation proceeding) challenging the validity or enforceability of any such Voyager Background Patent Right. Collaboration Patent Right or Joint Patent Right, or any claim thereof (each of (a) and (b), a "Patent Challenge"), then, to the extent permitted by Law and except as otherwise set forth in this Section 16.2.2, Voyager shall have the right, in its sole discretion, to terminate this Agreement upon at least twenty (20) days prior written notice to AbbVie; provided that Voyager shall not have the right to terminate this Agreement if AbbVie and each of its Affiliates, as applicable, withdraws or causes to be withdrawn all such Patent Challenges (or in the case of *ex-parte* proceedings, multi-party proceedings, or other Patent Challenges that AbbVie or such Affiliate does not have the power to unilaterally withdraw or cause to be withdrawn, AbbVie and each of its Affiliates, as applicable, ceases actively assisting any Person with respect to such Patent Challenge and, to the extent AbbVie or any of its Affiliates, is a party to such Patent Challenge, it withdraws from such Patent Challenge) within twenty (20) days after Voyager provides AbbVie notice regarding such Patent Challenge. Notwithstanding the foregoing, nothing in this Section 16.2.2 shall: (i) prevent AbbVie or its Affiliates from asserting any defense or counterclaim in, or otherwise responding to, an action for infringement of intellectual property in a court proceeding or in an administrative or regulatory proceeding against AbbVie or any of its Affiliates brought by, or, with respect to administrative or regulatory proceedings, triggered by the actions of, Voyager or any of its Affiliates or its or their sublicensees; or (ii) allow Voyager to terminate this Agreement if AbbVie or its Affiliates assert their rights as provided in clause (i). In addition, notwithstanding the foregoing, Voyager shall not have the right to terminate this Agreement pursuant to this Section 16.2.2 if any Affiliate that first becomes an Affiliate of AbbVie after the Effective Date was undertaking activities in connection with a Patent Challenge prior to such Affiliate first becoming an Affiliate of AbbVie if AbbVie causes such Patent Challenge to be withdrawn (or in the case of exparte proceedings, multi-party proceedings, or other Patent Challenges that such Affiliate does not have the power to unilaterally withdraw or cause to be withdrawn, such Affiliate ceases actively assisting any Person with respect to such Patent Challenge and, to the extent such Affiliate is a party to such Patent Challenge, it withdraws from such Patent Challenge) within [\*\*] of the later of (x) the date such Affiliate first becomes an Affiliate of AbbVie and (y) the date Voyager provides AbbVie notice regarding such Patent Challenge.

enforceability of any Voyager Background Patent Right that Covers a Licensed Product as Exploited by AbbVie or

- 16.2.3 <u>Termination by AbbVie</u>. AbbVie may terminate this Agreement (a) in its entirety at any time, or (b) with respect to one (1) or more countries in the Territory, on a country-by-country basis, after the License Option Effective Date, in each case ((a) and (b)), for any or no reason, upon one hundred eighty (180) days' prior written notice to Voyager.
- 16.2.4 <u>Termination for Infeasibility</u>. The Parties may terminate this Agreement in its entirety as set forth in Section 2.2.4(a) or Section 3.2.4(c).
- 16.2.5 <u>Termination for Insolvency</u>. In the event that either Party (or a parent of such Party) (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or

trustee over substantially all of its property that is not discharged within [\*\*] after such filing, (d) proposes a written agreement of composition or extension of its debts, (e) proposes or is a party to any dissolution or liquidation, (f) files a petition under any bankruptcy or insolvency Law or has any such petition filed against it that is not discharged within sixty (60) days of the filing thereof or (g) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

- 16.2.6 <u>Termination for Anti-Bribery or Anti-Corruption Non-Compliance</u>. AbbVie may terminate this Agreement in accordance with Section 14.8.
- 16.2.7 Termination for Failure or Delay to Obtain HSR Clearance. This Agreement shall terminate (a) upon notice given by AbbVie to Voyager in the event that AbbVie shall receive a Second Request and AbbVie delivers notice of termination within ten (10) Business Days after receipt of the Second Request, (b) upon notice given by one Party to the other Party in the event that the Effective Date has not occurred within one hundred eighty (180) days after the date on which the HSR Filing is made and such Party delivers notice of termination within fifteen (15) Business Days after the end of such one hundred eighty (180)-day period; provided, however, that if as of the end of such one hundred eighty (180)-day period AbbVie is pursuing HSR Clearance (whether by responding to a Second Request or through litigation or any other proceeding, whether judicial or administrative in nature (including an HSR Proceeding)) and AbbVie has provided written notice thereof to Voyager during such fifteen (15)-Business Day period, then Voyager shall not then have the right to terminate this Agreement pursuant to this clause (b) but may terminate this Agreement upon written notice to AbbVie in the event that the Effective Date has not occurred within three hundred sixty-five (365) days after the date on which the HSR Filing is made, provided that Voyager gives AbbVie written notice thereof within fifteen (15) Business Days after the end of such three hundred sixty-five (365)-day period, or (c) upon notice given by one Party to the other Party if no further legal recourse is possible to obtain HSR Clearance.
- 16.2.8 <u>AbbVie's Failure to Pay the Initial Fee</u>. Notwithstanding Section 16.2.1(a), if AbbVie does not pay Voyager the Initial Fee within fifteen (15) Business Days after the Effective Date, then, unless otherwise agreed by the Parties, this Agreement shall automatically terminate.
- 16.3 <u>Modification In Lieu of Termination</u>. If, at any time during the Term, AbbVie has the right to terminate this Agreement pursuant to Section 16.2.1 or Section 16.2.5, then AbbVie may, by written notice to Voyager, elect to continue this Agreement as modified by this Section 16.3, in which case, effective as of the date AbbVie delivers such notice of such election to Voyager:
- 16.3.1 the royalties payable by AbbVie to Voyager pursuant to Section 10.3.1 with respect to any Net Sales thereafter shall be equal to [\*\*] percent ([\*\*]%) of the applicable rate;

- 16.3.2 the amount of any Milestone Payments payable by AbbVie to Voyager pursuant to Section 10.2 for any Milestone Event achieved thereafter shall be reduced by [\*\*] percent ([\*\*]%) of the applicable amount set forth in Section 10.2;
- 16.3.3 AbbVie's exclusivity obligations under Section 11.1 and AbbVie's diligence obligations under Section 7.3.2 shall all terminate; and
- all other provisions of this Agreement shall remain in full force and effect without change.
- 16.4 <u>Effects of Termination</u>. Without limiting any other legal or equitable remedies that either Party may have under this Agreement:
  - 16.4.1 <u>Termination in its Entirety</u>. If this Agreement is terminated in its entirety:
- (a) <u>Post-Termination Licenses</u>. If this Agreement is terminated in its entirety at any time during the Term for any reason, the license grants to AbbVie in Section 6.1.1 and the license grants to Voyager in Section 6.4.1 shall terminate immediately. For clarity, each Party retains all rights under its interest in Collaboration IP and Joint IP for all purposes.
- (b) <u>Post-Termination Exclusivity</u>. If AbbVie terminates this Agreement pursuant to Section 16.2.1, Section 16.2.5 or Section 16.2.6 at any time, Voyager's obligations under Section 11.1, Section 11.2 and Section 11.3 shall survive until the third (3rd) anniversary of such termination (except with respect to Section 11.3, which shall survive for the duration of survival specifically set forth therein). For purposes of clarity, in the event of any termination of this Agreement other than as provided in the previous sentence, Voyager's obligations under Section 11.1, Section 11.2 and Section 11.3 shall terminate (except with respect to Section 11.3, which shall survive for the duration of survival specifically set forth therein).
- (c) <u>Post-Termination Transition to AbbVie</u>. If this Agreement is terminated in its entirety for any reason prior to the License Option Effective Date:
- (i) Voyager shall as promptly as practicable transfer to AbbVie or AbbVie's designee copies of all data, reports, records and materials, and other sales and marketing related information in Voyager's (or its Affiliate's) possession and Control to the extent that such data, reports, records, materials or other information that were created pursuant to the Research Program or the Development Program and relate to the Research or Development of any Research Compound, Research Product, Selected Research Compound or Selected Research Product, as applicable, in each case, that Encodes an AbbVie Designated Antibody (each, an "ADA Compound/Product"), including all of the foregoing that are non-clinical and clinical data relating to any of such ADA Compound/Product, and all of the foregoing that are adverse event or other safety data in the possession or Control of Voyager or any of its Affiliates with respect to any ADA Compound/Product;

- (ii) At AbbVie's request, Voyager shall transfer to AbbVie possession and ownership of all of its right, title, and interest in and to all Regulatory Filings (and deliver to AbbVie any documentation or correspondence, including conversation logs, relating to or supporting such Regulatory Filings) relating to the Research or Development of any ADA Compound/Product; and
- (iii) Voyager shall, upon AbbVie's written request, destroy any inventory of ADA Compound/Product owned by, in the possession of, or under the control of, Voyager or any Affiliates as of the termination date.
- 16.4.2 <u>Termination of a Terminated Territory</u>. If this Agreement is terminated with respect to a Terminated Territory, but not in its entirety:
- (a) <u>Post-Termination Licenses</u>. The license grants to AbbVie in Section 6.1.1 shall automatically be deemed to be amended to exclude the right to Research, Develop, Commercialize, Manufacture, have Manufactured, use and otherwise Exploit the Licensed Compounds and the Licensed Products in the Field in such Terminated Territory. For clarity, each Party retains all rights under its interest in Collaboration IP and Joint IP for all purposes.
- Terminated Territory Management. AbbVie shall not, and shall not permit any of its (b) Affiliates, and shall use commercially reasonable efforts not to permit any of its and their Sublicensees or Distributors to, distribute, market, promote, offer for sale or sell any Licensed Compounds or Licensed Products directly or indirectly (A) to any Person for use in such Terminated Territory or (B) to any Person in the Territory that AbbVie or any of its Affiliates or any of its or their Sublicensees or Distributors knows is likely to distribute, market, promote, offer for sale or sell any Licensed Compound or Licensed Product for use in such Terminated Territory or assist another Person to do so; provided that if such Terminated Territory includes one (1) or more (but not all) Major European Markets, then AbbVie, its Affiliates and its and their Sublicensees and Distributors may, to the extent passive sales cannot be prohibited under applicable Law and such passive sales are made in accordance with applicable Law, passively sell any Licensed Compound or Licensed Product into other jurisdictions in the European Union and Switzerland that are in the Terminated Territory that Voyager has exclusively reserved for itself or a Third Party, but may not actively sell or promote any Licensed Compound or Licensed Product in such Terminated Territory that Voyager has exclusively reserved for itself, an Affiliate or a Third Party. If AbbVie or any of its Affiliates receives or becomes aware of the receipt by a Sublicensee or Distributor of any orders for any Licensed Compound or Licensed Product for use in such Terminated Territory, such Person shall refer such orders to Voyager. AbbVie shall cause its Affiliates and its and their Sublicensees and Distributors to notify Licensor of any receipt of any orders for any Licensed Compound or Licensed Product for use in such Terminated Territory.
  - 16.5 Accrued Rights; Surviving Provisions of this Agreement.
- 16.5.1 Termination or expiration of this Agreement either in its entirety or with respect to one (1) or more Terminated Territories for any reason shall be without prejudice

