# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): May 10, 2018

# Voyager Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

**DELAWARE** (State or other jurisdiction of incorporation) **001-37625** (Commission File Number)

75 Sidney Street Cambridge, Massachusetts (Address of principal executive offices)

**02139** 

46-3003182

(I.R.S. Employer

Identification No.)

(Zip Code)

Registrant's telephone number, including area code (857) 259-5340

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company  $\boxtimes$ 

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. 🖂

#### Item 2.02. Results of Operations and Financial Condition.

On May 10, 2018, Voyager Therapeutics, Inc. (the "Company") announced first quarter 2018 financial results and corporate highlights. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

#### Item 9.01. Financial Statements and Exhibits

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press release dated May 10, 2018 entitled "Voyager Therapeutics Announces First Quarter 2018 Financial Results and
	Corporate Highlights"

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99.1	Press release dated May 10, 2018 entitled "Voyager Therapeutics Announces First Quarter 2018 Financial Results and Corporate Highlights"

### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 10, 2018

## **VOYAGER THERAPEUTICS, INC.**

By: /s/ Steven M. Paul Steven M. Paul, M.D. President and Chief Executive Officer (Principal Executive Officer)



# Voyager Therapeutics Announces First Quarter 2018 Financial Results and Corporate Highlights

VY-AADC pivotal Phase 2-3 program for Parkinson's disease on track for first patient dosing during the middle of this year

**Cambridge, Mass., May 10, 2018** – Voyager Therapeutics, Inc. (NASDAQ: VYGR), a clinical-stage gene therapy company focused on developing life-changing treatments for severe neurological diseases today reported its first quarter 2018 results, recent progress and corporate highlights.

"The accomplishments made during the first quarter reflected the team's ability to advance our clinical and preclinical programs and gene therapy platform while continuing to execute on our business development initiatives," said Steven Paul, M.D., president and chief executive officer of Voyager Therapeutics. "With clinical trial site initiation underway for our pivotal program for VY-AADC for Parkinson's disease, our optimization efforts continuing for our preclinical programs, and our collaboration underway with AbbVie targeting vectorized monoclonal antibodies directed against tau for the treatment of Alzheimer's disease and other neurodegenerative diseases, we are poised to deliver meaningful progress during the remainder of the year."

## **Recent Clinical and Preclinical Program Highlights and Updates**

*VY-AADC* for *Parkinson's* disease:

- Clearance of the Investigational New Drug (IND) application by the Food and Drug Administration (FDA) for VY-AADC in January 2018 allowed the Company to begin activating clinical trial sites for its pivotal Phase 2-3 program for Parkinson's disease. More than fifteen clinical trial sites (including neurosurgical and neurology patient referral sites) have been selected for participation in the trial since the IND clearance and institutional review board (IRB) submissions are underway. Anticipated approval of IRB submissions and activation of these clinical trial sites, along with feedback from a planned Type C meeting with the FDA, can allow for first patient dosing expected in the middle of this year.
- Recently, investigators successfully dosed an eighth patient with VY-AADC in a Phase 1 trial in patients with Parkinson's disease exploring the posterior (i.e., back of the head) infusion trajectory of VY-AADC. The posterior trajectory better aligns the infusion of VY-AADC with the anatomical structure of the putamen and

resulted in higher total volume of coverage of the putamen and shorter total procedure time compared to Cohorts 1 through 3 from the ongoing Phase 1b trial that employed a transfrontal, or top of the head, delivery approach into the putamen. Preliminary data from patients in the Phase 1 trial who have reached the six-month endpoint is planned for later this quarter. Based on the safety, coverage of the putamen, and reduced surgical times from the eight patients treated in this trial, the posterior approach will serve as the preferred infusion trajectory for the planned Phase 2-3 trials.

Preclinical programs for Huntington's, ALS SOD-1, Friedreich's ataxia and tau for Alzheimer's and other neurodegenerative diseases:

- Voyager continues to advance multiple preclinical programs towards clinical trials through further vector optimization and exploration of additional routes of administration, to support filing two IND applications from its preclinical programs targeting a monogenic form of Amyotrophic Lateral Sclerosis (ALS) called SOD1, Huntington's disease, and Friedreich's ataxia programs. Data from each of these programs will be presented at the American Society of Gene and Cell Therapy (ASGCT) taking place May 16-19, 2018, in Chicago, Ill.
- In February 2018, Voyager announced an exclusive strategic collaboration and option agreement with AbbVie to develop and commercialize vectorized antibodies directed against tau for the treatment of Alzheimer's disease and other neurodegenerative diseases, combining Voyager's gene therapy platform with AbbVie's monoclonal antibody expertise, global clinical development and commercial capabilities. With a recent joint governance committee meeting successfully concluded, the research period is underway for each company to identify up to five antibodies that target tau for inclusion in the collaboration.

