Voyager Reports Third Quarter 2024 Financial and Operating Results

11/12/24

- Enrollment and dosing complete in single ascending dose clinical trial of anti-tau antibody VY7523 for Alzheimer's; on track to generate top-line data H1 2025 -

- Recent third-party clinical data establish that an antibody can inhibit tau accumulation in the human brain; provide support for use of an antibody to target tau in Alzheimer's -

- Continued partnership progress in Q3 2024 evidenced by new capsid license and new gene therapy development candidate selection -

- INDs on track for three CNS gene therapies in 2025 in SOD1 ALS, GBA1 Parkinson's and other GBA1-mediated disease, and Friedreich's ataxia programs -

LEXINGTON, Mass., Nov. 12, 2024 (GLOBE NEWSWIRE) -- Voyager Therapeutics, Inc. (Nasdaq: VYGR), a biotechnology company dedicated to advancing neurogenetic medicines, today reported third quarter 2024 financial and operating results.

"An increasing body of clinical evidence implicates tau as a critical target in Alzheimer's disease," said Alfred W. Sandrock, Jr., M.D., Ph.D., Chief Executive Officer of Voyager. "Recent third-party clinical data give us increasing confidence that an antibody targeting the appropriate epitope of tau can slow the accumulation of tau in the brain of Alzheimer's patients, and that this slowing may offer a clinically significant benefit in some patients. These encouraging data build on previous positive third-party clinical data with a tau silencing program and, we believe, support Voyager's prioritization of both an anti-tau antibody and a tau silencing gene therapy. Our clinical-stage anti-tau antibody VY7523 is expected to generate initial tau PET imaging data in patients in H2 2026, and our tau silencing gene therapy is advancing toward IND in 2026. Our strong cash position of $345 million is expected to provide runway into 2027, enabling multiple data readouts."

Third Quarter 2024 and Recent Highlights

- **Licensed TRACER™ capsid to Novartis in 5th partnered program:** Voyager agreed to license to Novartis AG a novel TRACER capsid for use in a gene therapy program against an undisclosed rare neurologic disease target. This is the fifth partnered program between the two companies. Voyager received an upfront payment of $15 million in October and is eligible for up to $305 million in milestone payments, as well as royalties.
- **Achieved 3rd development candidate in partnership with Neurocrine:** The joint steering committee with collaborator Neurocrine Biosciences, Inc. selected a development candidate in a gene therapy program for the potential treatment of an undisclosed neurological disease, triggering a $3 million milestone payment to Voyager, which was received in October. This follows recent development candidate selections in programs for GBA1-mediated disorders and Friedreich's ataxia.
- **VY7523 anti-tau antibody for Alzheimer's disease:** Enrollment and dosing completed in the single ascending dose (SAD) clinical trial, with top-line safety and pharmacokinetic data expected in H1 2025.
- **Presented head-to-head preclinical data for murine surrogate of VY7523 vs. murine surrogates of other anti-tau antibodies:** Murine surrogate of VY7523 (C-terminal directed) demonstrated significant reduction in spread of human pathological tau in p301S mouse seeding model, as did murine surrogate of bepranemab (mid-domain directed). No significant reduction was seen for murine surrogates of two N-terminal directed antibodies that previously failed their primary endpoints in clinical trials. These data are expected to be presented at a future conference.

Anticipated Upcoming Milestones

- H1 2025: Initial safety and pharmacokinetic data expected from VY7523 SAD clinical trial
- Mid-2025: U.S. IND and Canadian clinical trial application (CTA) filings expected with SOD1 silencing gene therapy VY9323 in ALS patients, subsequent clinical trial has potential to generate proof-of-concept based on biomarkers
- 2025: Initiation of Multiple Ascending Dose (MAD) clinical trial in AD patients expected with VY7523
- 2025: IND filings anticipated with NBIX-partnered GBA-1 and Friedreich's ataxia gene therapies
- 2026: U.S. IND and Canadian CTA filings anticipated with tau silencing gene therapy for Alzheimer's disease
- H2 2026: Initial tau PET imaging data expected in MAD clinical trial of VY7523 in Alzheimer's disease