to any rights that shall have accrued to the benefit of either Party prior to such termination or expiration, including the payment obligations under ARTICLE 10, and any and all damages or remedies arising from any breach hereunder; provided that in no event shall Voyager accrue any rights to, and AbbVie shall have no obligation to make, any Milestone Payment under Section 10.2 based on any Milestone Event with respect to a Licensed Product (which, if this Agreement is terminated only with respect to one (1) or more Terminated Territories, is a Milestone Event described in Section 10.2.1(a)(iii)-(v) or Section 10.2.2(a)(iii)-(viii) achieved by such Licensed Product in the Terminated Territory, if applicable) that is achieved on or after the date of delivery by AbbVie of any termination notice pursuant to Section 16.2.1, Section 16.2.3 or Section 16.2.6; provided further that (a) if AbbVie does not pay Voyager a Milestone Payment for a Milestone Event that is achieved after delivery of a termination notice pursuant to Section 16.2.1 or Section 16.2.6 and (i) it is later determined pursuant to Section 17.2 that AbbVie was not entitled to terminate this Agreement pursuant to Section 16.2.1 or Section 16.2.6 or (ii) AbbVie rescinds the notice of termination, or (b) if AbbVie does not pay Voyager a Milestone Payment for a Milestone Event that is achieved after delivery of a termination notice pursuant to Section 16.2.3 and AbbVie rescinds the notice of termination, then, in each case (a) or (b), upon such determination or rescission AbbVie shall promptly pay such Milestone Payment to Voyager with interest pursuant to Section 10.12 from that date such Milestone Payment became due pursuant to Section 10.2.4 until the date AbbVie pays Voyager such Milestone Payment. Such termination or expiration shall not relieve either Party from obligations that are expressly indicated to survive expiration or termination of this Agreement.

16.5.2 Without limiting Section 16.5.1, the provisions of Section 4.1.2 clauses (c), (d) and (e); Section 6.1.2; Section 6.1.3; Section 6.4.2; Section 6.7; Section 6.8; Section 8.4; Section 10.8 - Section 10.12; Section 12.1.1; Section 12.1.2; Section 12.1.3; Section 13.1 - Section 13.3; Section 14.7; Section 15.1 - Section 15.3; Section 15.4 (for a period of one (1) year after the effective date of termination); Section 15.5; Section 16.4 (including the Sections referenced therein, as applicable); Section 16.5; Section 17.1; Section 17.2; Section 17.3.1; Section 17.4 (solely to the extent Section 11.3 survives); Section 17.7; Section 17.9 - Section 17.15; Section 17.17; and Section 17.18, and ARTICLE 11 (if applicable) shall survive the termination of this Agreement in its entirety or expiration of this Agreement for any reason, in accordance with their respective terms and conditions, and for the duration stated, and where no duration is stated, shall survive indefinitely.

16.5.3 Notwithstanding the termination of AbbVie's licenses and other rights under this Agreement, AbbVie and its Affiliates and Sublicensees shall have the right (to the extent consistent with applicable Law and subject to the Parties' negotiation and execution of a safety data exchange agreement and any other agreements necessary for the Parties and their Affiliates to comply with applicable Law) for [\*\*] after the effective date of such termination to sell or otherwise dispose of all Licensed Products then in its or their respective inventory and any in-progress inventory as though this Agreement had not terminated and such sale or disposition shall not constitute infringement of Voyager's or its Affiliates' Patent Rights or other intellectual property or other proprietary rights. For the avoidance of doubt, AbbVie shall continue to make payments thereon as provided in Section 10.3.

# ARTICLE 17 MISCELLANEOUS

## 17.1 <u>Governing Law; Jurisdiction and Service</u>.

- 17.1.1 <u>Governing Law.</u> This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed and enforced in accordance with the Laws of the State of Delaware without reference to conflicts of laws principles; <u>provided</u> that all questions concerning (a) inventorship and ownership of Patent Rights under this Agreement shall be determined in accordance with Section 12.1.3 and (b) the construction or effect of Patent Rights shall be determined in accordance with the Laws of the country or other jurisdiction in which the particular Patent Right has been filed or granted, as the case may be. The provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement or any subject matter hereof.
- 17.2 <u>Dispute Resolution</u>. Except for disputes resolved by the procedures set forth in Section 5.6, Section 10.9.3 or Section 17.11, if a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a "<u>Dispute</u>"), it shall be resolved pursuant to this Section 17.2.
- 17.2.1 <u>General</u>. Any Dispute shall first be referred to the Executive Officers of the Parties, who shall confer in good faith on the resolution of the issue. Any final decision mutually agreed to by the Executive Officers shall be conclusive and binding on the Parties. If the Executive Officers are not able to agree on the resolution of any such Dispute within [\*\*] (or such other period of time as mutually agreed by the Executive Officers) after such Dispute was first referred to them, then, except as otherwise set forth in Section 17.2.3, either Party may, by written notice to the other Party, elect to initiate an alternative dispute resolution ("<u>ADR</u>") proceeding pursuant to the procedures set forth in <u>Schedule 17.2.1</u> for purposes of resolving such Dispute. Subject to Section 17.2.2 and Section 17.2.3, any ADR proceeding under this Agreement shall take place pursuant to the procedures set forth in <u>Schedule 17.2.1</u>.
- 17.2.2 <u>Baseball Style Arbitration</u>. Notwithstanding Section 17.2.1, any Dispute arising under Sections 2.1.3 shall be determined according to the procedures set forth in Schedule 17.2.2.
- 17.2.3 <u>Intellectual Property Disputes</u>. Unless otherwise agreed by the Parties in writing, a Dispute between the Parties relating to the validity, scope, enforceability or inventorship of any Patent Right, Trademark or other intellectual property rights, if not resolved in accordance with Section 17.2.1, shall not be subject to ADR and shall be submitted to a court or patent office of competent jurisdiction in the relevant country in which such Patent Right was issued or, if not issued, in which the underlying patent application was filed. Each Party hereby submits to the jurisdiction of such court or patent office and irrevocably waives any assertion that the case should be heard in a different venue or forum.

- 17.2.4 <u>Adverse Ruling</u>. Any determination pursuant to this Section 17.2 that a Party is in material breach of its obligations hereunder shall specify a (nonexclusive) set of actions to be taken to cure such material breach, if feasible.
- 17.2.5 <u>Interim Relief.</u> Notwithstanding anything herein to the contrary, nothing in this Section 17.2 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction, or other interim equitable relief concerning a Dispute, if necessary to protect the interests of such Party. This Section shall be specifically enforceable.

## 17.3 Assignment.

- This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred (except to the extent provided in Section 9.3), whether by operation of law or otherwise, in whole or in part, by either Party without the written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that (a) AbbVie shall have the right, without such consent, (i) to perform any or all of its obligations under this Agreement through any of its Affiliates or Sublicensees or Distributors, (ii) to exercise any or all of its rights under this Agreement through any of its Affiliates or Sublicensees and (iii) assign any or all of its rights and delegate any or all of its obligations hereunder to any of its Affiliates or its or their Sublicensees or to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to one (1) or more Licensed Products or its business generally, and (b) either Party may, without the other Party's written consent, (i) undergo a Change of Control or (ii) assign this Agreement and its rights and obligations hereunder in whole or in part to the Acquirer in the context of a Change of Control; <u>provided</u> that the assigning Party (if it survives) or the assignee provides written notice thereof to the other Party within [\*\*] after such assignment or Change of Control. Any permitted Third Party successor of a Party or any permitted Third Party assignee of all of a Party's rights under this Agreement that has also assumed all of such Party's obligations hereunder in writing shall, upon any such succession or assignment and assumption, be deemed to be a party to this Agreement as though named herein in substitution for the assigning Party, whereupon the assigning Party shall cease to be a party to this Agreement and shall cease to have any rights or obligations under this Agreement. All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party. Any purported assignment in violation of this Section 17.3.1 shall be void. Notwithstanding any other provision of this Section 17.3.1, the terms of this Agreement may be varied, amended or modified or this Agreement may be suspended, canceled or terminated without the consent of any assignee or delegate that is not deemed pursuant to the provisions of this Section 17.3.1 to have become a party to this Agreement.
- AbbVie and Voyager each agrees that, notwithstanding any provision of this Agreement to the contrary, if Voyager or AbbVie, respectively, undergoes a Change of Control (the "Change of Control Party"), any Patent Right, Know-How or other intellectual property or other proprietary rights that are owned or otherwise controlled by the Acquirer or any of such Acquirer's Affiliates (other than the Change of Control Party and any Affiliate of the Change of Control Party that was an Affiliate of the Change of Control Party prior to such

Change of Control and any successor entity to the Change of Control Party or any such Affiliates thereof) (such Patent Rights, Know-How or other intellectual property or other proprietary rights, "Acquirer IP") shall be excluded from the licenses granted to the non-Change of Control Party under this Agreement; provided that with respect to Voyager as the Change of Control Party, such exclusion (a) shall not apply with respect to any Acquirer IP that: (i) was used by or on behalf of Voyager or any of its Affiliates in performing any of Voyager's obligations under this Agreement; (ii) is incorporated into any AbbVie Designated Antibody, Research Compound, Selected Research Compound, Research Product, Selected Research Product, Licensed Compound or Licensed Product; or (iii) until the Cut-Off Date, was generated through any use of, or access to (in more than a de minimis fashion) any Vectorization Technology, Voyager Background Know-How related to Vectorization Technology or Transferred Materials provided by AbbVie or is otherwise Covered by any Voyager Background Patent Rights related to Vectorization Technology and (b) shall not limit Voyager's obligations to disclose Voyager Manufacturing Improvements under Section 8.3.8 and shall not apply to any Acquirer IP that constitutes Voyager Manufacturing Improvements. Voyager covenants that, following a Change of Control, (x) there shall be no material change in the level or nature of efforts or resources expended by Voyager and its Affiliates with respect to, or the qualifications and experience of the personnel assigned to (including with respect to the allocation of their time to), the Research Program and the Development Program and (v) each employee of Voyager or any of its Pre-Existing Affiliates who worked on the Research Program or the Development Program during the [\*\*]-period immediately prior to the Change of Control or who would reasonably be expected to work on the Research Program or the Development Program thereafter shall continue to work on the Research Program or the Development Program, as applicable, for so long as s/he remains an employee of Voyager or any of its Affiliates.

