

**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): **August 9, 2019**

Voyager Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation)

001-37625
(Commission
File Number)

46-3003182
(I.R.S. Employer
Identification No.)

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

02139
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value	VYGR	Nasdaq Global Select Market

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

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 August 9, 2019, Voyager Therapeutics, Inc. (the “Company”) reported second quarter 2019 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 and is incorporated by reference herein.

The information in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On August 9, 2019, Perry Karsen provided notice to the Company’s board of directors (the “Board”) of his decision to resign from the Board and all committees thereof, effective as of August 31, 2019. Mr. Karsen informed the Board that his decision to resign was made in light of the geographical demands of serving on the Board and new commitments commencing in the fall as a fellow in the Stanford University Distinguished Careers Institute and that his resignation was not based upon any disagreement with the Board, or with the management of the Company, on any matter relating to the Company’s operations, policies or practices.

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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press release dated August 9, 2019 entitled “Voyager Therapeutics Announces Second Quarter 2019 Financial Results and Corporate Highlights”</u>

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: August 9, 2019

VOYAGER THERAPEUTICS, INC.

By: /s/ G. Andre Turenne
G. Andre Turenne
Chief Executive Officer, President, and Director
(Principal Executive Officer)



Voyager Therapeutics Reports Second Quarter 2019 Financial Results and Corporate Highlights

Gained worldwide rights to VY-HTT01 for Huntington's disease, expanding wholly-owned pipeline

Presented additional Phase 1b results for VY-AADC in patients with Parkinson's disease at the 2019 American Academy of Neurology (AAN) Annual Meeting

Strengthened leadership team with appointment of Omar Khwaja, M.D., Ph.D., as Head of R&D and recruitment of Kelly Bales, Ph.D., as SVP and Head of Neuroscience

CAMBRIDGE, Mass., August 9, 2019 – Voyager Therapeutics, Inc. (NASDAQ: VYGR), a clinical-stage gene therapy company focused on developing life-changing treatments for severe neurological diseases, today reported its second quarter 2019 financial results, program progress and corporate updates.

“During the second quarter we continued to make progress across our pipeline and strengthened our leadership team with key appointments. Through a restructuring of our relationship with Sanofi Genzyme, we were able to gain worldwide rights to the Huntington’s disease program. We were also able to successfully transition management within our research, development and clinical areas through the expansion of Omar’s role as Chief Medical Officer to include leadership of our full R&D organization. By combining leadership of these functions, we expect to advance program activities in a more integrated and efficient manner,” said Andre Turenne, President and Chief Executive Officer of Voyager. “We are pleased that Dinah Sah, our former Chief Scientific Officer who retired in June, has agreed to remain with us as a scientific advisor. We are also pleased to have recruited Kelly to join us as SVP and Head of Neuroscience. She brings tremendous expertise in neuroscience drug discovery from her prior leadership roles at Roche and Pfizer.”

Recent Corporate and Program Highlights

- In June 2019, Voyager announced a restructuring of the Company’s gene therapy relationship with Sanofi Genzyme. Voyager gained worldwide rights to the VY-HTT01 Huntington’s disease program and ex-U.S. rights to the VY-FXN01 Friedreich’s ataxia program. The ex-U.S. rights to VY-FXN01 were, in turn, transferred from Voyager to Neurocrine Biosciences under the terms of the collaboration agreement between Voyager and Neurocrine Biosciences announced in January 2019. Sanofi Genzyme’s
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rights under the original 2015 collaboration agreement were terminated in exchange for a \$10 million upfront payment by Voyager and the agreement by Voyager to make an additional \$10 million payment upon filing of an investigational new drug application for VY-HTT01. The collaboration between Voyager and Sanofi Genzyme concerning spinal muscular atrophy (SMA) was terminated, and intellectual property rights under the collaboration to the SMA program were returned or exclusively licensed to Sanofi Genzyme. Additionally, Sanofi Genzyme obtained exclusive option rights to license up to two novel AAV capsids owned or controlled by Voyager for up to two non-central nervous system indications. Voyager's upfront payment was partially offset by a \$5 million payment from Neurocrine Biosciences to the Company to facilitate the transfer of the ex-U.S. rights to VY-FXN01 from Voyager to Neurocrine Biosciences.

