Trevi Therapeutics Reports Fourth Quarter and Year End 2023 Financial Results and Provides Business Updates

March 20, 2024

Reaffirms guidance for the Phase 2a RIVER trial of Haduvio in RCC patients with topline data expected in the second half of 2024

Enrollment progressing in the Phase 2b CORAL dose-ranging trial of Haduvio for the treatment of chronic cough in IPF patients

Human Abuse Potential Study more than 50% enrolled

Management to host a conference call and webcast today at 4:30 p.m. ET

NEW HAVEN, Conn., March 20, 2024 /PRNewswire/ -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine ER) for the treatment of chronic cough in idiopathic pulmonary fibrosis (IPF) and refractory chronic cough (RCC), today announced financial results for the quarter and year ended December 31, 2023, as well as provided business updates.

Trevi is expecting 2024 to be a milestone year with important data readouts in chronic cough in the second half

"I am proud of the progress Trevi has made in 2023, with the initiation of clinical trials in the fourth quarter for RCC, chronic cough in IPF, and the final part of the Human Abuse Potential (HAP) study," said Jennifer Good, President and CEO of Trevi Therapeutics. "All three of these trials are enrolling patients and we reaffirm our guidance to read out topline data in the second half of this year for the RCC trial and the HAP study. During this time, we also plan to complete and release the results of the sample size re-estimation (SSRE) for the chronic cough in IPF trial. We are expecting 2024 to be a milestone year of important data readouts in areas of chronic cough where there is a significant unmet need with no approved treatments in the United States."

Key Business Updates

- Phase 2a RIVER trial for the treatment of RCC, in which we expect to enroll approximately 60 patients, was initiated in the fourth quarter of 2023. Enrollment continues across multiple sites with the majority of sites being activated in the first quarter of 2024. Topline data is expected in the second half of 2024. The RIVER trial will measure overall results, as well as results from the 1:1 stratification between patients with 10-19 coughs/hour (moderate 24-hour cough frequency) and those with ≥ 20 coughs/hour (high 24-hour cough frequency).
- Phase 2b CORAL trial for the treatment of chronic cough in IPF, in which we expect to enroll approximately 160 patients, was initiated in the fourth quarter of 2023. This trial is expected to be conducted at multiple sites in up to 11 countries. The SSRE is expected to occur in the second half of 2024 when 50% of the patients are evaluable for the primary endpoint. Assuming no adjustments are made to the sample size, topline results are expected in the first half of 2025.
- The final part of the HAP study, in which we expect to enroll approximately 56 patients, initiated dosing and we continue to expect topline data in the second half of 2024. This study is over 50% enrolled.
- The Company ended 2023 with $83.0 million in cash, cash equivalents and marketable securities with expected cash runway into 2026.

Fourth Quarter 2023 Financial Highlights

Research and development (R&D) expenses: R&D expenses for the fourth quarter of 2023 increased to $6.5 million from $4.3 million in the same period in 2022. The increase was primarily due to increased clinical trial costs in our Phase 2b CORAL trial and our Phase 2a RIVER trial, both of which were initiated in the fourth quarter of 2023.

General and administrative (G&A) expenses: G&A expenses were $2.4 million in the fourth quarter of 2023 compared to $2.3 million in the same period in 2022.

Other income, net: Other income, net was $1.1 million in both the fourth quarter of 2023 and 2022.

Net loss: For the fourth quarter of 2023, the Company reported a net loss of $7.8 million, compared to a net loss of $5.5 million in the same period in 2022.

Full-Year 2023 Financial Highlights

R&D expenses: R&D expenses for the year ended December 31, 2023, were $23.7 million compared to $19.8 million in 2022.

The increase was primarily due to increased clinical trial costs in our Phase 2b CORAL trial and our Phase 2a RIVER trial, both of which were started in 2023. Consultant services and personnel-related expenses in support of these studies also increased. These increases were partially offset by decreased clinical trial costs in our completed Phase 2b/3 PRISM and Phase 2 CANAL trials as well as decreased purchases of active drug substance.

G&A expenses: G&A expenses for the year ended December 31, 2023, were $10.2 million compared to $10.1 million in 2022.

Other income, net: Other income, net for the year ended December 31, 2023, was $4.8 million compared to $0.7 million in 2022. The increase was primarily due to an increase in interest income due to higher cash equivalent and marketable securities balances, and higher interest rate yields. Contributing to the increase was a reduction in interest expense due to the early payoff of our SVB term loan in May 2023.