Certain Strategic Transactions. Subject to Section 6.1.1, Section 8.4.1 and the remainder of this Section 17.4, the restrictions in Section 11.1, Section 11.2 and Section 13.7 shall not preclude (a) in the event of a Change of Control of a Party, the Acquirer or any of its Affiliates (other than such Party and any Person that was an Affiliate of the Change of Control Party prior to such Change of Control or any successor entity to such Party or any such Affiliates thereof (a "Pre-Existing Affiliate")) from Exploiting any Vectorized Alpha-Synuclein Antibody (other than a Licensed Compound or Licensed Product) or from granting any Third Party or any Affiliate (other than the Party and its Pre-Existing Affiliates) any right or licenses to do so; and (b) in the event that a Party acquires (whether by way of merger, acquisition, purchase of all or substantially all of the relevant business or assets, or otherwise) a Third Party (the "Acquired Third Party"), the Acquired Third Party from Exploiting any Vectorized Alpha-Synuclein Antibody (other than a Licensed Compound or Licensed Product) or from granting any Third Party any right or license to do so, or, in each case of (a) and (b) from making any publication or public disclosure about such activities or Alpha-Synuclein Antibodies; provided that (i) such Party shall ensure that all activities of such Acquirer or such Acquired Third Party (and its respective Affiliates) (A) do not use and are not based on or incorporate any Collaboration Know-How, Voyager Background Know-How, or AbbVie Designated Antibody Know-How, (B) are not covered by or otherwise related to and do not incorporate or reference the Collaboration Patent Rights, Voyager Background Patent Rights, or AbbVie Designated Antibody Patent Rights (or any Know-How or inventions disclosed in any of the foregoing), and (C) are kept separate from the activities performed under or in connection with this Agreement, and (ii) such Party shall establish

reasonable internal safeguards designed to prevent any Collaboration Know-How, Voyager Background Know-How, or AbbVie Designated Antibody Know-How from being disclosed to, or otherwise utilized by, any Affiliate (other than Pre-Existing Affiliates) or any Acquired Third Party and its Affiliates, as applicable; provided further that references to Voyager Background Know-How and Voyager Background Patent Rights in the preceding proviso shall not include any Voyager Background Know-How regarding, or Voyager Background Patents Covering, the Manufacture of Virus Capsids, Vector Genomes or Virus Vectors that is not specific to one (1) or more Alpha-Synuclein Antibodies or Vectorized Alpha-Synuclein Antibodies.

- 17.5 <u>Performance by Affiliates and Sublicensees</u>. Each Party hereby acknowledges and agrees that it shall be responsible for the full and timely performance as and when due under, and observance of all the covenants, terms, conditions and agreements set forth in, this Agreement by its Affiliate(s), (sub)licensee(s)/Sublicensees and Distributors, to the extent applicable. Any breach by any Affiliate of a Party, or any (sub)licensee/Sublicensee or Distributor, of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate(s) or its (sub)licensee(s)/Sublicensee(s) or Distributors.
- Force Majeure. No Party shall be held liable or responsible to the other Party nor be deemed to be in default under, or in breach of any provision of, this Agreement for failure or delay in fulfilling or performing any obligation (other than a payment obligation) of this Agreement when such failure or delay is due to force majeure. For purposes of this Agreement, force majeure is defined as any cause beyond the reasonable control of the non-performing Party and without the fault or negligence of such Party, which may include acts of God; war; civil commotion; destruction of production facilities or materials by fire, flood, earthquake, explosion or storm; strikes, lockouts or other labor disturbances; terrorist attacks; epidemic; omissions or delays in acting by any Governmental Authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement); and failure of public utilities or common carriers. In such event, the non-performing Party shall promptly (and in any event within [\*\*] of such occurrence) notify the other Party of such inability, the nature of any event causing such inability, the period for which such inability is expected to continue, and any action being taken to avoid or minimize its effect. The Party giving such notice shall thereupon be excused from such of its obligations under this Agreement as it is thereby disabled from performing for so long as it is so disabled for up to a maximum of [\*\*], after which time the Parties shall promptly meet to discuss in good faith how to best proceed in a manner that maintains and abides by this Agreement. To the extent possible, each Party shall use reasonable efforts to minimize the duration of any force majeure.
- 17.7 <u>Notices</u>. Any notice, request, demand, waiver, consent, approval or other communication required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), or internationally recognized overnight express courier service that maintains records of delivery (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

If to Voyager,

addressed to: Voyager Therapeutics, Inc.

75 Sidney Street Cambridge, MA 02139

Attention: Chief Executive Officer

Telephone: 857-259-5340 Facsimile: 617-621-2971

with a copy (which shall not constitute notice) to:

Wilmer Cutler Pickering Hale and Dorr LLP

7 World Trade Center 250 Greenwich Street New York, NY 10007

Attention: Brian A. Johnson, Esq.

Telephone: 212-937-7206 Facsimile: 212-230-8888

If to AbbVie,

addressed to: AbbVie Ireland Unlimited Company

70 Sir John Rogerson's Quay

Dublin 2
Ireland

Facsimile: [\*\*]

with a copy (which shall not constitute notice) to:

AbbVie Inc.

1 North Waukegan Road North Chicago, Illinois 60064

**United States** 

Attention: Executive Vice President, External Affairs, General

Counsel and Corporate Secretary

Facsimile: [\*\*]

or to such other address for such Party as it shall have specified by like notice to the other Party; <u>provided</u> that notices of a change of address shall be effective only after the date of delivery as set forth herein. If delivered personally or by facsimile transmission, the date of delivery shall be deemed to be the date on which such notice was delivered by hand or transmitted by facsimile. If sent by internationally recognized overnight express courier service, the date of delivery shall be deemed to be the second (2nd) Business Day (at the place of delivery) after such notice was deposited with such service. If sent by certified mail, the date of delivery shall be deemed to be the third (3rd) Business Day after such notice was deposited with the U.S. Postal Service. Any notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 17.7 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

- 17.8 <u>Export Clause</u>. Each Party acknowledges that the Laws of the United States restrict the export and re-export of commodities and technical data of United States origin. Each Party agrees that it will not export or re-export restricted commodities or the technical data of the other Party in any form without the appropriate United States and foreign government licenses.
- 17.9 <u>Waiver; Non-Exclusion of Remedies</u>. No waiver or release of any rights or interests of a Party under this Agreement shall be effective unless made in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party in any one (1) or more instances shall not be construed as a waiver of any other right hereunder or of any other failure to perform or breach by such other Party whether of a similar nature or otherwise, except to the extent set forth in writing. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by applicable Law or otherwise available except as expressly set forth herein.
- 17.10 <u>Severability</u>. If any provision of this Agreement should be held to be invalid, illegal or unenforceable in any jurisdiction, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties, and (d) all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction. To the fullest extent permitted by applicable Law, each Party hereby waives any provision of Law that would render any provision hereof illegal, invalid or unenforceable in any respect.
- 17.11 Equitable Relief. Each Party acknowledges and agrees that the restrictions, rights and obligations set forth in Section 8.3, Section 17.3.2, ARTICLE 2, ARTICLE 3, ARTICLE 11, ARTICLE 12 and ARTICLE 13 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions, rights and obligations and that any breach of any provision of such Articles shall result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Articles, the non-breaching Party shall be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, and specific performance, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. Both Parties agree to waive any requirement that the other post a bond or other security as a condition for obtaining any such relief. Nothing in this Section 17.11 is intended or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

- 17.12 Entire Agreement. This Agreement, together with the Schedules hereto, set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties and supersede and terminate all prior agreements and understanding between the Parties. In particular, and without limitation, this Agreement supersedes and replaces the Existing Confidentiality Agreement and any and all term sheets relating to the transactions contemplated by this Agreement and exchanged between the Parties prior to the Effective Date. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties. In the event of any inconsistencies between this Agreement and any schedules or other attachments hereto, the terms of this Agreement shall control.
- 17.13 <u>Independent Contractors</u>. Nothing herein shall be construed to create any relationship of employer and employee, agent and principal, partnership or joint venture between the Parties, including for all tax purposes. Each Party is an independent contractor. Except as expressly provided herein, neither Party shall assume, either directly or indirectly, any liability of or for the other Party. Neither Party shall have the authority to bind or obligate the other Party and neither Party shall represent that it has such authority.
- Headings; Construction; Interpretation. Headings and any table of contents used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. The terms of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, the language of this Agreement shall be deemed to be the language mutually chosen by the Parties, and each of the Parties hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of Law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause or Schedule shall be deemed to be a reference to any Article, Section, subsection, paragraph, clause or Schedule, of or to, as the case may be, this Agreement. Except where the context otherwise requires, (a) any definition of or reference to any agreement, instrument or other document refers to such agreement, instrument other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any Law refers to such Law includes all rules and regulations thereunder and any successor Law, in each case as from time to time enacted, repealed or amended, (c) the words "herein," "hereof" and "hereunder," and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof, (d) the words "include," "includes," "including," and "e.g.," shall be deemed to be followed by the phrase "but not limited to," "without limitation" or words of similar import, (e) the word "or" is used in the

inclusive sense (and/or), (f) words in the singular or plural form include the plural and singular form, respectively, (g) references to any gender refer to each other gender, (h) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement, (i) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term that is defined herein shall be interpreted in a correlative manner, (j) all references to "will" are interchangeable with the word "shall" and shall be understood to be imperative or mandatory in nature, and (k) with respect to references to a Party's or its Affiliate's "(sub)licensee" or "sublicensee," such references shall mean a licensee or direct or indirect sublicensee of such Party or any of its Affiliates under such Party's rights under the Voyager Background IP, AbbVie Background IP, AbbVie Designated Antibody IP, Collaboration IP or Joint IP, in each case to the extent such license or sublicense is granted to perform activities under this Agreement or to exercise rights under this Agreement with respect to any AbbVie Designated Antibody, Research Compound, Research Product, Selected Research Compound, Selected Research Product, Licensed Compound or Licensed Product, and (i) AbbVie, its Affiliates and Sublicensees shall not be considered "(sub)licensees" or "sublicensees" of Voyager or any of its Affiliates, and (ii) Voyager and its Affiliates shall not be considered Sublicensees of AbbVie or any of its Affiliates.

