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): November 2, 2021

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:

Ш	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 ($\S 230.405$ of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 ($\S 240.12b-2$ of this chapter). Emerging growth company \square

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. \Box

Item 2.02. Results of Operations and Financial Condition.

On November 2, 2021, Voyager Therapeutics, Inc. (the "Company") announced third quarter 2021 financial results and corporate updates. 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 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	<u>Press release dated November 2, 2021 entitled "Voyager Therapeutics Announces Second Quarter 2021 Financial Results and Corporate Updates".</u>						
Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).							

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: November 2, 2021 **VOYAGER THERAPEUTICS, INC.**

By: /s/ Michael Higgins

Michael Higgins

Interim Chief Executive Officer, President, and Director

(Principal Executive Officer)



Voyager Therapeutics Reports Third Quarter 2021 Financial and Operating Results

License option agreement with Pfizer provides Voyager \$30M up front and up to \$600M in potential exercise fees and milestones payments plus royalties in exchange for access to TRACER™ novel capsids for use with two Pfizer transgenes in neurologic and cardiovascular disease

TRACER platform identifies AAV9 and AAV5 capsid variants with broad CNS tropism and neuronal and glial cell targeting in non-human primates

Preclinical data demonstrate GBA1 gene therapy achieved widespread CNS distribution and sustained correction of GCase activity in multiple brain regions in mice

CAMBRIDGE, Mass., Nov. 2, 2021 -- Voyager Therapeutics, Inc. (Nasdaq: VYGR), a gene therapy company developing life-changing treatments and next-generation adenoassociated virus (AAV) technologies, today reported third quarter 2021 financial and operating results.

"We've taken notable steps in recent months to execute on our new strategy, including our recent capsid licensing agreement with Pfizer, continued progress with our RNA-driven AAV TRACER screening platform, and initial data from our GBA1 gene replacement program," said Michael Higgins, interim CEO of Voyager. "The licensing transaction with Pfizer showcases TRACER's ability to produce not only enhanced blood-brain barrier penetrant capsids, but also novel capsids with enhanced tropism for cardiac muscle, offering promise to unlock the fullest potential of gene therapies for a wide array of diseases. We've retained all rights to our capsid library outside of their use with two particular Pfizer transgenes, and we believe there is significant opportunity for similar transactions, leveraging the entirety of our libraries for other targets inside and outside CNS."

"We're pleased to also announce that, in addition to our prior results with AAV9 variants, our TRACER screening campaigns have identified AAV5 capsid variants with enhanced brain and spinal cord tropism compared to conventional AAV5 and AAV9, as well as a new class of AAV9 variants selective for glial cells, which may enable more precise targeting of CNS diseases affecting non-neuronal cells," said Glenn Pierce, M.D., Ph.D., interim CSO of Voyager. "In parallel, we're advancing an innovative gene therapy pipeline, leveraging our novel TRACER capsids. Preclinical data from our GBA1 gene replacement program illustrates the potential of a single-dose, IV administered therapy to

significantly raise target protein levels in the CNS, potentially impacting Parkinson's disease, Lewy body dementia, and Gaucher disease."

Pfizer License Option Agreement Supports TRACER Platform Potential for Multiple Therapeutic Areas

- In October, Voyager and Pfizer Inc. (NYSE: PFE) entered an agreement through which Pfizer may exercise options to license novel capsids generated from Voyager's RNA-driven TRACER (Tropism Redirection of AAV by Cell-type-specific Expression of RNA) screening technology. Under the agreement, Pfizer may evaluate novel TRACER capsids and exercise options to license up to two capsids for transgene-exclusive Pfizer gene therapy programs for neurologic and cardiovascular disease associated with those transgenes.
- The Pfizer transgenes are distinct from those planned for Voyager's internal pipeline, and Voyager retains global rights to all TRACER capsids for use with other transgenes and to all other applications of its TRACER technology.
- Voyager received a \$30 million upfront payment from Pfizer and is entitled to receive up to \$20 million in exercise fees in aggregate for two options, exercisable by Pfizer within 12 months of signing. Voyager is also eligible to earn up to \$580 million in total development, regulatory, and commercial milestones associated with licensed products incorporating the two undisclosed Pfizer transgenes together with a Voyager licensed capsid. Voyager is also eligible to receive mid- to high-single-digit tiered royalties based on net sales of Pfizer's products incorporating the licensed capsids.

