Voyager Reports First Quarter 2025 Financial and Operating Results

05/06/25

– Tau silencing gene therapy VY1706 to be featured in oral presentation at ASGCT 2025; has shown up to 73% knockdown of tau mRNA in the CNS in NHPs following a single IV dose of 1.3e13 vg/kg –

– Recent Voyager data on VY7523 and VY1706 presented at AD/PD™ 2025 continue to support tau as next critical target in Alzheimer's disease –

LEXINGTON, Mass., May 06, 2025 (GLOBE NEWSWIRE) -- Voyager Therapeutics, Inc. (Nasdaq: VYGR), a biotechnology company dedicated to leveraging genetics to treat neurological diseases, today reported first quarter 2025 financial and operating results.

"Voyager ended the first quarter of 2025 with a strong cash position of $295 million, which we expect to provide runway into mid-2027. This runway guidance does not include potential milestone payments from existing partnerships, such as the up to $35 million we could earn in 2025-2026 from the Neurocrine-partnered FA and GBA1 programs," said Alfred W. Sandrock, Jr., M.D., Ph.D., Chief Executive Officer of Voyager. "We continue to thoughtfully and strategically advance our pipeline, including our two wholly-owned tau targeting programs VY7523 and VY1706 for Alzheimer's disease, as well as the FA and GBA1 programs, which are advancing towards INDs this year."

First Quarter 2025 and Recent Highlights

- **Neurocrine partnership update:** Neurocrine continues to expect investigational new drug (IND) submissions in 2025 for the Friedreich's ataxia (FA) and GBA1 gene therapy programs, provided the ongoing GLP toxicology studies support clinical development. The GBA1 program will focus on both Gaucher and Parkinson's disease. Initiation of the first clinical trials for the FA and GBA1 programs are expected in 2026, and the associated regulatory and clinical milestones that Voyager could realize related to these indications within this period total $35 million. Additionally, Neurocrine deprioritized two discovery-stage programs against undisclosed targets. The joint steering committee agreed to discontinue these programs, so that rights to these targets return to Voyager. The discontinuations were not due to any safety concerns and do not impact Voyager's cash runway guidance.
- **Progressed MAD trial of anti-tau antibody VY7523 for AD:** Dosing in multiple ascending dose (MAD) clinical trial for Alzheimer's Disease (AD) is ongoing. Continue to expect initial tau positron emission tomography (PET) data in the second half of 2026.
- **Advanced tau silencing gene therapy VY1706 for AD:** Completed a pre-IND interaction with the U.S. Food and Drug Administration (FDA). IND-enabling work is ongoing to support U.S. IND and Canadian clinical trial application (CTA) submissions expected in 2026.
- **Multiple abstracts accepted for presentation at ASGCT 2025:** Voyager will make multiple presentations at the upcoming American Society of Gene & Cell Therapy's (ASGCT) 28th annual meeting, including oral presentations on tau silencing gene therapy VY1706 and on Voyager's immune-evading capsids. Additional featured data include the first murine data on Voyager's vectorized anti-amyloid antibody for AD, as well as multiple presentations on Voyager's intravenous (IV)-delivered, blood-brain barrier (BBB)-penetrant capsids. In multiple NHP studies utilizing a variety of payloads, a single intravenous 3e13 vg/kg dose of these capsids has transduced up to 98% of dopaminergic neurons in substantia nigra, up to 94% of motor neurons in the spinal cord, up to 66% of neurons in the thalamus, up to 43% of neurons in the motor cortex, and 87-99% of astrocytes broadly across brain regions.
- **Presented VY1706 and VY7523 data at AD/PD™ 2025:** Data on tau silencing gene therapy VY1706 and anti-tau antibody VY7523 were presented at the 2025 International Conference on Alzheimer's and Parkinson's Diseases and Related Neurological Disorders (AD/PD™ 2025). In an NHP study, a single IV administration of VY1706 significantly reduced tau mRNA (up to 73%), with broad brain distribution and 30X liver de-targeting following a single IV dose of 1.3e13 vg/kg. Separately, preclinical murine data showed VY7523 specifically targets pathologic forms of tau and reduced tau spread in a P301S mouse hippocampal seeding model.