- 17.15 <u>Books and Records</u>. Any books and records to be maintained under this Agreement by a Party or its Affiliates or Sublicensees shall be maintained in accordance with applicable Accounting Standards.
- 17.16 <u>Further Actions</u>. Each Party shall execute, acknowledge and deliver, or cause to be duly executed, acknowledged and delivered, such further instruments, and do and cause to be done all such other acts, including the filing of such assignments, agreements, documents and instruments, as may be necessary or appropriate or as the other Party may reasonable request in connection with this Agreement in order to carry out more effectively the expressly stated purposes and the clear intent of this Agreement or to better assure and confirm unto such other Party its rights and remedies under this Agreement.
- 17.17 <u>Parties in Interest</u>. Except as provided in ARTICLE 15, all of the terms and provisions of this Agreement shall be binding upon, and shall inure to the benefit of and be enforceable solely by the Parties and their respective successors, heirs, administrators and permitted assigns and they shall not be construed as conferring any rights on any other Persons.
- 17.18 <u>Counterparts</u>. This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies from separate computers or printers. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

[Signature page to follow]

IN WITNESS WHEREOF, and intending to be legally bound hereby, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

#### Voyager Therapeutics, Inc.

By:/s/ G. Andre Turenne

Name: G. Andre Turenne

Title: President and Chief Executive Officer

#### **AbbVie Ireland Unlimited Company**

By:/s/ Ronald Robison

Name: Ronald Robison

Title: Director

[Signature Page to Collaboration and Option Agreement]

#### **SCHEDULES**

to

#### **COLLABORATION AND OPTION AGREEMENT**

(the "Agreement")

By and between

VOYAGER THERAPEUTICS, INC.

**AND** 

#### ABBVIE IRELAND UNLIMITED COMPANY

February 21, 2019

Note: Defined terms used in these Schedules to the Agreement that are not otherwise defined in these Schedules shall have the meaning set forth in the Agreement.

Page 1 of 62

**Development Plan** 

# **DEVELOPMENT PLAN**

AAV-Mediated Delivery of Anti-Alpha-Synuclein mAb Candidates for treatment of Parkinson's disease, MSA & Other Synucleinopathies

(Voyager Development Period: IND-Enabling Studies and Phase 1 Clinical Trials)

Page 2 of 67

# Table of Contents\*

1.0 Overview 4

[\*\*]

Page 3 of 67

# 1.0 Overview

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 12 pages were omitted. [\*\*].

Page 4 of 67

# **SCHEDULE 1.62**

#### **FTE Rates**

[\*\*]

Page 5 of 67

#### **SCHEDULE 1.112**

**Research Plan** 

# **RESEARCH PLAN**

AAV-Mediated Delivery of Anti-Alpha-Synuclein mAb Candidates for the Treatment of Parkinson's disease, MSA & Other Synucleinopathies

(Voyager Research Period: Advancement of Research Compounds)

Page 6 of 67

# **Table of Contents**

1.0 Overview [\*\*]

Page 7 of 67

#### 1.0 Overview

Pursuant to that certain Collaboration and Option Agreement by and between Voyager Therapeutics, Inc. ("Voyager") and AbbVie Ireland Unlimited Company ("AbbVie") dated as of February 21, 2019 (the "Agreement"), the Parties have developed a 2-stage Research and Development collaboration for the discovery and development of gene therapy candidates for the treatment of synucleinopathies (indications linked to Alpha-Synuclein dysregulation), including Parkinson's disease, Multiple System Atrophy (MSA) and Dementia with Lewy Bodies (DLB). The terms used in this Research Plan, not otherwise defined herein, shall have the meanings set forth in the Agreement.

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 12 pages were omitted. [\*\*].

Page 8 of 67

# **SCHEDULE 1.143**

# Voyager Background VA Patent Rights

| Voyager Ref | Status | Application No. Publication No. Patent No. | Filing Date/<br>Pub Date/<br>Issue Date | Assignment<br>Recordation<br>Date;<br>Reel/Frame | Named Inventors | Application Title |
|-------------|--------|--|---|--|-----------------|-------------------|
| [**]        | [**]   | [**]                                       | [**]                                    | [**]   | [**]            | [**]              |

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 3 pages were omitted. [\*\*]

Page 9 of 67

# **SCHEDULE 6.1**

# Terms of Third Party Licensee Agreements to which AbbVie's Rights under Section 6.1.1 are Subject

None.

Page 10 of 67

#### SCHEDULE 9.3.2

# **Preapproved Subcontractors**

| <u>Name</u> | Address | <u>Date Requested by</u><br><u>VYGR</u> | <u>Date Approved by</u><br><u>AbbVie*</u> |
|-------------|---------|---|---|
| [**]        | [**]    | [**]                                    | [**]                                      |

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 3 pages were omitted. [\*\*]

[\*\*]

#### **SCHEDULE 12.8**

# Terms of Third Party IP Prosecution and Enforcement Agreements to which AbbVie's Article 12 Rights are Subject

- 1. **[\*\*]** Agreement: As set forth below, under Section [\*\*], Section [\*\*], Section [\*\*], Section [\*\*] and Section [\*\*] of that certain [\*\*] Agreement, dated as of [\*\*], by and between [\*\*] has certain rights to [\*\*].
  - · Under Section [\*\*] of the [\*\*] Agreement, subject to the rights and licenses grant to, and the obligations of, [\*\*] and VYGR, either VYGR or [\*\*] is entitled to [\*\*] (as defined in the [\*\*] Agreement), which may [\*\*] IP (as defined in the Agreement), and to [\*\*].
  - · Under Section [\*\*] of the [\*\*] Agreement, if VYGR [\*\*] (as defined in the [\*\*] Agreement), which may [\*\*] (as defined in the Agreement), or [\*\*] (as defined in the Agreement), Voyager [\*\*].
  - · Under Section [\*\*] and Section [\*\*] of the [\*\*] Agreement, with respect to any [\*\*] (as defined in the [\*\*] Agreement) or [\*\*] (as defined in the [\*\*] Agreement) with respect to [\*\*] (as defined in the [\*\*] Agreement), which may [\*\*] (as defined in the Agreement), Voyager [\*\*] (as defined in the [\*\*] Agreement) or [\*\*] (as defined in the [\*\*] Agreement).
  - · Under Section [\*\*] and Section [\*\*] of the [\*\*] Agreement, with respect to any [\*\*] (as defined in the [\*\*] Agreement) or any [\*\*] (as defined in the [\*\*] Agreement), which may [\*\*] (as defined in the Agreement), [\*\*] (as defined in the [\*\*] Agreement) [\*\*] (as defined in the [\*\*] Agreement).
  - · Under Section [\*\*] and Section [\*\*] of the [\*\*] Agreement, with respect to any [\*\*] (as defined in the [\*\*] Agreement) or any [\*\*] (as defined in the [\*\*] Agreement) with respect to any [\*\*] (as defined in the [\*\*] Agreement), if [\*\*] (as defined in the [\*\*] Agreement) [\*\*] (as defined in the [\*\*] Agreement) [\*\*] (as defined in the [\*\*] Agreement) within [\*\*] of the [\*\*].
  - · Under Section [\*\*] of the [\*\*] Agreement, [\*\*] has [\*\*] (as defined in the [\*\*] Agreement), which may [\*\*] (as defined in the Agreement), or [\*\*] (as defined in the [\*\*] Agreement), which may [\*\*] (as defined in the Agreement), in connection with the [\*\*] (as defined in the [\*\*] Agreement) or [\*\*] (as defined in the [\*\*] Agreement) or [\*\*] (as defined in the [\*\*] Agreement) in connection with the [\*\*] (as defined in the [\*\*] Agreement) or [\*\*] (as defined in the [\*\*] Agreement).

- · Under Section [\*\*] of the [\*\*] Agreement, [\*\*] has the [\*\*] (as defined in the [\*\*] Agreement), and may [\*\*] (as defined in the [\*\*] Agreement) for (i) [\*\*] (as defined in the [\*\*] Agreement), which may [\*\*] (as defined in the Agreement) and (ii) [\*\*] (as defined in the [\*\*] Agreement), which may [\*\*] (as defined in the Agreement).
- · Under Section [\*\*] of the [\*\*] Agreement, [\*\*] has the [\*\*] (as defined in the [\*\*] Agreement), which may constitute [\*\*].
- 2. **[\*\*] Agreement**: As set forth below, under Section [\*\*], Section [\*\*], Section [\*\*], Section [\*\*], Section [\*\*] and Section [\*\*] of that certain [\*\*] Agreement, dated as of [\*\*], by and between [\*\*] has certain rights to [\*\*].
  - · Under Section [\*\*] of the [\*\*] Agreement, subject to the rights and licenses grant to, and the obligations of, [\*\*] and VYGR, either VYGR or [\*\*] is entitled to [\*\*] (as defined in the [\*\*] Agreement), which [\*\*] IP (as defined in the Agreement), and to [\*\*].
  - · Under Section [\*\*] of the [\*\*] Agreement, VYGR shall notify [\*\*] with respect to any decision to [\*\*] (as defined in the [\*\*] Agreement), of, or to [\*\*] (as defined in the Agreement), [\*\*].
  - Under Section [\*\*] of the [\*\*] Agreement, subject to the terms of any applicable [\*\*] (each as defined in the [\*\*] Agreement), [\*\*] shall have the [\*\*] (as defined in the [\*\*] Agreement), which may constitute [\*\*] (as defined in the Agreement) and for [\*\*] (as defined in the [\*\*] Agreement) relating thereto, with some exception. [\*\*] is required to notify VYGR of any [\*\*] (as defined in the [\*\*] Agreement) of or to not [\*\*] (as defined in the [\*\*] Agreement).
  - · Under Section [\*\*] of the [\*\*] Agreement, subject to the terms of any applicable [\*\*] (as defined in the [\*\*] Agreement) and to a requirement that [\*\*] notify VYGR of any [\*\*] (as defined in the [\*\*] Agreement) of or to not [\*\*] (as defined in the [\*\*] Agreement), [\*\*] shall have the [\*\*] (as defined in the Agreement). Notwithstanding the foregoing, [\*\*]'s right as described herein with respect to the [\*\*] do not apply to any [\*\*] (each such term is as defined in the [\*\*] Agreement) that was [\*\*] and that was [\*\*] pursuant to Section [\*\*] of the [\*\*] Agreement.
  - · Under Section [\*\*] of the [\*\*] Agreement, [\*\*] shall have the right to [\*\*] (as defined in the [\*\*] Agreement) or [\*\*] (as defined in the [\*\*] Agreement), in each case [\*\*] (as defined in the [\*\*] Agreement) any [\*\*] (as defined in the [\*\*] Agreement) (except that [\*\*] shall not have the right to [\*\*] (as defined in the [\*\*] Agreement) that Voyager intends to [\*\*] (as defined in the [\*\*] Agreement) reasonably available to extend), which, in each case, may also constitute [\*\*] (as defined in the Agreement).

