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): **December 28, 2023**

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 Hayden Avenue **Lexington, Massachusetts**	**02421**
(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 1.01 Entry into a Material Definitive Agreement

License and Collaboration Agreement

On December 28, 2023 (the "Effective Date"), Voyager Therapeutics, Inc. (the "Company") entered into a License and Collaboration Agreement (the "Collaboration Agreement") with Novartis Pharma AG ("Novartis") to (a) provide rights to Novartis with respect to certain proprietary adeno-associated virus ("AAV") capsids discovered by the Company (the "Voyager Capsids") for use in the research, development, and commercialization by Novartis of AAV gene therapy products and product candidates, comprising such Voyager Capsids and payloads intended for the treatment of spinal muscular atrophy (the "SMA Program") and (b) collaborate to develop AAV gene therapy products and product candidates intended for the treatment of Huntington's disease (the "HD Program"), in each case, leveraging Voyager Capsids and other intellectual property controlled by the Company.

SMA Program and HD Program Licenses. Under the terms of the Collaboration Agreement, the Company has agreed to grant to Novartis and its affiliates:

- a non-exclusive, non-transferable, non-sublicensable (except in limited circumstances for contractors), worldwide, royalty-free right and license under any patents or know-how controlled by the Company and related to the Voyager Capsids to evaluate the same for use in the development of a product or product candidate under the SMA Program (a "SMA Program Product") comprising such a Voyager Capsid and a payload selected by Novartis during the period beginning on the Effective Date and ending on the third anniversary of the Effective Date;

- an exclusive (even as to the Company), sublicensable, non-transferable, worldwide, royalty-bearing right and license under any patents or know-how controlled by the Company and relating to the selected Voyager Capsids to exploit the same as incorporated into an SMA Program Product for all human and veterinary diagnostic, prophylactic and therapeutic uses during the Term (as defined below); and

- an exclusive (even as to the Company), non-transferable, sublicensable, worldwide, royalty-bearing right and license under any patents and know-how controlled by the Company and relating to the development of a product or product candidate under the HD Program (an "HD Program Product") to exploit the same for all human and veterinary diagnostic, prophylactic and therapeutic uses during the Term.

Governance. The Company and Novartis have agreed to manage the HD Program through a joint steering committee until dissolved after the first investigational new drug ("IND") application filing for an HD Program Product. The Company and Novartis have further agreed that day-to-day activities of both the SMA Program and the HD Program shall be managed through designees from each of the Company and Novartis, acting as alliance managers.

Development, Regulatory Approval, Commercialization and Diligence. Under the Collaboration Agreement, Novartis is solely responsible for, and has sole decision-making authority with respect to, at its own expense, the exploitation of an SMA Program Product.

With respect to the HD Program, the parties have agreed to conduct research and pre-clinical development of HD Program Products pursuant to a research plan, with Novartis reimbursing the Company for its activities thereunder in accordance with the agreed-to budget. From and after the first IND application filing for the HD Program, the parties have agreed that Novartis will assume sole responsibility for the development and commercialization of HD Program Products, including all further preclinical and clinical development and any commercialization of the HD Program products and product candidates.

With respect to each of the SMA Program Products and HD Program Products, Novartis is obligated to use commercially reasonable efforts to develop and obtain regulatory approval for at least one of each such product in the United States and in certain other international markets specified in the Collaboration Agreement.

Financial Terms. Under the Collaboration Agreement, Novartis has agreed to pay the Company an initial upfront payment of $80 million and to purchase 2,145,002 shares of common stock of the Company (the "Shares") for an aggregate purchase price of approximately $20 million (collectively, the "Upfront Payment") pursuant to the Stock Purchase Agreement (as defined below). The Company is eligible to receive specified development, regulatory, and commercialization milestone payments of up to an aggregate of $200 million for the SMA Program and up to an aggregate of $225 million for the HD Program, in each case for the first corresponding product to achieve the corresponding milestone. The Company is also eligible to receive (a) specified sales milestone payments of up to an aggregate of $400 million for the SMA Program and up to an aggregate of $375 million for the HD Program and (b) tiered, escalating royalties in the high single-digit to low double-digit percentages of annual net sales of the SMA Program Products and the HD Program Products. The royalties are subject to potential customary reductions, including patent claim expiration, payments for certain third-party licenses, and biosimilar market penetration, subject to specified limits.