Anticipated Upcoming Milestones

- May 2025: Voyager to make multiple data presentations on gene therapy programs and platform at ASGCT 2025
- 2025: IND submissions anticipated with Neurocrine-partnered FA and GBA1 programs
- 2025 – 2026: Potentially informative data read-outs expected with tau-targeting agents from multiple third parties
- 2026: Clinical trial initiations anticipated in Neurocrine-partnered FA and GBA1 programs
- 2026: U.S. IND and Canadian CTA filings anticipated with VY1706 for AD
- H2 2026: Initial tau PET imaging data expected in MAD clinical trial of VY7523 in AD

First Quarter 2025 Financial Results

- **Collaboration Revenues:** Voyager had collaboration revenue of $6.5 million for the first quarter of 2025, compared to $19.5 million for the same period in 2024. The decrease was primarily due to decreased revenue recognized under our

Neurocrine collaboration agreements.

- **Net Loss:** Net loss was $31.0 million for the first quarter of 2025, compared to $11.3 million for the same period in 2024. The difference is primarily due to the decreases in collaboration revenue discussed above, along with the increases in operating expenses discussed below.
- **R&D Expenses:** Research and development expenses were $31.5 million for the first quarter of 2025, compared to $27.1 million for the same period in 2024. The increase in R&D expenses was primarily due to increased program-related spending to support our advancing pipeline.
- **G&A Expenses:** General and administrative expenses were $9.6 million for the first quarter of 2025, compared to $8.6 million for the same period in 2024. The increase in G&A expenses was primarily attributable to increased employee-related costs, along with increased professional services fees.
- **Cash Position:** Cash, cash equivalents and marketable securities as of March 31, 2025, were $295 million, as compared to $332 million as of December 31, 2024. Cash use during the first quarter was higher than typical due to one-time payments at the start of the year, as well as start-up activities for the VY7523 MAD trial.

Financial Guidance
Voyager is committed to maintaining a strong balance sheet that supports the advancement and growth of its platform and pipeline. Voyager continues to assess its planned cash needs both during the current period and in future periods. We expect our cash, cash equivalents, and marketable securities, along with amounts expected to be received as reimbursement for development costs under the Neurocrine and Novartis collaborations and interest income, to be sufficient to meet Voyager's planned operating expenses and capital expenditure requirements into mid-2027.

Voyager's first quarter 2025 financial and operating results press release and SEC filings are available on the Investors section of the Voyager website at https://ir.voyagertherapeutics.com/. The Company does not plan to host quarterly financial results conference calls moving forward.

About Voyager Therapeutics
Voyager Therapeutics, Inc. (Nasdaq: VYGR) is a biotechnology company dedicated to leveraging the power of human genetics to modify the course of – and ultimately cure – neurological diseases. Our pipeline includes programs for Alzheimer's disease, Friedreich's ataxia, Parkinson's disease, amyotrophic lateral sclerosis (ALS), and multiple other diseases of the central nervous system. Many of our programs are derived from our TRACER™ AAV capsid discovery platform, which we have used to generate novel capsids and identify associated receptors to potentially enable high brain penetration with genetic medicines following intravenous dosing. Some of our programs are wholly owned, and some are advancing with partners including Alexion, AstraZeneca Rare Disease; Novartis Pharma AG; and Neurocrine Biosciences, Inc. For more information, visit http://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 "will," "anticipated," "expect," "believe," "anticipate," "potential," "may," or "continue," and other similar expressions are intended to identify forward-looking statements.

For example, all statements Voyager makes regarding Voyager's ability to advance its AAV-based gene therapy programs and tau antibody program, including expectations for Voyager's achievement of preclinical and clinical development milestones for its potential development candidates such as the IND and CTA filings, the initiation of clinical trials, clinical trial enrollment, and the generation of clinical data; the potential for an antibody targeting tau to impact the accumulation of tau in the brain of Alzheimer's patients and for this impact to offer a clinically significant benefit in some patients; the potential for third-party clinical data to inform Voyager's clinical development plans; Voyager's ability to advance gene therapy product candidates under the Neurocrine collaboration, including anticipated submission of IND filings and initiation of clinical trials by Neurocrine in two partnered programs; Voyager's anticipated financial results, including the anticipated receipt by Voyager of revenues or reimbursement payments from collaboration partners; and Voyager's cash runway and ability to generate sufficient cash resources to enable it to continue its business and operations 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 and 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 expectations and decisions of regulatory authorities; the timing, initiation, conduct and outcomes of Voyager's preclinical and clinical studies; the availability of data from clinical trials; the availability or commercial potential of product candidates under collaborations; the success of Voyager's product candidates; the willingness and ability of Voyager's collaboration partners to meet obligations under collaboration agreements with Voyager; the continued development of Voyager's technology platforms, including Voyager's TRACER platform and its non-viral discovery platform ; Voyager's scientific approach and program development progress, and the restricted supply and increased costs of critical research components; the development by third parties of capsid identification platforms that may be competitive to Voyager's TRACER capsid discovery platform; Voyager's ability to create and protect intellectual property rights associated with the TRACER capsid discovery platform, the capsids identified by the platform, and development candidates for Voyager's pipeline programs; the possibility or the timing of Voyager's receipt of program reimbursement, development or commercialization milestones, option exercise, and other payments under Voyager's existing licensing or collaboration agreements; the ability of Voyager to negotiate and complete licensing or collaboration agreements with other parties on terms acceptable to Voyager and the third parties; the success of programs controlled by third-party collaboration partners in which Voyager retains a financial interest; the ability to attract and retain talented directors, employees, and contractors; and the sufficiency of Voyager's cash resources to fund its operations and pursue its corporate objectives.