· Under Section [\*\*] of the [\*\*] Agreement, [\*\*] has the primary right to [\*\*] (as defined in the [\*\*] Agreement) of any [\*\*] (as defined in the [\*\*] Agreement) or [\*\*] (as defined in the [\*\*] Agreement), which in each case may also constitute [\*\*] (as defined in the Agreement), provided that [\*\*] shall not unreasonably refuse to [\*\*] with respect to such proceeding.

The disclosures set forth on this <u>Schedule 12.8</u> shall not limit Voyager's obligations or AbbVie's rights under Section 12.8.2 of the Agreement.

Page 14 of 67

# **SCHEDULE 13.6**

# **Press Release**

[See attached.]

Page 15 of 67





# Voyager Therapeutics and AbbVie Announce Collaboration to Develop Vectorized Antibodies to Treat Parkinson's Disease and Other Synucleinopathies

Deal expands collaborative efforts on vectorized antibodies to target pathological species of alpha-synuclein

Voyager to receive \$65 million upfront and up to \$245 million in preclinical and Phase 1 option payments as well as potential development, regulatory, and commercial milestone payments and royalties

**CAMBRIDGE, Mass., and NORTH CHICAGO, Ill., February 22, 2019** – Voyager Therapeutics, Inc. (Nasdaq: VYGR), a clinical-stage gene therapy company focused on developing life-changing treatments for severe neurological diseases, and AbbVie (NYSE: ABBV), a global biopharmaceutical company, today announced an exclusive, global strategic collaboration and option agreement to develop and commercialize vectorized antibodies directed at pathological species of alpha-synuclein for the potential treatment of Parkinson's disease and other diseases (synucleinopathies) characterized by the abnormal accumulation of misfolded alpha-synuclein protein.

The delivery of sufficient quantities of antibodies across the blood-brain barrier is one of the major limitations of current biologic therapies for neurodegenerative diseases that require frequent systemic injections with large amounts of antibodies. Voyager's vectorized antibody platform and approach aims to circumvent this limitation by delivering, with a potential, one-time intravenous administration, the genes that encode for the production of therapeutic antibodies utilizing Voyager's blood-brain barrier penetrant adeno-associated virus (AAV) capsids. This approach could result in the potential for higher levels of therapeutic antibodies in the brain compared with current systemic administration of antibodies.

"The expansion of AbbVie's partnership with Voyager represents the potential we see in the ability of its vectorized antibody platform to surpass the blood-brain barrier and more effectively deliver biologic therapies," said Jim Summers, Ph.D., vice president, discovery neuroscience research, AbbVie. "We are hopeful that Voyager's technology will enable further development of transformative treatments for patients with neurodegenerative diseases."

"Our scientific platform allows us to develop unique AAV gene therapies that are designed to knock down diseasecausing gene expression, increase the expression of missing proteins, or enable the expression of therapeutic antibodies through vectorization," said Andre Turenne, president and chief executive officer of Voyager Therapeutics. "We are excited to expand our efforts towards pathological species of alpha-synuclein given its role in the progression of disease, and AbbVie is the ideal partner to advance this exciting new target and therapeutic modality."

Parkinson's disease is the second most common neurodegenerative disorder worldwide. A hallmark of Parkinson's disease is the accumulation of misfolded alpha-synuclein that can eventually lead to the formation of protein deposits and progressive neurodegeneration. Approaches to interfere with this process could potentially delay the progression of Parkinson's disease and other synucleinopathies including Lewy Body Dementia and multiple system atrophy.

#### **Details of the Alpha-Synuclein Collaboration and Financial Terms**

Under the terms of the collaboration and option agreement, Voyager will perform research and preclinical development work to vectorize antibodies directed against alpha-synuclein that are designated by AbbVie, after which AbbVie may select one or more vectorized antibodies to advance into IND-enabling studies and clinical development. Voyager will be responsible for the research, IND-enabling and Phase 1 clinical activities and costs. Following completion of Phase 1 clinical development, AbbVie has an option to license the vectorized alpha-synuclein antibody program for further clinical development and global commercialization for indications including Parkinson's disease and other synucleinopathies.

Voyager will receive an upfront cash payment of \$65 million and has the potential to earn up to \$245 million in preclinical and Phase 1 option payments. Voyager is also eligible to receive up to an additional \$728 million in potential development and regulatory milestone payments for each alpha-synuclein vectorized antibody compound. Voyager is eligible to receive tiered royalties on the global commercial net sales of each alpha-synuclein vectorized antibody and may also earn up to a total of \$500 million in commercial milestones.

#### **About Voyager Therapeutics**

Voyager Therapeutics is a clinical-stage gene therapy company focused on developing life-changing treatments for severe neurological diseases. Voyager is committed to advancing the field of AAV gene therapy through innovation and investment in vector engineering and optimization, manufacturing and dosing and delivery techniques. Voyager's pipeline focuses on severe neurological diseases in need of effective new therapies, including Parkinson's disease, a monogenic form of ALS called SOD1, Huntington's disease, Friedreich's ataxia, neurodegenerative diseases related to defective or excess aggregation of tau protein in the brain including Alzheimer's disease and severe, chronic pain. Voyager has strategic collaborations with Sanofi Genzyme, AbbVie and Neurocrine Biosciences. Founded by scientific and clinical leaders in the fields of AAV gene therapy, expressed RNA interference and neuroscience,

Voyager Therapeutics is headquartered in Cambridge, Massachusetts. For more information on Voyager Therapeutics, please visit the company's website at www.voyagertherapeutics.com or follow @VoyagerTx on Twitter and LinkedIn.

#### About AbbVie

AbbVie is a global, research-driven biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments across four primary therapeutic areas: immunology, oncology, virology and neuroscience. In more than 75 countries, AbbVie employees are working every day to advance health solutions for people around the world. For more information about AbbVie, please visit us at www.abbvie.com. Follow @abbvie on Twitter, Facebook, LinkedIn or Instagram.

#### **Voyager Forward-Looking Statements**

This press release contains forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as "may," "might," "will," "would," "should," "expect," "plan," "anticipate," "believe," "estimate," "undoubtedly," "project," "intend," "future," "potential," or "continue," and other similar expressions are intended to identify forward-looking statements. For example, all statements Voyager makes regarding the initiation, timing, progress, activities, goals and reporting of results of its preclinical programs and clinical trials and its research and development programs, the potential benefits and future operation of the collaboration agreement with AbbVie, including any potential future payments thereunder, its ability to advance its AAV-based gene therapies into, and successfully initiate, enroll and complete, clinical trials, the potential clinical utility of its product candidates, its ability to continue to develop its gene therapy platform, its ability to develop manufacturing capability for its products and successfully transition its manufacturing process, its ability to perform under existing collaborations with, among others, Sanofi Genzyme, AbbVie and Neurocrine and to add new programs to its pipeline, its ability to enter into new partnerships or collaborations, the sufficiency of its cash resources and the regulatory pathway of, and the timing or likelihood of its regulatory filings and approvals for, any of its product candidates, are forward looking. All forward-looking statements are based on estimates and assumptions by Voyager's management that, although Voyager believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Voyager expected. Such risks and uncertainties include, among others, those related to the initiation and conduct of preclinical studies and clinical trials; the availability of data from clinical trials; the expectations for regulatory communications, submissions and approvals; the continued development of the gene therapy platform; Voyager's scientific approach and general development progress; the sufficiency of cash resources; and the

availability or commercial potential of Voyager's product candidates. These statements are also subject to a number of material risks and uncertainties that are described in Voyager's most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, as updated by its subsequent filings with the Securities and Exchange Commission. Any forward-looking statement speaks only as of the date on which it was made. Voyager undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

#### **AbbVie Forward-Looking Statements**

Some statements in this news release are, or may be considered, forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," of AbbVie's 2017 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

###

#### **Voyager Investor Relations:**

Matt Osborne Vice President of Corporate Affairs, Communications and Investor Relations 857-259-5353 mosborne@vygr.com

#### Voyager Media:

Sheryl Seapy W2Opure 949-903-4750 sseapy@purecommunications.com

#### **AbbVie Investors:**

Liz Shea 847-935-2211

Page 19 of 67

liz.shea@abbvie.com

#### **AbbVie Media:**

Adelle Infante 847-938-8745 adelle.infante@abbvie.com

#### **SCHEDULE 14.1.4**

Any conflict or violation, any agreement or any provision or obligation thereof, or any instrument or understanding, oral or written, to which it is a party or by which it is bound

1, None.

Page 20 of 67

# **SCHEDULE 14.1.5**

# List of Obligations that would Materially Impede the Diligent and Complete Fulfillment of Obligations Hereunder

None.

