



Voyager Therapeutics Reports Third Quarter 2023 Financial and Operating Results

11/06/23

- GLP toxicology studies initiated for VY-TAU01 anti-tau antibody for Alzheimer's disease to enable anticipated 1H 2024 IND filing -

- SOD1 ALS gene therapy program on track for development candidate selection by end of year –

- Conference call at 4:30 p.m. ET today -

LEXINGTON, Mass., Nov. 06, 2023 (GLOBE NEWSWIRE) -- Voyager Therapeutics, Inc. (Nasdaq: VYGR), a biotechnology company dedicated to breaking through barriers in gene therapy and neurology, today reported third quarter 2023 financial and operating results.

"Voyager continues to advance our prioritized programs towards the clinic: the initiation of GLP toxicology studies for our anti-tau antibody VY-TAU01 keeps us on track for an anticipated IND filing in the first half of 2024. Further, we expect to select a development candidate for our wholly-owned SOD1 ALS gene therapy program by end-of-year, and our broader gene therapy pipeline presents multiple opportunities for INDs in 2025 across our wholly-owned and partnered programs," said Alfred W. Sandroek, Jr., M.D., Ph.D., Chief Executive Officer of Voyager. "In addition to advancing our pipeline, we continue to evolve and refine our neurotropic TRACER AAV capsids and look forward to continuing to share data at scientific meetings."

Key Milestones Achieved in Q3 2023 and Subsequent Period:

- **Advancement of anti-tau antibody program:** Voyager initiated Good Laboratory Practice (GLP) toxicology studies to support the investigational new drug (IND) filing of VY-TAU01, its humanized anti-tau antibody. The Company expects to file an IND for the program in the first half of 2024.
- **Capsid license agreement assigned to Alexion, AstraZeneca Rare Disease:** In September, Alexion, AstraZeneca Rare Disease, announced it had completed a definitive purchase and license agreement for a portfolio of preclinical rare disease gene therapy programs and enabling technologies from Pfizer Inc. The portfolio includes the license for a novel capsid generated from Voyager's TRACER™ capsid discovery platform to enable a potential gene therapy program against an undisclosed rare neurologic disease target. The assignment of the license does not impact the terms of the licensing agreement.

Key Upcoming Milestones:

- VY-TAU01 anti-tau antibody program for Alzheimer's disease: Voyager expects to file an IND in the first half of 2024.
- SOD1 gene therapy program for amyotrophic lateral sclerosis (ALS): Voyager expects to identify a lead development candidate in 2023 to support an IND in mid-2025.
- Voyager and Neurocrine Biosciences collaboration: Voyager and Neurocrine Biosciences continue to collaboratively advance the GBA1 gene therapy program for Parkinson's disease and other GBA1-mediated diseases, as well as the FXN gene therapy program for Friedreich's Ataxia.

Third Quarter 2023 Financial Results

- **Collaboration Revenues:** Voyager had collaboration revenue of \$4.6 million for the third quarter of 2023, compared to \$41.1 million for the same period in 2022. The decrease was primarily due to \$40.0 million in collaboration revenue recognized during the third quarter of 2022 in connection with Pfizer exercising its option to license a novel capsid generated from the TRACER capsid discovery platforms.
- **Net (Loss) Income:** Net loss was \$25.9 million for the third quarter of 2023, compared to net income of \$17.6 million for the same period in 2022. The difference is primarily due to the decrease in collaboration revenue discussed above.
- **R&D Expenses:** Research and development expenses were \$25.9 million for the third quarter of 2023, compared to \$19.3 million for the same period in 2022. The increase in R&D expenses was primarily a result of increased program-related spending, particularly manufacturing and IND-enabling studies for the anti-tau antibody program, along with increased Neurocrine program support, during the third quarter of 2023. The increase was also a result of increased compensation costs driven by headcount increases, including targeted development team hires to support the advancing pipeline, during the third quarter of 2023.
- **G&A Expenses:** General and administrative expenses were \$8.3 million for the third quarter of 2023, compared to \$7.3 million for the same period in 2022. The increase in G&A expenses was primarily a result of increased compensation costs driven by headcount increases.
- **Cash Position:** Cash, cash equivalents and marketable securities as of September 30, 2023, were \$252.9 million.