- In connection with restructuring the Company's gene therapy relationship with Sanofi Genzyme, Voyager announced the intention to seek a partner to advance its preclinical program for SOD1 ALS in order to focus resources on its wholly-owned Huntington's disease program and new discovery efforts.
- In May 2019, Voyager and Neurocrine Biosciences presented Phase 1 results at AAN, evaluating the safety and efficacy of VY-AADC in eight patients with Parkinson's disease and further assessing the posterior surgical delivery approach. Treatment with VY-AADC improved patients' mean good ON time by 1.7 hours and reduced mean OFF time by 2.2 hours at 12 months from baseline. Results confirmed the posterior trajectory as an alternative surgical delivery route.

Management and Board of Directors Updates

- In May 2019, Voyager announced that Omar Khwaja, M.D., Ph.D., would assume the expanded role of Chief Medical Officer and Head of Research and Development effective June 28, 2019 following the retirement of Dinah Sah, Ph.D., as Voyager's Chief Scientific Officer. Dr. Sah will continue to serve as an advisor, and the Company expects she will become a member of its scientific advisory board.
 - The Company recently appointed Kelly R. Bales, Ph.D., to Senior Vice President and Head of Neuroscience. Prior to joining Voyager, Dr. Bales served as Vice President & Global Head Neuroscience Discovery at Roche Pharma Research & Early Development.
 - Michael Higgins assumed the role of Board chairman on June 13, 2019. He succeeds Mark Levin, who continues to serve as a member of the Board.
 - Perry Karsen informed the Company of his decision to resign as a member of the Board effective August 31, 2019. Mr. Karsen reached this decision in light of the geographical demands of serving on the Voyager Board and new commitments commencing this fall as a fellow in the Stanford University Distinguished Careers Institute.
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Second Quarter 2019 Financial Results

For the second quarter of 2019, Voyager reported:

A net income of \$11.2 million, or \$0.30 per basic share, for the second quarter of 2019, compared to a net loss of \$25.5 million, or \$0.80 per basic share, for the second quarter of 2018.

Collaboration revenues of \$46.1 million for the second quarter of 2019, compared to \$2.6 million for the second quarter of 2018. This increase for the quarter primarily reflects the termination of the Sanofi Genzyme Collaboration in June 2019, which resulted in the recognition of \$28.7 million of previously deferred amounts. In addition, the increase reflects the recognition of non-cash amounts related to research services performed by Voyager under the AbbVie and Neurocrine Biosciences collaborations, as well as the recognition of amounts expected to be reimbursed under the Neurocrine Biosciences collaboration.

Operating expenses of \$36.9 million for the second quarter of 2019 compared to operating expenses of \$28.3 million for the second quarter of 2018. The increase in operating expenses related primarily to the increased efforts to support the Company's preclinical pipeline and clinical program, including increases in research and development and general and administrative headcount.

Research and development (R&D) expenses of \$28.6 million for the second quarter of 2019 compared to R&D expenses of \$16.5 million for the second quarter of 2018. The increase in R&D expenses related primarily to an increase in costs associated with the advancement of the VY-AADC RESTORE-1 Phase 2 clinical program and the Company's preclinical programs, including an increase in employee-related expenses and facility costs.

General and administrative (G&A) expenses of \$8.3 million for the second quarter of 2019 compared to G&A expenses of \$11.8 million for the second quarter of 2018. The decrease in G&A expenses was primarily due to the one-time recognition of \$5.4 million of stock-based compensation related to the modification of stock options during the three months ended June 30, 2018, partially offset by an increase in employee-related expenses, and consulting and professional fees to support the advancement of Voyager's pipeline programs, R&D platform initiatives and manufacturing capabilities.

Cash, cash equivalents, and marketable debt securities as of June 30, 2019 were \$327.5 million, as compared to \$358.5 million on March 31, 2019. Based on the Company's current operating plan, the Company continues to anticipate full-year 2019 operating expenses to range between \$130 million and \$140 million, before accounting for amounts reimbursable under the Neurocrine Biosciences collaboration, and anticipates cash, cash equivalents and marketable debt securities at year end of approximately \$280 million to \$290 million. Voyager continues to anticipate that its cash, cash equivalents and marketable debt securities will be sufficient to fund projected operating expenses and capital expenditure requirements to mid-2022.