Page 21 of 67

#### **SCHEDULE 14.2**

#### **Exceptions to Representations and Warranties in Section 14.2**

#### As of the Effective Date:

**Section 14.2.14:** [\*\*] **Agreement**: In the [\*\*] Agreement dated [\*\*] by and between the [\*\*] and Voyager Therapeutics, Inc. ("<u>VYGR</u>"), as amended by [\*\*], Section [\*\*] provides that the [\*\*] (as defined in the [\*\*] Agreement) for [\*\*] of the Agreement.

Page 22 of 67

# SCHEDULE 14.2.1

# **Existing In-License Agreements**

1. [\*\*].

#### **SCHEDULE 14.2.4**

# Existing Patent Rights as allocated between Voyager Managed Patent Rights and Third Party Managed Patent Rights

#### **Voyager Managed Patent Rights**

Each of the patent applications listed below is owned and managed exclusively by Voyager:

| Voyager Ref | Status | Application<br>No.<br>Publication<br>No.<br>Patent No. | Filing Date/<br>Pub Date/<br>Issue Date | Assignment<br>Recordation<br>Date;<br>Reel/Frame | Named<br>Inventors | Application<br>Title |
|-------------|--------|--|---|--|--------------------|----------------------|
| [**]        | [**]   | [**]   | [**]                                    | [**]   | [**]               | [**]                 |

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 3 pages were omitted. [\*\*]

#### **Third Party Managed Patent Rights**

Each of the patent applications listed below is licensed to Voyager and managed by a Third Party:

[\*\*]

| Voyager Ref | Status | Application No. Publication No. Patent No. | Filing Date/<br>Pub Date/<br>Issue Date | Assignment<br>Recordation<br>Date;<br>Reel/Frame | Named<br>Inventors | Application<br>Title |
|-------------|--------|--|---|--|--------------------|----------------------|
| [**]        | [**]   | [**]                                       | [**]                                    |  | [**]               | [**]                 |

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 8 pages were omitted. [\*\*]

#### **SCHEDULE 14.2.6**

#### **Existing In-License Agreements and Future Voyager In-License Agreements**

- 1. Existing In-License Agreements:
  - a. The [\*\*]
- 2. Future In-License Agreements: As of the Effective Date, there are no known Future In-License Agreements. This list would be updated after the Effective Date when and as any such agreements are signed.

Page 25 of 67

#### **SCHEDULE 17.2.1**

#### **ADR Procedures**

Any Dispute referred to ADR under this Agreement shall be resolved as follows:

- 1. To begin an ADR proceeding, a Party shall provide written notice to the other Party of the Dispute to be resolved by ADR. Within [\*\*] after its receipt of such notice, the other Party may, by written notice to the Party initiating the arbitration, add additional issues to be resolved within the same ADR.
- 2. Within [\*\*] following the initiation of the ADR proceeding, the Parties shall select a mutually acceptable independent, impartial and conflicts-free neutral to preside in the resolution of all issues in this ADR proceeding. If the Parties are unable to agree on a mutually acceptable neutral within such period, each Party will select one (1) independent, impartial and conflicts-free neutral and those two (2) neutrals will select a third independent, impartial and conflicts-free neutral within [\*\*] thereafter (such neutral(s), the "Neutral"). None of the neutrals selected may be current or former employees, officers or directors of either Party or its Affiliates.
- 3. No earlier than [\*\*] or later than [\*\*] after selection, the Neutral shall hold a hearing to resolve each of the issues identified by the Parties. The ADR proceeding shall take place in New York, NY.
- 4. At least [\*\*] prior to the hearing, each Party shall submit the following to the other Party and the Neutral:
  - (a) a copy of all exhibits on which such Party intends to rely in any oral or written presentation to the Neutral;
  - (b) a list of any witnesses such Party intends to call at the hearing, and a short summary of the anticipated testimony of each witness;
  - (c) a proposed ruling on each issue to be resolved, together with a request for a specific damage award or other remedy for each issue. The proposed ruling shall not contain any recitation of the facts or any legal arguments, and the proposed remedy shall not include any punitive damages. The proposed ruling and the proposed remedy collectively shall not exceed [\*\*] per issue.
  - (d) a brief in support of such Party's proposed rulings and remedies; *provided*, that the brief shall not exceed [\*\*]. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.

- (e) Except as expressly set forth in subparagraphs 4(a) 4(d), no discovery shall be required or permitted by any means, including depositions, interrogatories, requests for admissions, or production of documents.
- 5. The hearing shall be conducted on [\*\*] and shall be governed by the following rules:
  - (a) Each Party shall be entitled to [\*\*] of hearing time to present its case. The Neutral shall determine whether each Party has had the [\*\*] to which it is entitled.
  - (b) Each Party shall be entitled, but not required, to make an opening statement, to present regular and rebuttal testimony, documents, or other evidence, to cross-examine witnesses, and to make a closing argument. Cross-examination of witnesses shall occur immediately after their direct testimony, and cross-examination time shall be charged against the Party conducting the cross-examination.
  - (c) The Party initiating the ADR shall begin the hearing and, if it chooses to make an opening statement, shall address therein not only issues it raised but also any issues raised by the responding Party. The responding Party, if it chooses to make an opening statement, also shall address all issues raised in the ADR. Thereafter, the presentation of regular and rebuttal testimony and documents, other evidence, and closing arguments shall proceed in the same sequence.
  - (d) Except when testifying, witnesses shall be excluded from the hearing until closing arguments.
  - (e) Settlement negotiations, including any statements made therein, shall not be admissible under any circumstances. Affidavits prepared for purposes of the ADR hearing also shall not be admissible. As to all other matters, the Neutral shall have sole discretion regarding the admissibility of any evidence.
- 6. Within [\*\*] following completion of the hearing, each Party may submit to the other Party and the Neutral a post-hearing brief in support of its proposed rulings and remedies; *provided*, that such brief shall not contain or discuss any new evidence and shall not exceed [\*\*]. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.
- 7. The Neutral shall rule on each disputed issue within [\*\*] following completion of the hearing. Such ruling shall adopt in its entirety the proposed ruling and remedy of one (1) of the Parties on each disputed issue but may adopt one (1) Party's proposed rulings and remedies on some issues and the other Party's proposed rulings and remedies on other issues. The Neutral shall not issue any written opinion or otherwise explain the basis of the ruling.
- 8. The Neutral shall be paid a reasonable fee plus expenses. These fees and expenses, along with the reasonable legal fees and expenses of the prevailing Party (including all expert

witness fees and expenses), the fees and expenses of a court reporter, and any expenses for a hearing room, shall be paid as follows:

- (a) If the Neutral rules in favor of one (1) Party on all disputed issues in the ADR, the losing Party shall pay [\*\*] percent ([\*\*]%) of such fees and expenses.
- (b) If the Neutral rules in favor of one (1) Party on some issues and the other Party on other issues, the Neutral shall issue with the rulings a written determination as to how such fees and expenses shall be allocated between the Parties. The Neutral shall allocate fees and expenses in a way that bears a reasonable relationship to the outcome of the ADR, with the Party prevailing on more issues, or on issues of greater value or gravity, recovering a relatively larger share of its legal fees and expenses.
- 9. The rulings of the Neutral and the allocation of fees and expenses shall be binding, non-reviewable, and non-appealable, and may be entered as a final judgment in any court having jurisdiction.
- 10. Except as provided in paragraph 9 or as required by law, the existence of the Dispute, any settlement negotiations, the ADR proceeding, any submissions (including exhibits, testimony, proposed rulings, and briefs), and the rulings shall be deemed to be Confidential Information of both Parties. The Neutral shall have the authority to impose sanctions for unauthorized disclosure of Confidential Information.
- 11. All ADR proceedings shall be conducted in the English language.
- 12. Each Party shall have the right to be represented by counsel in all aspects of any ADR proceeding.



#### **SCHEDULE 17.2.2**

#### **Baseball Style Arbitration**

- 1. If the Parties are unable to agree on whether there should be, or the amount of, any commercially reasonable increase to the royalty rates set forth in Section 10.3 and, in connection with any such increase in such royalties, the corresponding commercially reasonable decrease to the milestones set forth in Section 10.2.3 for an additional or substitute AbbVie Designated Antibody as set forth in Section 2.1.3 (a "Royalty/Milestone Adjustment") within [\*\*] after AbbVie provides Voyager notice of its desire to add or substitute such AbbVie Designated Antibody, then upon either Party's written request made within [\*\*] after the expiration of such [\*\*] period, each Party shall provide the other Party in writing with such Party's last best offer regarding the Royalty/Milestone Adjustment (a "Final Offer") within [\*\*] after such Party's request. Either Party shall have the right, upon written notice to the other Party (a "Valuation Notice"), to engage one (1) independent, impartial and neutral Third Party valuation expert (a "Valuation Expert") to determine a commercially reasonable Royalty/Milestone Adjustment based on how the royalty rates set forth in Section 10.3 (as may be adjusted pursuant to Section 10.5) and the milestones set forth in Section 10.2.3 compare to the royalty rates and milestones applicable in the Tau Agreement (including any adjustments herein and therein with respect thereto), taking into account (a) whether such antibody is, prior to such designation by AbbVie, Controlled by Voyager, and (b) the royalty rates, milestone and other fees payable by AbbVie or any of its Affiliates to any Third Party for the use of such additional or substitute AbbVie Designated Antibody (including the fact that any such royalties payable by AbbVie may not be deducted from royalties payable hereunder pursuant to Section 10.5.3). The Valuation Expert shall be mutually agreed to by the Parties; provided that if the Parties are unable to agree on one (1) Valuation Expert within [\*\*] after a Party provides the other Party the Valuation Notice, then each Party shall select one (1) Third Party Valuation Expert and those two (2) Third Party Valuation Experts will select the one (1) Valuation Expert within [\*\*] thereafter, which one (1) Valuation Expert selected shall determine a commercially reasonable Royalty/Milestone Adjustment; provided further that such selected Valuation Expert shall not be a current or former employee, officer, director, consultant or subcontractor of either Party or any of its Affiliates. The Parties shall use their best efforts to cause the one (1) Valuation Expert to be selected and retained within [\*\*] after a Party provides the other Party the Valuation Notice.
- 2. Each Party shall submit to the Valuation Expert and the other Party (a) the Final Offer such Party provided to the other Party pursuant to Paragraph 1 above and such information concerning such Party's requested Royalty/Milestone Adjustment as such Party may deem appropriate, including any supporting information with respect to such Final Offer, within [\*\*] after the retention of the Valuation Expert, (b) a proposed amendment to this Agreement that would further effectuate such Party's Final Offer (for clarity, no other amendments to this Agreement not directly related to the

Page 29 of 67

Royalty/Milestone Adjustment shall be included), and (c) such other information as may be requested by the Valuation Expert within [\*\*] after such request. Any such information provided to the Valuation Expert by a Party shall be simultaneously provided to the other Party. The Valuation Expert shall determine the most commercially reasonable Royalty/Milestone Adjustment based solely on the above factors within [\*\*] after its retention by selecting one (1) or the other of the two (2) Final Offers submitted by the Parties (such determined Royalty/Milestone Adjustment, the "Determined Adjustment", and the proposed amendment to this Agreement corresponding to such Determined Adjustment, the "Determined Amendment"), which determination shall be final and shall serve as the only basis for AbbVie's election set forth under Paragraph 3 below. The Valuation Expert shall promptly notify the Parties of such Determined Adjustment in writing.