Nine Months Ended September 30, 2023, Financial Results

- **Collaboration Revenues:** Voyager had collaboration revenue of \$159.9 million for the nine months ended September 30, 2023 period, compared to \$42.5 million for the same period in 2022. The increase was primarily due to revenue recognized during the first quarter of 2023 on the 2023 strategic collaboration with Neurocrine Biosciences, as well as revenue recognized on the Novartis license of novel TRACER capsids.
- **Net Income (Loss):** Net income was \$75.9 million for the nine months ended September 30, 2023 period, compared to net loss of \$22.8 million for the same period in 2022. The difference was primarily due to the revenue increases noted above.
- **R&D Expenses:** Research and development expenses were \$66.4 million for the nine months ended September 30, 2023 period, compared to \$46.2 million for the same period in 2022. The increase in R&D expenses was primarily a result of increased program-related spending, particularly manufacturing and IND-enabling studies for the anti-tau antibody program, along with increased Neurocrine program support, during the 2023 period. The increase was also a result of increased compensation costs driven by headcount increases, including targeted development team hires to support the advancing pipeline, during the 2023 period.
- **G&A Expenses:** General and administrative expenses were \$25.6 million for the nine months ended September 30, 2023 period, compared to \$22.5 million for the same period in 2022. The increase in G&A expenses was primarily a result of increased compensation costs driven by headcount increases.

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 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 collaborations and interest income, to be sufficient to meet Voyager's planned operating expenses and capital expenditure requirements into mid-2025.

Conference Call

Voyager will host a conference call and webcast today at 4:30 p.m. ET to discuss the third quarter 2023 financial and operating results. To participate via telephone and join the call live, please register in advance [here](#). Upon registration, telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number and a unique passcode. A live webcast of the call will also be available on the Investors section of the Voyager website at 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 the TRACER™ Capsid Discovery Platform

Voyager's TRACER™ (Tropism Redirection of AAV by Cell-type-specific Expression of RNA) capsid discovery platform is a broadly applicable, RNA-based screening platform that enables rapid discovery of AAV capsids with robust penetration of the blood-brain barrier and enhanced central nervous system (CNS) tropism in multiple species, including non-human primates (NHPs). TRACER generated capsids have demonstrated superior and widespread gene expression in the CNS compared to conventional AAV capsids as well as cell- and tissue-specific transduction, including to areas of the brain that have been traditionally difficult to reach, while de-targeting the liver and dorsal root ganglia. As part of its external partnership strategy, Voyager has established multiple collaboration agreements providing access to its next-generation TRACER capsids to potentially enable its partners' gene therapy programs to treat a variety of diseases.

About Voyager Therapeutics

Voyager Therapeutics (Nasdaq: VYGR) is a biotechnology company dedicated to breaking through barriers in gene therapy and neurology. The potential of both disciplines has been constrained by delivery challenges; Voyager is leveraging cutting-edge expertise in capsid discovery and deep neuropharmacology capabilities to address these constraints. Voyager's TRACER™ AAV capsid discovery platform has generated novel capsids with high target delivery and blood-brain barrier penetration at low doses, potentially addressing the narrow therapeutic window associated with conventional gene therapy delivery vectors. This platform is fueling alliances with Alexion, AstraZeneca Rare Disease; Novartis Pharma AG; Neurocrine Biosciences, Inc. and Sangamo Therapeutics, Inc., as well as multiple programs in Voyager's own pipeline. Voyager's pipeline includes wholly-owned and collaborative preclinical programs in Alzheimer's disease, amyotrophic lateral sclerosis (ALS), Parkinson's disease, and other diseases of the central nervous system, with a focus on validated targets and biomarkers to enable a path to rapid potential proof-of-biology. 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," "plan," "believe," "target," "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 evolve and refine its neurotropic TRACER AAV capsids; Voyager's ability to advance its AAV-based gene therapy programs and tau antibody program, including the preclinical development of its potential development candidates and timing of IND filings; Voyager's ability to advance gene therapy product candidates under the Neurocrine collaborations; Voyager's anticipated financial results, including the receipt by Voyager of revenues or reimbursement payments from collaboration partners; and Voyager's cash runway and Voyager's 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. 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 continued development of Voyager's technology platforms, including Voyager's TRACER platform and its antibody screening technology; the ability to initiate and conduct preclinical studies in animal models; 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 initiation, timing, conduct and outcomes of Voyager's preclinical studies; the possibility or the timing of the exercise of development, commercialization, license and other options under the Pfizer and Novartis license option agreements and Neurocrine collaborations; 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 ability to attract and retain talented directors, employees, and contractors; and the sufficiency of 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.