Net loss: For the year ended December 31, 2023, the Company reported a net loss of $29.1 million, compared to a net loss of $29.2 million in 2022.

Conference Call/Webcast
To participate in today's live conference call by phone, please dial (888) 317 6003 (domestic) or (412) 317 6061 (international) and provide access code 4401006. A live audio webcast will be accessible from the 'Investors & News' section on the Company's website at www.TreviTherapeutics.com. An archived replay of the webcast will also be available for 30 days on the Company's website following the event.

Upcoming Meetings
The Company plans to participate in the following events:

- April 8-11: 23rd Annual Needham Virtual Healthcare Conference
- April 26-28: 3rd European Pulmonary Fibrosis Patient Summit 2024 – Barcelona, Spain

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine ER) for the treatment of chronic cough in idiopathic pulmonary fibrosis (IPF) and refractory chronic cough (RCC). Trevi is also developing Haduvio for prurigo nodularis. Haduvio is a dual κ-opioid receptor agonist and μ-opioid receptor antagonist that works both centrally in the brain as well as peripherally in the lungs and has the potential for a synergistic antitussive effect to treat chronic cough.

The impact of chronic cough is significant and often leads to a decline in patients' social, physical, and psychological quality of life. In IPF, chronic cough may lead to worsening disease and may be associated with a higher risk of progression, death, or need for lung transplant. There are no approved therapies for the treatment of chronic cough in IPF and current treatment options provide minimal relief to patients. RCC affects up to 10% of the adult population, and Haduvio's expansion into RCC has the potential to reach patients suffering from moderate to severe chronic cough. There are also no approved therapies for RCC in the US.

Parenteral nalbuphine is not scheduled by the U.S. Drug Enforcement Agency. Trevi intends to propose Haduvio as the trade name for oral nalbuphine ER. Its safety and efficacy have not been evaluated by any regulatory authority.

For more information, visit www.TreviTherapeutics.com and follow Trevi on X (formerly Twitter) and LinkedIn.

Forward-Looking Statements
Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties and actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding Trevi's business plans and objectives, including future plans or expectations for Haduvio and plans and timing with respect to clinical trials, expectations regarding Trevi's uses and sufficiency of capital, and other statements containing the words "believes," "anticipates," "plans," "expects," and similar expressions. Risks that contribute to the uncertain nature of the forward-looking statements include: uncertainties regarding the success, cost and timing of Trevi's product candidate development activities and ongoing and planned clinical trials; the risk that positive data from a clinical trial may not necessarily be predictive of the results of later clinical trials in the same or a different indication; uncertainties regarding Trevi's ability to execute on its strategy; uncertainties with respect to regulatory authorities' views as to the data from Trevi's clinical trials and next steps in the development path for Haduvio in the United States and foreign countries, including Trevi's ability to submit and get clearance of an IND and other regulatory filings on a timely basis; uncertainties inherent in estimating Trevi's cash runway, future expenses and other financial results, including Trevi's ability to fund future operations, including clinical trials, as well as other risks and uncertainties set forth in the quarterly report on Form 10-Q for the quarter ended September 30, 2023 filed with the Securities and Exchange Commission and in subsequent filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Trevi undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Trevi Therapeutics, Inc.
Selected Balance Sheet Data

(unaudited)
(amounts in thousands)

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 32,397	$ 12,589
Marketable securities	50,574	107,921
Working capital	81,723	109,216
Total assets	89,403	123,015
Total debt	—	9,151
Stockholders' equity	82,547	107,459

Trevi Therapeutics, Inc.
Selected Statement of Operations Data
(unaudited)
(amounts in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 6,519	$ 4,317	$ 23,683	$ 19,834
General and administrative	2,415	2,339	10,240	10,073
Total operating expenses	8,934	6,656	33,923	29,907
Loss from operations	(8,934)	(6,656)	(33,923)	(29,907)
Other income, net	1,130	1,132	4,826	719
Loss before income taxes	(7,804)	(5,524)	(29,097)	(29,188)
Income tax (provision) benefit	(18)	20	32	36
Net loss	$ (7,822)	$ (5,504)	$ (29,065)	$ (29,152)
Basic and diluted net loss per common share outstanding	$ (0.08)	$ (0.06)	$ (0.29)	$ (0.45)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	99,485,873	98,132,668	99,033,373	64,541,911

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