Intellectual Property. Under the terms of the Collaboration Agreement, each party owns the entire right, title, and interest in and to all patents or know-how controlled by such party and existing as of or before the Effective Date, or invented, authored, discovered, developed, created or acquired solely by or on behalf of such party after the Effective Date outside of its activities under the Collaboration Agreement.

The parties have further agreed that all know-how created by either or both parties in the performance of the activities as undertaken pursuant to the performance of the HD Program plan or in the course of development, manufacture and commercialization of HD Program Products and all patent rights covering such know-how (collectively, the "Arising IP") is to be owned as follows: (i) the Company solely owns all Arising IP comprised of know-how or other intellectual property rights related to any Voyager Capsid, including the use or manufacture of any Voyager Capsid, and that is created jointly by representatives of the Company and Novartis or created solely by representatives of Novartis through the use of the Company's confidential information; and (ii) with respect to all other Arising IP, (A) the Company solely owns all such Arising IP created solely by its representatives, (B) Novartis solely owns all such Arising IP created solely by its representatives; and (C) the parties jointly own all such Arising IP created jointly by representatives of both Novartis and the Company.

Exclusivity. Subject to certain limitations and exceptions, the Company has agreed during the Term not to (i) conduct any internal program or program on behalf of a third party that is directed to the development or commercialization of any capsids for use in any therapeutic product containing a capsid in combination with a payload designed to have therapeutic effect on the gene agreed between the parties as the target of the SMA Program when packaged into a capsid and delivered to the appropriate cells; (ii) develop or commercialize any competing HD Program Product intended to have a therapeutic effect on genes agreed between the parties as the targets of the HD Program; or (iii) grant any third party any right, license, option, covenant not to assert or similar right, under any patents or know-how controlled by the Company or its affiliates (excluding an acquiring entity) as of the Effective Date or during the Term, that would enable a third party to do any of the foregoing.

Termination. Unless earlier terminated, with respect to any licensed product(s) under the Collaboration Agreement, on a country-by-country basis, the Collaboration Agreement expires upon the expiration of the last-to-expire royalty term with respect to such licensed product in such country in the territory (the "Term"). Subject to a cure period, either party may terminate the Collaboration Agreement, in whole or in part, subject to specified conditions, in the event of the other party's uncured material breach. Novartis may also terminate the Collaboration Agreement, in whole or in part, subject to specified conditions, for the Company's insolvency, for the occurrence of a violation of global trade control laws, or for the Company's non-compliance with certain anti-bribery or anti-corruption covenants. Novartis may terminate the Collaboration Agreement, in whole or in part, for any or no reason upon ninety days' written notice to the Company. In the event that Novartis has the right to terminate the Collaboration Agreement as a result of an uncured material breach by the Company that materially impairs the ability of Novartis to exploit one or more licensed products, Novartis may, in lieu of such termination, elect for the Collaboration Agreement to remain in full force and effect, and all milestone payments and royalties that would have otherwise been payable by Novartis under such licenses had the Collaboration Agreement not been breached would be substantially reduced.

The foregoing description of the terms of the Collaboration Agreement is qualified in its entirety by reference to the full text of the Collaboration Agreement, a copy of which the Company intends to file with the Securities and Exchange Commission (the "SEC") as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2023 (the "2023 Annual Report").

Stock Purchase Agreement

In connection with the execution of the Collaboration Agreement, Novartis and the Company also entered into a stock purchase agreement on the Effective Date (the "Stock Purchase Agreement") for the sale and issuance of the Shares to Novartis at a price of $9.324 per share, for an aggregate purchase price of approximately $20 million.

The consummation of the transactions contemplated by the Stock Purchase Agreement is subject to the Collaboration Agreement and the Investor Agreement (as defined below) remaining in full force and effect and the satisfaction or waiver of other customary closing conditions. The parties have agreed to hold the closing of the purchase and sale of the Shares (the "Closing") on the third business day after the satisfaction or waiver of such closing conditions or such other time as the parties may agree (the "Closing Date").