Contacts

Investors

investors@vogr.com

Andrew Funderburk

afunderburk@kendalllr.com

Media

Trista Morrison

tmorrison@vogr.com

Peg Rusconi

prusconi@vergescientific.com

Selected Financial Information

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|------------|------------------------------------|-------------|
| | 2023 | 2022 | 2023 | 2022 |
| Statement of Operations Items: | | | | |
| Collaboration revenue | \$ 4,614 | \$ 41,086 | \$ 159,947 | \$ 42,457 |
| Operating expenses: | | | | |
| Research and development | 25,863 | 19,337 | 66,416 | 46,213 |
| General and administrative | 8,258 | 7,307 | 25,580 | 22,518 |
| Total operating expenses | 34,121 | 26,644 | 91,996 | 68,731 |
| Operating (loss) income | (29,507) | 14,442 | 67,951 | (26,274) |
| Total other income | 3,429 | 3,182 | 8,570 | 3,492 |
| (Loss) income before income taxes | (26,078) | 17,624 | 76,521 | (22,782) |
| Income tax (benefit) provision | (177) | — | 586 | — |
| Net (loss) income | \$ (25,901) | \$ 17,624 | \$ 75,935 | \$ (22,782) |
| Net (loss) income per share, basic | \$ (0.59) | \$ 0.46 | \$ 1.85 | \$ (0.59) |
| Net (loss) income per share, diluted | \$ (0.59) | \$ 0.45 | \$ 1.78 | \$ (0.59) |
| Weighted-average common shares outstanding, basic | 43,864,838 | 38,507,542 | 40,962,116 | 38,292,497 |
| Weighted-average common shares outstanding, diluted | 43,864,838 | 39,570,394 | 42,610,724 | 38,292,497 |

| | September 30, | | December 31, | |
|--|---------------|------------|--------------|------------|
| | 2023 | 2022 | 2023 | 2022 |
| Selected Balance Sheet Items | | | | |
| Cash, cash equivalents, and marketable debt securities | \$ 252,936 | \$ 118,848 | \$ 294,653 | \$ 159,356 |
| Total assets | \$ 294,653 | \$ 159,356 | \$ 14,321 | \$ 10,382 |
| Accounts payable and accrued expenses | \$ 82,087 | \$ 65,827 | \$ 176,220 | \$ 59,020 |
| Deferred revenue | | | | |
| Total stockholders' equity | | | | |

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, both of which exclude the impact of reimbursement by Neurocrine Biosciences (Neurocrine) for expenses we incur in conducting pre-clinical 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 September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|-----------|------------------------------------|-----------|
| | 2023 | 2022 | 2023 | 2022 |
| GAAP collaboration revenue | \$ 4,614 | \$ 41,086 | \$ 159,947 | \$ 42,457 |
| Revenue recognized for reimbursed research and development services (Note 1) | \$ 3,678 | \$ 225 | \$ 7,030 | \$ 579 |
| Net collaboration revenue | \$ 936 | \$ 40,861 | \$ 152,917 | \$ 41,878 |
| GAAP total research and development expenses | \$ 25,863 | \$ 19,337 | \$ 66,416 | \$ 46,213 |
| Expenses incurred for reimbursed research and development services (Note 1) | \$ 3,678 | \$ 225 | \$ 7,030 | \$ 579 |
| Net research and development expenses | \$ 22,185 | \$ 19,112 | \$ 59,386 | \$ 45,634 |

Note 1: Under the Company's existing collaboration agreements with Neurocrine, Neurocrine has agreed to be responsible for all costs the Company incurs in conducting pre-clinical development activities for each Neurocrine collaboration program, 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 and nine months ended September 30, 2023, we incurred \$3.7 million and \$7.0 million, respectively, of reimbursable research and development services recorded within collaboration revenue and research and development expenses. During the three and nine months ended September 30, 2022, we incurred \$0.2 million and \$0.6 million, respectively, of reimbursable research and development services recorded within collaboration revenue and research and development expenses.



Source: Voyager Therapeutics, Inc.