3. AbbVie shall have the right, upon written notice to Voyager within [\*\*] after the Valuation Expert notifies the Parties of the Determined Adjustment, to elect to accept the Determined Adjustment, in which case, upon such election, this Agreement shall be deemed to automatically incorporate the Determined Amendment. If AbbVie does not make such election during such [\*\*] period, then the Determined Amendment shall not be effective and AbbVie's proposed additional or substitute Alpha-Synuclein Antibody shall not become an AbbVie Designated Antibody.

Page 30 of 67

#### **VOYAGER THERAPEUTICS, INC.**

#### RESTRICTED STOCK UNIT AWARD AGREEMENT

# INDUCEMENT GRANT PURSUANT TO NASDAQ STOCK MARKET RULE 5635(C)(4)

| Name of Grantee:               |  |
|--------------------------------|--|
| No. of Restricted Stock Units: |  |
| Grant Date:                    |  |

This agreement (the "Agreement") evidences the grant by Voyager Therapeutics, Inc. (the "Company"), to the Grantee named above, an employee of the Company, of the number of restricted stock units (the "Restricted Stock Units" or the "Award") specified above, with each such Restricted Stock Unit representing the right to receive one share of common stock, par value \$0.001 per share, of the Company (the "Stock"), on the terms, and subject to the conditions, set forth herein. Except as otherwise indicated by the context, the term "Grantee" as used herein, shall be deemed to include any person who acquires the Award validly under its terms.

- 1. <u>Inducement Grant</u>. This Award of Restricted Stock Units was granted to the Grantee pursuant to the inducement grant exception under NASDAQ Stock Market Rule 5635(c)(4), and not pursuant to the Company's 2014 Stock Option Plan, 2015 Stock Option and Incentive Plan or any other equity incentive plan of the Company, as a material inducement to the Grantee's employment with the Company.
- 2. <u>Restrictions on Transfer of Award</u>. This Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of by the Grantee, and any shares of Stock issuable with respect to the Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until (i) the Restricted Stock Units have vested as provided in Paragraph 3 of this Agreement and (ii) shares of Stock have been issued to the Grantee in accordance with the terms of this Agreement.
- 3. <u>Vesting of Restricted Stock Units</u>. The restrictions and conditions of Paragraph 2 of this Agreement shall lapse on the Vesting Date or Dates specified in the following schedule so long as the Grantee remains an employee of the Company or a Subsidiary on such Vesting Dates. If a series of Vesting Dates is specified, then the restrictions and conditions in Paragraph 2 shall lapse only with respect to the number of Restricted Stock Units specified as vested on such date.

| Incremental Number of         |                     |
|-------------------------------|---------------------|
| Restricted Stock Units Vested | <u>Vesting Date</u> |
|                               | _                   |
| (%)                           |                     |
| (%)                           |                     |
| (%)                           |                     |
| (%)                           |                     |

The Administrator may at any time accelerate the vesting schedule specified in this Paragraph 3.

- 4. <u>Termination of Employment</u>. If the Grantee's employment with the Company and its Subsidiaries terminates for any reason (including death or disability) prior to the satisfaction of the vesting conditions set forth in Paragraph 3 above, then, except as provided in Section 9(c) below or in another agreement between the Grantee and the Company, any Restricted Stock Units that have not vested as of such date shall automatically and without notice terminate and be forfeited, and neither the Grantee nor any of his or her successors, heirs, assigns, or personal representatives will thereafter have any further rights or interests in such unvested Restricted Stock Units.
- 5. <u>Issuance of Shares of Stock</u>. As soon as practicable following each Vesting Date (but in no event later than two and one-half months after the end of the year in which the Vesting Date occurs), the Company shall issue to the Grantee the number of shares of Stock equal to the aggregate number of Restricted Stock Units that have vested pursuant to Paragraph 3 of this Agreement on such date and the Grantee shall thereafter have all the rights of a stockholder of the Company with respect to such shares.
- 6. Tax Withholding. The Grantee acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Grantee any federal, state, local or other taxes of any kind required by law to be withheld with respect to the vesting of the Restricted Stock Units. At such time as the Grantee is not aware of any material nonpublic information about the Company or the Stock, the Grantee shall execute the instructions set forth in Schedule A attached hereto (the "Durable Automatic Sale Instructions") as the means of satisfying such tax obligation. If the Grantee does not execute the Durable Automatic Sale Instructions prior to an applicable vesting date, then the Grantee agrees that if under applicable law the Grantee will owe taxes at such vesting date on the portion of the Award then vested the Company shall be entitled to immediate payment from the Grantee of the amount of any tax required to be withheld by the Company. The Company shall not deliver any shares of Stock to the Participant until it is satisfied that all required withholdings have been made.
- 7. Section 409A of the Code. This Agreement shall be interpreted in such a manner that all provisions relating to the settlement of the Award are intended to be exempt from the requirements of Section 409A of the Internal Revenue Code ("Section 409A") as "short-term deferrals" as described in Section 409A. However, to the extent this Award of Restricted Stock Units is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A, the Award shall be subject to such additional rules and requirements as specified by the Administrator from time to time in order to comply with Section 409A. In this regard, if any amount under the Restricted Stock Units is payable upon a "separation from service" (within

the meaning of Section 409A) to the Grantee and the Grantee is considered a "specified employee" (within the meaning of Section 409A), then no such payment shall be made prior to the date that is the earlier of (i) six months and one day after the Grantee's separation from service, or (ii) the Grantee's death, but only to the extent such delay is necessary to prevent such payment from being subject to interest, penalties and/or additional tax imposed pursuant to Section 409A.

- 8. <u>No Obligation to Continue Employment</u>. Neither the Company nor any Subsidiary is obligated by or as a result of this Agreement to continue the Grantee in employment, nor shall this Agreement interfere in any way with the right of the Company or any Subsidiary to terminate the employment of the Grantee at any time.
  - 9. <u>Adjustments for Changes in Stock and Sale Events</u>.

## a. <u>Definitions</u>.

- i. "Sale Event" shall mean (i) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity, (ii) a merger, reorganization or consolidation pursuant to which the holders of the Company's outstanding voting power and outstanding stock immediately prior to such transaction do not own a majority of the outstanding voting power and outstanding stock or other equity interests of the resulting or successor entity (or its ultimate parent, if applicable) immediately upon completion of such transaction, (iii) the sale of all of the Stock of the Company to an unrelated person, entity or group thereof acting in concert, or (iv) any other transaction in which the owners of the Company's outstanding voting power immediately prior to such transaction do not own at least a majority of the outstanding voting power of the Company or any successor entity immediately upon completion of the transaction other than as a result of the acquisition of securities directly from the Company.
- ii. "Sale Price" shall mean the value as determined by the Administrator of the consideration payable, or otherwise to be received by stockholders, per share of Stock pursuant to a Sale Event.
- b. <u>Changes in Stock</u>. Subject to Section 9(c) hereof, if, as a result of any reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar change in the Company's capital stock, the outstanding shares of Stock are increased or decreased or are exchanged for a different number or kind of shares or other securities of the Company, or additional shares or new or different shares or other securities of the Company or other non-cash assets are distributed with respect to such shares of Stock or other securities, or, if, as a result of any merger or consolidation, sale of all or substantially all of the assets of the Company, the outstanding shares of Stock are converted into or exchanged for securities of the Company or any successor entity (or a parent or subsidiary thereof), the Administrator shall make an appropriate or proportionate adjustment in the number and kind of shares or other securities subject to this Award of Restricted Stock Units. The Administrator shall also make equitable or proportionate adjustments in the number of Restricted Stock Units subject to this Award to take into consideration cash dividends paid (other than in the ordinary course) or any other extraordinary corporate event. The adjustment by the Administrator shall be final, binding and conclusive. No fractional shares of Stock shall be issued under this Award of

Restricted Stock Units resulting from any such adjustment, but the Administrator in its discretion may make a cash payment in lieu of fractional shares.

c. <u>Sale Events</u>. In the case of and subject to the consummation of a Sale Event, the parties thereto may cause the assumption or continuation of this Award of Restricted Stock Units, or the substitution of the Award of Restricted Stock Units with a new award of the successor entity or parent thereof, with appropriate adjustment as to the number and kind of shares as such parties shall agree. To the extent the parties to such Sale Event do not provide for the assumption, continuation or substitution of the Award of Restricted Stock Units, upon the effective time of the Sale Event, the Restricted Stock Units shall become fully vested and then shall terminate following the issuance of the shares of Stock hereunder. In the event of such termination, the Company shall have the option (in its sole discretion and in lieu of the issuance of shares of Stock subject to the Restricted Stock Units) to make or provide for a cash payment to the Grantee in exchange for the cancellation of the Restricted Stock Units in an amount equal to the Sale Price multiplied by the number of shares of Stock subject to the Restricted Stock Units.

If the Restricted Stock Units are assumed, continued or substituted in connection with a Sale Event, the Restricted Stock Units shall become fully vested and nonforfeitable if the Grantee is terminated without Cause by the Company (or its successor) in connection with, or within 12 months following, the Sale Event. "Cause" shall have the meaning set forth in the employment agreement between the Grantee and the Company.