TRACER Identifies AAV9 and AAV5 Capsid Variants with Broad CNS Tropism, Neuronal and Glial Cell Targeting; Screening Campaigns Advancing

- Voyager is performing further screening with its TRACER platform to identify additional proprietary AAV9- and AAV5-derived capsids targeting multiple tissue and cell types for use in gene therapies to treat a broad range of diseases.
- Numerous promising capsids have been identified from these screens, which are
 undergoing rigorous testing across multiple non-human primate and rodent species to
 evaluate their clinical translatability.
- In addition to capsids with substantially enhanced CNS tropism for neurons in non-human primates, a new array of TRACER AAV9 and AAV5 variants shows robust CNS targeting in both non-human primates and rodents and demonstrate a strong tropism for glial cells, which may enable more effective targeting of certain CNS diseases.
- Capsid candidates derived from AAV5 present significant potential advantages in terms
 of lower prevalence of preexisting neutralizing antibodies in the general population and
 manufacturing. In addition, these variants demonstrate cross-species translatability
 among primates and rodents. Initial testing on these AAV5-derived capsids has
 demonstrated approximately 20-fold improvements in brain transduction compared
 with AAV9 in non-human primates.

As previously disclosed, initial data from AAV9-derived TRACER capsids
demonstrated robust delivery across the blood-brain barrier and widespread CNS
transduction in non-human primates compared to AAV9 delivery following intravenous
(IV) administration. In addition, a proprietary capsid displayed strong cardiac
transduction and significant dorsal root ganglia detargeting in non-human primates,
which may avoid dose-related toxicities associated with AAV9 delivery.

Positive Preclinical Data from GBA1 Program

- Voyager continues to advance its early-stage programs including multiple programs
 utilizing proprietary AAV capsids derived from the TRACER platform. Voyager
 believes these capsids may enable new, best-in-class gene therapy programs with
 systemic IV delivery and lower risk of dose-limiting toxicities. Pipeline programs
 include those for Huntington's disease, monogenic ALS (SOD1), spinal muscular
 atrophy, and diseases linked to GBA1 mutations, which may include Parkinson's
 disease, Lewy body dementia, and Gaucher disease.
- Voyager presented initial preclinical data from its GBA1 gene replacement program at the virtual 2021 Annual Congress of the European Society of Gene & Cell Therapy, Oct. 19-22, 2021. The results demonstrated that an IV-administered gene replacement therapy using a proprietary AAV capsid achieved widespread distribution in the central nervous system and peripheral tissues, and raised levels of the deficient GCase enzyme by 300% 660% over endogenous levels in a mouse model. By comparison, increases of 30% 50% are expected to be clinically impactful. These data support the potential of a novel therapeutic approach for diseases associated with GBA mutations, including Parkinson's disease, Lewy body dementia, and Gaucher disease.

Upcoming Events and Presentations

• Society for Neuro-Oncology 26th Annual Meeting, Nov. 18-21, 2021

Third Quarter 2021 Financial Results

• Collaboration Revenues: Collaboration revenue was \$1.5 million for the third quarter of 2021, compared to collaboration revenue of \$117.8 million for the same period of 2020. The decrease in collaboration revenue was largely due to a reduction of revenue related to research services and cost reimbursements from the collaborations with Neurocrine and AbbVie. In February 2021, Neurocrine provided notice that effective August 2, 2021 it was terminating its participation in the VY-AADC program for Parkinson's disease under the collaboration agreement between Voyager and Neurocrine, and that wind-down activities, including the termination by Neurocrine of its support for ongoing development activities for the VY-AADC program would commence immediately. Additionally, the collaborations with AbbVie were terminated in August 2020 and resulted in recognition of \$47.2 million of revenue related to the collaboration targeting tauopathies and \$59.4 million of revenue related to the collaboration targeting synucleinopathies during the

- quarter ended September 30, 2020, as Voyager had no further service obligations at that
- **Net Loss:** Net loss was \$25.1 million for the third quarter of 2021, compared to net income of \$85.6 million for the same period of 2020.
- **R&D Expenses:** Research and development expenses were \$17.9 million for the third quarter of 2021, compared to \$25.0 million for the same period in 2020. The decrease in R&D expenses was primarily related to lower research and development employee-related expenses as well as manufacturing and clinical expenses for the VY-AADC program for Parkinson's disease.
- **G&A Expenses:** General and administrative expenses were \$8.7 million for the third quarter of 2021, compared to \$8.3 million for the same period in 2020. The increase in G&A expenses was primarily related to increased employee-related expenses in connection with a reduction in force and facility costs.
- **Cash Position:** Cash, cash equivalents, and marketable debt securities as of September 30, 2021 were \$121.5 million.

