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): **February 2, 2021**

Voyager Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE	**001-37625**	**46-3003182**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

75 Sidney Street **Cambridge, Massachusetts**	**02139**
(Address of principal executive offices)	(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 1.02 Termination of a Material Definitive Agreement.

On February 2, 2021, Neurocrine Biosciences, Inc. ("Neurocrine") notified Voyager Therapeutics, Inc. (the "Company") of its partial termination of the Collaboration and License Agreement, dated January 28, 2019, by and between the Company and Neurocrine (as amended to date, the "Collaboration Agreement"). In accordance with the terms of the Collaboration Agreement, Neurocrine has the right to terminate the Collaboration Agreement in its entirety, on a program-by-program basis, or on a country-by-country basis, subject to specified conditions. Pursuant to the notice received by the Company, Neurocrine has elected to terminate the Collaboration Agreement solely with regards to the NBIb-1817 (VY-AADC) development program for the treatment of Parkinson's disease (the "Parkinson's Program"), effective August 2, 2021 (the "Effective Date"). The Collaboration Agreement remains in full force and effect for each other program thereunder.

As previously disclosed, under the Collaboration Agreement, the Company and Neurocrine agreed to collaborate on the conduct of four programs for the research, development, and commercialization of adeno-associated virus gene therapy product candidates on a worldwide basis: the Parkinson's Program, a program for the treatment of Friedreich's ataxia, and two programs for indications to be mutually agreed by the Company and Neurocrine. Pursuant to the Collaboration Agreement, in respect of the Parkinson's Program, the Company granted Neurocrine an exclusive, royalty-bearing, non-transferable, sublicensable license to certain of the Company's intellectual property rights, and Neurocrine agreed to fund all development costs associated with the RESTORE-1 Phase 2 clinical trial, an ongoing randomized, double-blind, placebo-surgery controlled trial evaluating the safety and efficacy of NBIb-1817 (VY-AADC) for the treatment of Parkinson's disease in patients with motor fluctuations that are refractory to medical management ("RESTORE-1"). After the data readout of RESTORE-1, the Company had the option to either (i) co-commercialize NBIb-1817 (VY-AADC) with Neurocrine 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 (ii) grant Neurocrine full global commercial rights in exchange for milestone payments and royalties based on global sales. The Collaboration Agreement also provided for (i) aggregate development milestone payments from Neurocrine to the Company in connection with the Parkinson's Program of up to $170.0 million; (ii) aggregate commercial milestone payments from Neurocrine to the Company of up to $275.0 million for each collaboration product developed under the Parkinson's Program, subject to an aggregate cap on commercial milestones across all programs of $1.1 billion; and (iii) the payment by Neurocrine to the Company of tiered royalties, based on future net sales of any collaboration products developed under the Parkinson's Program. Such royalty percentages ranged from the mid-teens to thirty percent for net sales inside the United States and from the low-teens to twenty percent for net sales outside the United States.

As a result of the termination, as of the Effective Date, the license granted by the Company to Neurocrine thereunder regarding the Parkinson's Program shall expire and the Company shall regain worldwide intellectual property rights regarding the Parkinson's Program, in each case in accordance with the terms of the Collaboration Agreement. The Company plans to support Neurocrine, the sponsor of RESTORE-1 and the holder of the investigational new drug application, on any ongoing matters related to imaging and clinical assessments requested by the Data Safety & Monitoring Board ("DSMB") for RESTORE-1 and other information that may be requested by the U.S. Food and Drug Administration ("FDA") for RESTORE-1.

The Company is evaluating the complete financial impact of the termination of the Parkinson's Program and the future of the Parkinson's Program and expects to provide a subsequent update.

The foregoing description of the terms and conditions of the Collaboration Agreement material to the Company is qualified in its entirety by reference to the Collaboration and License Agreement, dated January 28, 2019, by and between the Company and Neurocrine, a copy of which has been filed with the Securities and Exchange Commission (the "Commission") on the Company's Annual Report on Form 10-K on February 26, 2019, and Amendment No. 1 to the Collaboration and License Agreement, dated June 14, 2019, by and between the Company and Neurocrine, a copy of which has been filed with the Commission on a Quarterly Report on Form 10-Q on August 8, 2019, each of which is incorporated by reference herein.

Item 8.01 Other Events.

The information set forth in Item 1.02 above is incorporated herein by reference.

In December 2020, the Company announced that the FDA had notified Neurocrine that the FDA had placed a clinical hold on RESTORE-1. The FDA notification followed a request by the study's independent DSMB for a pause in dosing pending the receipt of information about magnetic resonance imaging abnormalities observed in trial participants. In January 2021, the FDA informed Neurocrine of the information required to provide a complete response to the FDA in connection with the clinical hold. Information required by the FDA includes an assessment of how the investigational product may have given rise to the adverse findings, a mitigation plan to manage the adverse findings, and supportive data to justify that a favorable benefit/risk profile remains for the product.

Cautionary Note Concerning Factors That May Affect Future Results

This Current Report on Form 8-K 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 the Company makes regarding the progress, activities, goals and reporting of results of its clinical trials, the potential benefits and future operation of its collaboration with Neurocrine and the activities thereunder, the Company’s ability to perform its obligations under the collaboration agreement with Neurocrine, the ability of Neurocrine and the Company to gather additional information to further characterize the safety profile of NBIb-1817 (VY-AADC) and to work with the FDA to determine the next steps for RESTORE-1, the regulatory pathway of, and the timing or likelihood of its regulatory filings and approvals for, any of the Company’s product candidates, and its anticipated financial results, including the financial impact of the termination of the NBIb-1817 (VY-AADC) program, are forward looking.

All forward-looking statements are based on estimates and assumptions by the Company’s management that, although the Company 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 the Company 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; the Company’s scientific approach and general development progress; the sufficiency of its cash resources; the availability or commercial potential of the Company’s product candidates; and the ability of Neurocrine and the Company to complete their evaluation and to meet the information requests of, and to resolve questions raised by, the FDA required to bring an end to the clinical hold on RESTORE-1. These statements are also subject to a number of material risks and uncertainties that are described in the Company’s 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. All information in the Current Report on Form 8-K is as of the date of this Current Report on Form 8-K, and any forward-looking statement speaks only as of the date on which it was made. The Company 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.

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: February 2, 2021

VOYAGER THERAPEUTICS, INC.

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