- 10. Administrator. This Agreement shall be administered by either the Board of Directors of the Company (the "Board"), the Compensation Committee of the Board, or a similar committee performing the functions of the compensation committee and which is comprised of not less than two non-employee directors who are independent (the "Administrator"). The Administrator shall have the power and authority to: (i) determine and modify from time to time the terms and conditions, including restrictions, of this Award of Restricted Stock Units; (ii) accelerate at any time the vesting of all or any portion of the Award of Restricted Stock Units; (iii) amend this Agreement to provide that this Award of Restricted Stock Units shall vest based on service to the Company or a Subsidiary other than employment (such as service as a consult, advisor or director); (iv) interpret the terms and provisions of the Award of Restricted Stock Units (including related written instruments); (v) make all determinations it deems advisable for the administration of the Award of Restricted stock Units; (vi) decide all disputes arising in connection with the Award of Restricted Stock Units; and (vii) otherwise supervise the administration of the Award of Restricted Stock Units. All decisions and interpretations of the Administrator shall be binding on all persons, including the Company and the Grantee.
- 11. <u>Stockholder Rights</u>. Until Stock is deemed delivered in accordance with Section 15, no right to vote or receive dividends or any other rights of a stockholder will exist with respect to shares of Stock to be issued in connection with the vesting of the Restricted Stock Units, notwithstanding the vesting of the Restricted Stock Units or any action by the Grantee with respect thereto.
- 12. <u>Integration</u>. This Agreement constitutes the entire agreement between the parties with respect to this Award and supersedes all prior agreements and discussions between the parties concerning such subject matter.

- 13. <u>Amendment</u>. The Administrator may, at any time, amend or cancel this Award of Restricted Stock Units for the purpose of satisfying changes in law or for any other lawful purpose, but no such action shall adversely affect the Grantee's rights under the Agreement without the Grantee's consent. Nothing in this Section 13 shall limit the Administrator's authority to take any action permitted pursuant to Section 9.
- 14. <u>Indemnification</u>. Neither the Board nor the Administrator, nor any member of either or any delegate thereof, shall be liable for any act, omission, interpretation, construction or determination made in good faith in connection with this Award of Restricted Stock Units, and the members of the Board and the Administrator (and any delegate thereof) shall be entitled in all cases to indemnification and reimbursement by the Company in respect of any claim, loss, damage or expense (including, without limitation, reasonable attorneys' fees) arising or resulting therefrom to the fullest extent permitted by law and/or under the Company's articles of incorporation or bylaws or any directors' and officers' liability insurance coverage which may be in effect from time to time and/or any indemnification agreement between such individual and the Company.
- Delivery of Stock Certificates. Stock certificates to the Grantee under this Award of Restricted Stock Units shall be deemed delivered for all purposes when the Company or a stock transfer agent of the Company shall have mailed such certificates in the United States mail, addressed to the Grantee, at the Grantee's last known address on file with the Company. Uncertificated Stock shall be deemed delivered for all purposes when the Company or a stock transfer agent of the Company shall have given to the Grantee by electronic mail (with proof of receipt) or by United States mail, addressed to the Grantee, at the Grantee's last known address on file with the Company, notice of issuance and recorded the issuance in its records (which may include electronic "book entry" records). Notwithstanding anything herein to the contrary, the Company shall not be required to issue or deliver any certificates evidencing shares of Stock pursuant to the vesting of the Restricted Stock Units, unless and until the Administrator has determined, with advice of counsel (to the extent the Administrator deems such advice necessary or advisable), that the issuance and delivery of such certificates is in compliance with all applicable laws, regulations of governmental authorities and, if applicable, the requirements of any exchange on which the shares of Stock are listed, quoted or traded. All Stock certificates delivered pursuant to the Award of Restricted Stock Units shall be subject to any stop-transfer orders and other restrictions as the Administrator deems necessary or advisable to comply with federal, state or foreign jurisdiction, securities or other laws, rules and quotation system on which the Stock is listed, quoted or traded. The Administrator may place legends on any Stock certificate to reference restrictions applicable to the Stock. In addition to the terms and conditions provided herein, the Administrator may require that an individual make such reasonable covenants, agreements, and representations as the Administrator, in its discretion, deems necessary or advisable in order to comply with any such laws, regulations, or requirements. The Administrator may require each person acquiring Stock pursuant to the Award of Restricted Stock Units to represent and agree with the Company in writing that such person is acquiring the shares without a view to distribution thereof.
- 16. <u>Trading Policy Restrictions</u>. The sale of any shares of Stock received upon vesting of this Award of Restricted Stock Units shall be subject to the Company's insider trading policies and procedures, as in effect from time to time.

- 17. <u>Clawback Policy</u>. This Award of Restricted Stock Units shall be subject to the Company's clawback policy, if any, as in effect from time to time.
- 18. Data Privacy Consent. In order to administer this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of this Agreement (the "Relevant Information"). By entering into this Agreement, the Grantee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Grantee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Grantee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.
- 19. <u>Status of Grantee</u>. With respect to any portion of the Restricted Stock Units that have not vested, the Grantee shall have no rights greater than those of a general creditor of the Company unless the Administrator shall otherwise expressly determine. In its discretion, the Administrator may authorize the creation of a trust or other arrangement to meet the Company's obligation to deliver Stock, provided that the existence of such trusts or other arrangements is consistent with the foregoing sentence.
- 20. <u>Governing Law</u>. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, applied without regard to conflict of law principles.
- 21. <u>Notices</u>. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Grantee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

[Remainder of Page Intentionally Left Blank]

## VOYAGER THERAPEUTICS, INC.

| By:  |                             |  |
|--|-----------------------------|--|
|  | Title:                      |  |
| The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable. |                             |  |
| Dated:   |                             |  |
|  | Grantee's Signature         |  |
|  | Grantee's name and address: |  |
|  |                             |  |
|  |                             |  |
|  | 7                           |  |

## SCHEDULE A

## **DURABLE AUTOMATIC SALE INSTRUCTION**

This Durable Automatic Sale Instruction is being delivered to Voyager Therapeutics, Inc. by the undersigned on the date set forth below.

I hereby acknowledge that Voyager has granted, or may in the future from time to time grant, to me restricted stock units, or "RSUs," whether as an "inducement grant" or under Voyager's long-term equity incentive plans as in effect from time to time.

I acknowledge that upon the vesting dates applicable to any such RSUs, I will have compensation income equal to the fair market value of the shares of Voyager common stock subject to the RSU that vest on such date and that Voyager is required to withhold income and employment taxes in respect of that compensation income on the applicable vesting date.

I desire to establish a process to satisfy such withholding obligation in respect of all RSUs that have been, or may in the future be, granted by Voyager to me through an automatic sale of a portion of the shares of Voyager common stock that would otherwise be issued to me on each applicable vesting date, such portion to be in an amount sufficient to satisfy such withholding obligation, with the proceeds of such sale delivered to Voyager in satisfaction of such withholding obligation.

I understand that Voyager has arranged for the administration and execution of its equity awards and long-term equity incentive plans and the sale of securities by award holder thereunder pursuant to an Internet-based platform administered by a third party, which is referred to herein as the "Administrator," and the Administrator's designated brokerage partner.

Upon any vesting of my RSUs from and after the date of this Durable Automatic Sale Instruction, I hereby appoint the Administrator to automatically sell such number of shares of Voyager common stock issuable with respect to my RSUs that vest as is sufficient to generate net proceeds sufficient to satisfy Voyager's minimum statutory withholding obligations with respect to the income recognized by me upon the vesting of the RSUs (based on minimum statutory withholding rates for all tax purposes, including payroll and social security taxes, that are applicable to such income), and Voyager shall receive such net proceeds in satisfaction of such tax withholding obligation.

I agree to execute and deliver such further documents, instruments and certificates as may reasonably be required by the Administrator in connection with the sale of the shares pursuant to these automatic sale instructions.

By signing below, I hereby represent to Voyager that, as of the date hereof, I am not aware of any material nonpublic information about Voyager or its common stock. I have structured these automatic sale instructions to constitute a "binding contract" relating to the sale of common stock, consistent with the affirmative defense to liability under Section 10(b) of the Securities Exchange Act of 1934 under Rule 10b5-1(c) promulgated under such Act.

| Print Name: |  |  |
|-------------|--|--|
| Date:       |  |  |
|             |  |  |
| 8           |  |  |

## SUBSIDIARIES OF THE REGISTRANT

| Name of Entity     | State/Country of Organization |
|--------------------|-------------------------------|
|                    |                               |
| Voyager Securities | Corporation Massachusetts     |
|                    |                               |
|                    |                               |

## Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- Registration Statement (Form S-3 No. 333-214861) of Voyager Therapeutics, Inc. Registration Statement (Form S-8 No. 333-207958) pertaining to the 2014 Stock Option and Grant Plan, the 2015 Stock Option and Incentive Plan, and the 2015 Employee Stock Purchase Plan of Voyager Therapeutics, Inc.
- Registration Statement (Form S-8 No. 333-210258) pertaining to the 2015 Stock Option and Incentive Plan and the 2015 Employee Stock Purchase Plan of Voyager Therapeutics, Inc.
- Registration Statement (Form S-8 No. 333-216699) pertaining to the 2015 Stock Option and Incentive Plan and the 2015 Employee Stock Purchase Plan of Voyager Therapeutics, Inc.
  Registration Statement (Form S-8 No. 333-223638) pertaining to the 2015 Stock Option and Incentive Plan and the
- 2015 Employee Stock Purchase Plan of Voyager Therapeutics, Inc.

of our report dated February 26, 2019, with respect to the consolidated financial statements of Voyager Therapeutics, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2018.

/s/ Ernst & Young, LLP Boston, Massachusetts February 26, 2019

### Certification

- I, G. Andre Turenne, certify that:
- 1. I have reviewed this Annual Report on Form 10-K of Voyager Therapeutics, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2019 /s/ G. Andre Turenne

G. Andre Turenne President and Chief Executive Officer (Principal Executive Officer)

### Certification

- I, Allison Dorval, certify that:
- 1. I have reviewed this Annual Report on Form 10-K of Voyager Therapeutics, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2019 /s/ Allison Dorval

Allison Dorval
Chief Financial Officer
(Principal Financial and Accounting Officer)

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Voyager Therapeutics, Inc. (the "Company") for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his or her knowledge:

- the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 26, 2019 /s/ G. Andre Turenne

G. Andre Turenne

President and Chief Executive Officer

(Principal Executive Officer)

Date: February 26, 2019 /s/ Allison Dorval

Allison Dorval Chief Financial Officer

(Principal Financial and Accounting Officer)