The Stock Purchase Agreement may be terminated upon the mutual consent of the parties. Either party may terminate the Stock Purchase Agreement upon written notice to the other party if certain closing conditions are unable to be met within three months of the Effective Date. Subject to specified exceptions, either party also may terminate the Stock Purchase Agreement prior to the Closing upon material breach of certain covenants or agreements by the other party or upon certain representations and warranties of such other party becoming untrue. In addition, subject to specified exceptions, Novartis also may terminate the Stock Purchase Agreement prior to the Closing if there has been any change or occurrence since the Effective Date that has constituted a material adverse effect on the Company.

The foregoing description of the terms of the Stock Purchase Agreement is qualified in its entirety by reference to the full text of the Stock Purchase Agreement, a copy of which the Company intends to file with the SEC as an exhibit to the 2023 Annual Report.

Investor Agreement

In connection with the execution of the Collaboration Agreement, Novartis and the Company also entered into an investor agreement on the Effective Date (the "Investor Agreement"), to become effective as of the Closing Date, providing for standstill and lock-up restrictions.

Pursuant to the terms of the Investor Agreement, Novartis has agreed not to, without the prior written approval of the Company and subject to specified conditions, directly or indirectly acquire shares of the Company's outstanding common stock, publicly seek or propose a tender or exchange offer or merger between the parties, solicit proxies or consents to vote any voting securities of the Company, or undertake other specified actions related to the potential acquisition of additional equity interests in the Company (the "Standstill Restrictions"). Further, Novartis has also agreed not to, and to cause its affiliates not to, sell or transfer any of the Shares without the prior approval of the Company, subject to specified conditions (the "Lock-Up Restrictions").

Each of the Standstill Restrictions and the Lock-Up Restrictions terminate upon the earliest to occur of: (i) the expiration or earlier termination of the Collaboration Agreement; (ii) the date that is the third anniversary of the Closing Date; (iii) a liquidation or dissolution of the Company; and (iv) the deregistration of the Company's common stock. The Lock-Up Restrictions also terminate on a change of control of the Company or the date on which Novartis and its affiliates beneficially own less than three percent of the common stock of the Company on an outstanding basis.

The foregoing description of the terms of the Investor Agreement is qualified in its entirety by reference to the full text of the Investor Agreement, a copy of which the Company intends to file with the SEC as an exhibit to the 2023 Annual Report.

Item 2.02 Results of Operations and Financial Condition

The Company is currently completing its reports of its operational and financial results for the year ended December 31, 2023. However, the Company estimates its preliminary unaudited cash and cash equivalents and marketable securities to be approximately $230.7 million as of December 31, 2023, and that its preliminary unaudited cash and cash equivalents and marketable securities as of December 31, 2023, as adjusted to give effect to anticipated receipt by the Company of the $100.0 million in aggregate upfront payments under the Collaboration Agreement and the Stock Purchase Agreement described above, would be approximately $330.7 million. The Company expects its cash and cash equivalents and marketable securities as of December 31, 2023, as adjusted to give effect to the anticipated $100.0 million in aggregate upfront payments from Novartis, along with amounts expected to be received as reimbursement for development costs under the Company's collaborations with Neurocrine Biosciences, Inc. ("Neurocrine") and Novartis, to be sufficient to meet the Company's planned operating expenses and capital expenditure requirements into mid-2026.

The estimated cash and cash equivalent and marketable securities amounts as of December 31, 2023, discussed above are based on preliminary and unaudited information and management's estimates as of the date of this Current Report on Form 8-K and are subject to completion of the Company's customary financial closing procedures. The receipt of the $100.0 million in upfront payments is subject to the satisfaction or waiver of customary closing conditions for the Stock Purchase Agreement as described above. The Company's independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, these amounts.

The information in Item 2.02 of this Current Report on Form 8-K 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 (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 3.02 Unregistered Sales of Equity Securities

The information set forth in Item 1.01 above under the caption "Stock Purchase Agreement" is incorporated herein by reference. Based in part upon the representations of Novartis in the Stock Purchase Agreement, the Company expects the Shares to be issued in reliance on the exemption from registration under Section 4(a)(2) of the Securities Act for a transaction by an issuer not involving any public offering within the meaning of Section 4(a)(2) and/or under Rule 506 of Regulation D promulgated under the Securities Act and corresponding provisions of state securities or "blue sky" laws.