### Voyager investor and analyst breakfast event at ASGCT:

Voyager's senior management team will review data being presented at the ASGCT meeting during the following event:

Date/time: Friday, May 18, 2018, 7:30 a.m. CDT Location: Joliet Room, 3<sup>rd</sup> Floor, Hilton Chicago Hotel, 720 S. Michigan Ave., Chicago, Ill.

### **First Quarter 2018 Financial Results**

Voyager reported a GAAP net loss of \$19.9 million, or \$0.63 per share, for the first quarter ended March 31, 2018, compared to a GAAP net loss of \$16.6 million, or \$0.65 per share, for the same period in 2017.

Collaboration revenue of \$0.9 million for the first quarter of 2018 compared to \$1.5 million for the first quarter of 2017. Collaboration revenues reflect recognition of payment for research and development services provided by Voyager for various programs under the Collaboration Agreements with Sanofi Genzyme and AbbVie. The decrease in

collaboration revenues for the first quarter of 2018 compared to the same period in 2017 primarily reflects the adoption on January 1, 2018, of certain accounting rules related to revenue recognition. Voyager now uses a proportional performance basis for estimating progress of research and development services that has resulted in a decrease in collaboration revenue related to the Sanofi Genzyme collaboration in the first quarter of 2018 compared to the same period in 2017. This decrease was offset by revenue recognized in the first quarter of 2018 related to the AbbVie collaboration.

Research and development (R&D) expenses of \$14.9 million for the first quarter ended March 31, 2018 compared to \$14.1 million for the same period in 2017. The increase in R&D expenses related primarily to expenditures associated with increased personnel and facility costs to support the advancement of the pipeline programs.

General and administrative (G&A) expenses of \$7.2 million for the first quarter 2018 compared to \$4.9 million for the same period in 2017. The increase in G&A expenses was primarily due to personnel and facility costs to support Voyager's pipeline programs and increased professional fees related to the AbbVie collaboration.

Cash, cash equivalents, and marketable debt securities as of March 31, 2018 were \$218.2 million. Based on the Company's current operating plan, Voyager continues to expect to end 2018 with total cash, cash equivalents and marketable debt securities of approximately \$125 million to \$135 million and projects that its existing cash, cash equivalents and marketable debt securities will be sufficient to fund operating expenses and capital expenditure requirements into early 2020.

# **About Voyager Therapeutics**

Voyager Therapeutics is a clinical-stage gene therapy company focused on developing lifechanging 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 broad strategic collaborations with Sanofi Genzyme, the specialty care global business unit of Sanofi, AbbVie, and the University of Massachusetts Medical School. 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, please visit www.voyagertherapeutics.com.

## **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 and reporting of results of its preclinical programs and clinical trials and its research and development programs, 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 and AbbVie and to add new programs to its pipeline, its ability to enter into new partnerships or collaborations, and the timing or likelihood of its regulatory filings and approvals, 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, the initiation and conduct of preclinical studies and clinical trials; the availability of data from clinical trials; the expectations for regulatory submissions and approvals; the continued development of the product engine; Voyager's scientific approach and general development progress; 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.

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Investor Relations: Matt Osborne Vice President of Investor Relations & Corporate Communications 857-259-5353 mosborne@vygr.com

### Media:

Elliot Fox W2O Group 212-257-6724 efox@w2ogroup.com

# Selected Financial Information

(\$-amounts in thousands, except per share data) (Unaudited)

		Three Months Ended			
		March 31,			
Statement of Operations Items:		2018		2017	
Collaboration revenue	\$	942	\$	1,464	
Operating expenses:					
Research and development		14,853		14,072	
General and administrative		7,182		4,914	
Total operating expenses		22,035		18,986	
Operating loss		(21,093)		(17,522)	
Total other income		987		648	
Loss before income taxes		(20,106)		(16,874)	
Income tax benefit		180		226	
Net loss	\$	(19,926)	\$	(16,648)	
Net loss per share, basic and diluted	\$	(0.63)	\$	(0.65)	
Weighted-average common shares outstanding, basic and diluted	3	31,759,870 25,791,59		5,791,591	

March 31,		March 31,	December 31,	
Selected Balance Sheet Items		2018		2017
Cash, cash equivalents, and marketable debt securities	\$	218,198	\$	169,052
Total assets	\$	235,026	\$	184,477
Accounts payable and accrued expenses	\$	10,723	\$	12,517
Deferred revenue	\$	119,723	\$	31,560
Total stockholders' equity	\$	98,293	\$	134,051