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 wholly-owned and partnered pipeline focuses on severe neurological diseases for which effective new therapies are needed, including Parkinson's disease, Huntington's disease, a monogenic form of ALS called SOD1, Friedreich's ataxia, Alzheimer's disease, and other neurodegenerative diseases related to defective or excess aggregation of tau and alpha-synuclein proteins in the brain. Voyager has strategic collaborations with AbbVie and Neurocrine Biosciences. Founded by scientific and clinical leaders in the fields of AAV gene therapy, expressed RNA interference and neuroscience, Voyager is headquartered in Cambridge, Massachusetts. For more information on Voyager, please visit the Company's website at www.voyagertherapeutics.com or follow [@VoyagerTx](https://twitter.com/VoyagerTx) on Twitter and [LinkedIn](https://www.linkedin.com/company/voyager-therapeutics).

Voyager Therapeutics® is a registered trademark, and TRACER™ is a trademark, of Voyager Therapeutics.

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, timing and future operation of the collaboration agreements with Sanofi Genzyme, AbbVie and Neurocrine Biosciences, including any potential future payments thereunder, its ability to identify and attract parties to participate in research and development collaborations, 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 and its TRACER system, its ability to perform under existing collaborations including those with AbbVie and Neurocrine Biosciences, its ability to add new programs to its pipeline, the regulatory pathway of, and the timing or likelihood of its regulatory filings and approvals for, any of its product candidates, its ability to operate its research and development activities efficiently and effectively, the utility and value of Voyager's patent portfolio, anticipated financial results, including Voyager's available cash and cash equivalents, the receipt by Voyager of revenues from collaboration partners and Voyager's operating expenses, are forward looking. All forward-looking statements are based on estimates and assumptions by Voyager's management that, although Voyager believes such forward-looking statements 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 and its TRACER system; Voyager's scientific approach and general development progress; the ability to attract and retain talented contractors and employees; the ability to create and protect intellectual property; the sufficiency of cash resources; the possibility or the timing of the exercise of development, commercialization, license and other options under collaborations; 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 Annual Report on Form 10-K filed for the year ended December 31, 2018 with the Securities and Exchange Commission, as updated by its subsequent filings with the Securities and Exchange Commission. All information in the press release is as of the date of this press release, and any forward-looking statement speaks only as of the date on which it was made. Voyager undertakes no obligation to publicly update or revise this information or any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

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

Statement of Operations Items:	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
Collaboration revenue	\$ 46,087	\$ 2,575	\$ 51,284	\$ 3,517
Operating expenses:				
Research and development	28,576	16,507	53,407	31,360
General and administrative	8,322	11,762	17,981	18,945
Total operating expenses	36,898	28,269	71,388	50,305
Operating income (loss)	9,189	(25,694)	(20,104)	(46,788)
Total other income	1,964	153	4,087	1,140
Income (loss) before income taxes	11,153	(25,541)	(16,017)	(45,648)
Income tax benefit	—	—	—	180
Net income (loss)	<u>\$ 11,153</u>	<u>\$ (25,541)</u>	<u>\$ (16,017)</u>	<u>\$ (45,468)</u>
Net income (loss) per share, basic	<u>\$ 0.30</u>	<u>\$ (0.80)</u>	<u>\$ (0.46)</u>	<u>\$ (1.43)</u>
Net income (loss) per share, diluted	<u>\$ 0.29</u>	<u>\$ (0.80)</u>	<u>\$ (0.46)</u>	<u>\$ (1.43)</u>
Weighted-average common shares outstanding, basic	<u>36,610,918</u>	<u>31,976,922</u>	<u>34,990,989</u>	<u>31,868,995</u>
Weighted-average common shares outstanding, diluted	<u>37,941,257</u>	<u>31,976,922</u>	<u>34,990,989</u>	<u>31,868,995</u>

Selected Balance Sheet Items	June 30,	December 31,
	2019	2018
Cash, cash equivalents, and marketable debt securities	\$ 327,462	\$ 155,806
Total assets	\$ 388,592	\$ 177,029
Accounts payable and accrued expenses	\$ 14,012	\$ 10,826
Deferred revenue	\$ 219,727	\$ 113,046
Total stockholders' equity	\$ 118,404	\$ 46,446