Item 8.01 Other Events

Update on VY-TAU01 for the Treatment of Alzheimer's Disease

The Company plans to submit an IND application for VY-TAU01, its anti-tau antibody product candidate for the treatment of Alzheimer's disease, to the U.S. Food and Drug Administration (the "FDA") in the first half of 2024. The planned Phase 1 clinical trial is designed to assess the safety of VY-TAU01 in a multi-arm dose escalation study, with a single ascending dose arm expected to be conducted in healthy subjects to be initiated in 2024 and a multiple ascending dose arm expected to be conducted in subjects with mild cognitive impairment or early Alzheimer's disease to be initiated in 2025. In connection with the planned trial, the Company also anticipates evaluating positron emission topography scans of subjects from the multiple ascending dose arm for an indication of biological activity of VY-TAU01 in the second half of 2026.

Update on SOD1 Silencing Gene Therapy for the Treatment of SOD1 ALS

The Company plans to submit an IND application to the FDA in mid-2025 for its gene therapy product candidate designed to deliver a vectorized, highly potent small interfering RNA construct for the treatment of superoxide dismutase 1-mutated amyotrophic lateral sclerosis ("SOD1 ALS") and to initiate a Phase 1 clinical trial in subjects with SOD1 ALS for the program as soon as possible thereafter. The Company expects to evaluate the safety and biological activity of its SOD1 ALS product candidate in this Phase 1 trial.

Update on Other Programs

The Company is actively advancing additional wholly-owned programs for the treatment of Alzheimer's disease and is party to collaboration or licensing arrangements with Neurocrine; Novartis; Alexion, AstraZeneca Rare Disease; and Sangamo Therapeutics, Inc. In addition to the IND applications described above, the Company expects that its collaborative partners and licensees will submit at least two additional IND applications for other partnered programs in the Company's pipeline and initiate clinical development for the associated programs by the end of 2025.

Forward-Looking Statements

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," "target," "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 consummation of the collaboration with Novartis and the sale and issuance of the Shares to Novartis, the satisfaction of closing conditions necessary for the consummation of the collaboration and the sale and issuance of the Shares to Novartis, the Company's entitlement to receive the Upfront Payment, milestone payments and royalties from Novartis under the Collaboration Agreement, the creation of value and the establishment of new opportunities that may arise as a result of the collaboration, the ability of the Company and Novartis to perform under the Collaboration Agreement, including the Company's and Novartis's abilities to advance gene therapy product candidates under this collaboration into, and successfully initiate, enroll and complete, clinical trials, the ability of the Company and Novartis to perform their obligations under the Investor Agreement, the ability of the Company to add new programs to its pipeline, the ability of the Company to develop its pipeline programs, the timing, initiation, and design of the Company's preclinical studies and clinical trials, the ability of the Company to enter into new partnerships or collaborations, the regulatory pathway of, and the timing or likelihood of its and its collaboration partners' or licensors' regulatory filings and approvals for, any of the Company's product candidates, the Company's preliminary unaudited cash and cash equivalent and marketable securities amounts as of December 31, 2023, the Company's cash runway, the assumed achievement of $8 million of milestones under the Company's collaborations with Neurocrine, and the sufficiency of the Company's cash resources are forward-looking.

All forward-looking statements are based on estimates and assumptions by the Company's management that, although the Company believes them 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, the expectations and decisions of regulatory authorities; the initiation and conduct of preclinical studies and clinical trials; the availability of data from clinical trials; the continued development of the Company's capsid and gene therapy platforms; the availability or commercial potential of product candidates under the collaboration; the willingness and ability of the Company's collaboration partners to meet obligations under collaboration agreements with the Company; and uncertainties as to the Company's preliminary unaudited cash and cash equivalent and marketable securities amounts as of December 31, 2023, which are estimates based on preliminary and unaudited information, subject to the completion of the Company's customary financial closing procedures and have not been audited or reviewed by the Company's independent public accounting firm.

These statements are also subject to a number of material risks and uncertainties that are described in the Company's most recent Annual Report on Form 10-K filed with the SEC, as updated by its subsequent filings with the SEC. All information in this Form 8-K is as of the date of this 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.

VOYAGER THERAPEUTICS, INC.

Date: January 2, 2024

By: /s/ Alfred Sandrock, M.D., Ph.D.
Alfred Sandrock, M.D., Ph.D.
Chief Executive Officer, President, and Director
(Principal Executive Officer)