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. 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 March 31, 2025	Three Months Ended March 31, 2024
Collaboration revenue	$ 6,473	$ 19,516
Operating expenses:		
Research and development	31,526	27,092
General and administrative	9,640	8,607
Total operating expenses	41,166	35,699
Operating loss	(34,693)	(16,183)
Total other income	3,709	4,867
Loss before income taxes	(30,984)	(11,316)
Income tax provision	37	14
Net loss	$ (31,021)	$ (11,330)
Net loss per share, basic and diluted	$ (0.53)	$ (0.20)
Weighted-average common shares outstanding, basic and diluted	58,349,769	57,117,046

Selected Balance Sheet Items	March 31, 2025	December 31, 2024
Cash, cash equivalents, and marketable securities	$ 295,122	$ 332,388
Total assets	$ 353,240	$ 393,050
Accounts payable and accrued expenses	$ 11,687	$ 18,167
Deferred revenue	$ 25,855	$ 30,397
Total stockholders' equity	$ 272,702	$ 299,760

GAAP vs. Non-GAAP Financial Measures

Voyager's financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP, and represent revenue and expenses as reported to the Securities and Exchange Commission. Voyager has provided in this release certain financial information that has not been prepared in accordance with GAAP, including net collaboration revenue and net research and development expenses, which exclude the impact of reimbursement by Neurocrine Biosciences (Neurocrine) and Novartis Pharma AG (Novartis) for expenses we incur in conducting preclinical development activities under our collaboration agreements. Management uses these non-GAAP measures to evaluate the Company's operating performance in a manner that allows for meaningful period-to-period comparison and analysis of trends in its business. Management believes that such non-GAAP measures are important in comparing current results with prior period results and are useful to investors and financial analysts in assessing the Company's operating performance. Non-GAAP financial measures are not required to be uniformly applied, are not audited and should not be considered in isolation. The non-GAAP measures give investors and financial analysts a better understanding of our net revenue and net research and development expenses without the pass-through impact of Neurocrine costs. The non-GAAP financial information presented here should be considered in conjunction with, and not as a substitute for, the financial information presented in accordance with GAAP. Investors are encouraged to review the reconciliation of these non-GAAP measures to their most directly comparable GAAP financial measures set forth below.

Reconciliation of GAAP to Non-GAAP Measures

(in thousands)

	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024
GAAP collaboration revenue	$ 6,473	$ 19,516
Revenue recognized for reimbursed research and development services (Note 1)	$ 1,628	$ 3,178
Net collaboration revenue	$ 4,845	$ 16,338
GAAP total research and development expenses	$ 31,526	$ 27,092
Expenses incurred for reimbursed research and development services (Note 1)	$ 1,628	$ 3,178
Net research and development expenses	$ 29,898	$ 23,914

Note 1: Under the Company's existing collaboration agreements with Neurocrine and Novartis, Neurocrine and Novartis have agreed to be responsible for all costs the Company incurs in conducting preclinical development activities for certain collaboration programs, in accordance with joint steering committee agreed upon workplans and budgets. Reimbursable research and development services performed during the period are captured within collaboration revenue and research and development expenses in the Company's consolidated statements of operations. During the three months ended March 31, 2025, we incurred $1.6 million of reimbursable research and development services recorded within collaboration revenue and research and development expenses. During the three months ended March 31, 2024, we incurred $3.2 million of reimbursable research and development services recorded within collaboration revenue and research and development expenses.

Source: Voyager Therapeutics, Inc.