Third Quarter 2024 Financial Results

- **Collaboration Revenues:** Voyager had collaboration revenue of $24.6 million for the third quarter of 2024, compared to $4.6 million for the same period in 2023. The increase was primarily due to increased revenue recognized under our Novartis and Neurocrine agreements.
- **Net Loss:** Net loss was $9.0 million for the third quarter of 2024, compared to net loss of $25.9 million for the same period in 2023. The decrease is primarily due to increased collaboration revenue recognized during the third quarter of 2024, as discussed above.

- **R&D Expenses:** Research and development expenses were $30.2 million for the third quarter of 2024, compared to $25.9 million for the same period in 2023. The increase in R&D expenses was primarily a result of increased targeted development team hires to support our advancing pipeline, along with increased facilities costs related to our lease for additional laboratory and office space.
- **G&A Expenses:** General and administrative expenses were $8.2 million for the third quarter of 2024, compared to $8.3 million for the same period in 2023. The consistent spend reflects continued disciplined expense management.
- **Cash Position:** Cash, cash equivalents and marketable securities as of September 30, 2024, were $345.4 million. This does not include the $15.0 million upfront payment from Novartis or the $3.0 million milestone payment from Neurocrine, both of which were received in October 2024.

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 2027.

Conference Call

Voyager will host a conference call and webcast today at 4:30 p.m. ET to discuss third quarter 2024 financial and operating results. A live webcast of the call will be available on the Investors section of the Voyager website at https://ir.voyagertherapeutics.com/, and a replay of the call will be available at the same link approximately two hours after its completion. The replay will be available for at least 30 days following the conclusion of the call.

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, amyotrophic lateral sclerosis (ALS), Parkinson's disease, 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; Neurocrine Biosciences, Inc.; and Sangamo Therapeutics, Inc. For more information, visit www.voyagertherapeutics.com.

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

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 "expect," "believe," "anticipate," "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 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 identification of lead development candidates, IND filings, the initiation of clinical trials, clinical trial enrollment, and the generation of clinical data and proof-of-concept; the potential for an antibody targeting tau to slow the accumulation of tau in the brain of Alzheimer's patients and for this slowing 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; 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 antibody screening technology; Voyager's scientific approach and program development progress, and the restricted supply 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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
Statement of Operations Items:	**2024**	**2023**	**2024**	**2023**
Collaboration revenue	$ 24,629	$ 4,614	$ 73,723	$ 159,947
Operating expenses:				
Research and development	30,241	25,863	91,785	66,416
General and administrative	8,168	8,258	26,926	25,580
Total operating expenses	38,409	34,121	118,711	91,996
Operating (loss) income	(13,780)	(29,507)	(44,988)	67,951
Total other income	4,779	3,429	14,554	8,570
(Loss) income before income taxes	(9,001)	(26,078)	(30,434)	76,521
Income tax provision (benefit)	43	(177)	81	586
Net (loss) income	$ (9,044)	$ (25,901)	$ (30,515)	$ 75,935
Net (loss) income per share, basic	$ (0.16)	$ (0.59)	$ (0.53)	$ 1.85
Net (loss) income per share, diluted	$ (0.16)	$ (0.59)	$ (0.53)	$ 1.78
Weighted-average common shares outstanding, basic	57,851,110	43,864,838	57,564,413	40,962,116
Weighted-average common shares outstanding, diluted	57,851,110	43,864,838	57,564,413	42,610,724

	September 30,	December 31,
Selected Balance Sheet Items	**2024**	**2023**
Cash, cash equivalents, and marketable securities	$ 345,360	$ 230,875
Total assets	$ 426,041	$ 351,281
Accounts payable and accrued expenses	$ 14,602	$ 18,427
Deferred revenue	$ 34,782	$ 75,240
Total stockholders' equity	$ 330,310	$ 236,320

Source: Voyager Therapeutics, Inc.