Financial Guidance

 Based on Voyager's current operating plan and excluding any potential financing or business development activities in 2021, Voyager anticipates cash, cash equivalents, and marketable debt securities will be greater than \$130 million at the end of 2021.

About the TRACER AAV Capsid Discovery Platform

Voyager's TRACER system is a broadly applicable, RNA-based functional screening platform that allows for rapid in vivo evolution of AAV capsids with enhanced tropisms and cell- and tissue-specific transduction properties in multiple species, including non-human primates (NHPs). Initial data from the first of many libraries screened in NHPs demonstrated the proprietary capsid variants effectively penetrated the blood-brain barrier and achieved widespread biodistribution and transduction of multiple regions of the brain. Separate results have demonstrated the ability of certain capsids to transduce cardiac muscle and to de-target the dorsal root ganglia. Voyager is proceeding with additional capsid campaigns derived from unique capsid serotypes to identify novel AAV vectors optimized for specific therapeutic applications.

About Voyager Therapeutics

Voyager Therapeutics (Nasdaq: VYGR) is leading the next generation of AAV gene therapy to unlock the potential of the technology to treat devastating diseases. Proprietary capsids born from the Company's TRACER screening platform are powering a rich early-stage pipeline of new and second-generation programs and may elevate the field to overcome the limitations of conventional gene therapy vectors across neurologic disorders and other therapeutic areas.

voyagertherapeutics.com LinkedIn Twitter

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 Voyager's ability to continue to identify and develop proprietary capsids from its TRACER AAV screening platform; Voyager's ability to identify and develop proprietary capsids from its TRACER AAV screening platform with increased transgene expression, increased blood-brain barrier penetration and increased biodistribution compared to conventional AAV5 and AAV9 capsids; Voyager's ability to utilize its novel proprietary capsids in its own product development programs; Voyager's ability to attract parties to license its novel proprietary capsids or to participate with Voyager in research and development collaborations utilizing its novel proprietary capsid; Voyager's ability to advance its AAV-based gene therapy programs; Voyager's ability to perform its obligations under its license option agreement with Pfizer; Voyager's entitlement to receive upfront, milestone and royalty based fees from Pfizer under the license option agreement; Voyager's ability to maintain its current partnerships and collaborations and to enter into new partnerships or collaborations; and Voyager's ability to generate sufficient cash resources to enable it to continue to identify and develop proprietary capsids from its TRACER AAV screening platform 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, the severity and length of the COVID-19 health crisis, the imposition of governmental controls and guidance addressing the COVID health crisis, and the financial and human resources available to Voyager to manage the COVID-19 health crisis; the continued development of various technology platforms, including Voyager's TRACER platform; Voyager's scientific approach and general development progress; the ability to attract and retain talented contractors and employees, including key scientists and business leaders; 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 the Pfizer license option agreement and other collaborations; the ability of Voyager to negotiate and complete licensing or collaboration agreements on terms acceptable to Voyager and third parties; 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. 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.

Voyager Contacts

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Selected Financial Information

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

	Three Months Ended				Nine Months Ended				
Statement of Operations Items:	_	Septem 2021	ber .	30, 2020		September 30, 2021 2020			
Collaboration revenue	\$	1,482	\$	117,843	\$	9,342	\$	164,591	
Operating expenses:	-	_,		,	•	-,	-		
Research and development		17,914		25,039		59,767		86,757	
General and administrative		8,714		8,277		28,895		26,721	
Total operating expenses		26,628		33,316		88,662		113,478	
Operating (loss) income		(25,146)		84,527		(79,320)		51,113	
Total other income		9		1,084		2,414		1,554	
Net (loss) income	\$	(25,137)	\$	85,611	\$	(76,906)	\$	52,667	
Net (loss) income per share, basic	\$	(0.67)	\$	2.30	\$	(2.04)	\$	1.42	
Net (loss) income per share, diluted	\$	(0.67)	\$	2.27	\$	(2.04)	\$	1.40	
	_				_				
Weighted-average common shares									
outstanding, basic	3	37,780,547	3	37,242,504		37,623,309	3	7,079,242	
Weighted-average common shares								,	
outstanding, diluted	3	37,780,547	_ 3	37,672,328		37,623,309	3	7,500,155	

	Se	ptember 30,	December 31,	
Selected Balance Sheet Items		2021		2020
Cash, cash equivalents, and marketable debt securities	\$	121,499	\$	174,782
Total assets	\$	184,774	\$	261,584
Accounts payable and accrued expenses	\$	11,916	\$	14,839
Deferred revenue	\$	39,176	\$	43,817
Total stockholders' equity	\$	87,422	\$	154,320