Trevi Therapeutics Reports Third Quarter 2024 Financial Results and Provides Business Updates

November 6, 2024

Completed enrollment of the Phase 2a RIVER trial in refractory chronic cough (RCC) with topline results expected in the first quarter of 2025

Reached 50% enrollment for the Phase 2b CORAL trial in chronic cough in idiopathic pulmonary fibrosis (IPF), with sample size re-estimation outcome expected in December 2024

Ended the third quarter of 2024 with $65.5 million in cash, cash equivalents and marketable securities, with expected cash runway into the second half of 2026

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

NEW HAVEN, Conn., Nov. 6, 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 ended September 30, 2024, as well as provided business updates.

"Our team has made excellent progress advancing our clinical programs this year, and we are eagerly anticipating the upcoming clinical results starting in December," said Jennifer Good, President and CEO of Trevi Therapeutics. "Positive results over the upcoming months would bring us closer to potentially addressing the significant unmet need and market opportunity in both chronic cough in IPF and RCC through Haduvio's unique mechanism."

Haduvio acts on the cough reflex arc both centrally and peripherally as a kappa agonist and a mu antagonist (KAMA), which are opioid receptors that play a key role in controlling cough hypersensitivity.

Third Quarter and Recent Business Highlights

- Completed enrollment in the Phase 2a RIVER trial for the treatment of RCC in October 2024. The Company expects topline data in the first quarter of 2025.
- Enrolled 50% of the planned 160 patients in the Phase 2b CORAL trial for the treatment of chronic cough in patients with IPF as of October 2024. The Company expects to release the sample size re-estimation (SSRE) outcome in December 2024. Topline results are expected in the first half of 2025, assuming no adjustments are made to the sample size as a result of the SSRE.
- Completed dosing in the Human Abuse Potential (HAP) study in the third quarter of 2024, with topline results expected in December 2024.
- Announced during the third quarter the appointment of James V. Cassella, Ph.D., as Chief Development Officer.
- Ended the third quarter of 2024 with $65.5 million in cash, cash equivalents and marketable securities, with expected cash runway into the second half of 2026.

Third Quarter 2024 Financial Highlights

Research and development (R&D) expenses: R&D expenses for the third quarter of 2024 increased to $11.2 million from $6.3 million in the same period in 2023, primarily due to increased clinical development expenses for the Phase 2b CORAL trial, the Phase 2a RIVER trial, and the HAP study, as well as an increase in personnel related expenses.

General and administrative (G&A) expenses: G&A expenses for the third quarter of 2024 increased to $2.9 million from $2.7 million in the same period in 2023, primarily due to an increase in stock-based compensation expense.

Net loss: For the third quarter of 2024, the Company reported a net loss of $13.2 million, compared to a net loss of $7.7 million in the same period in 2023.

Conference Call/Webcast
To participate in the live conference call by phone, please dial (877) 870 4263 (domestic) or (412) 317 0790 (international) and ask to join the Trevi Therapeutics call. No code is necessary for access. 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:

- November 18-19: Stifel 2024 Healthcare Conference
- December 3-5: Piper Sandler 36th Annual Healthcare Conference

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine extended-release (ER)) for the treatment of chronic cough in patients with idiopathic pulmonary fibrosis (IPF) and refractory chronic cough (RCC). Haduvio acts on the cough reflex arc both centrally and peripherally as a kappa agonist and a mu antagonist (KAMA), which are opioid receptors that play a key role in controlling cough hypersensitivity. Nalbuphine is not currently scheduled by the U.S. Drug Enforcement Agency.

Chronic cough is highly prevalent among approximately 140,000 IPF patients in the U.S., with up to 85% of IPF patients experiencing chronic cough. The impact of chronic cough is significant with IPF patients coughing up to 1,500 times per day and may lead to worsening disease, a higher risk of progression, death, or need for lung transplant. Chronic cough also often leads to a decline in patients' social, physical, and psychological quality of life. There are no approved therapies for the treatment of chronic cough in IPF and current treatment options provide minimal benefit to patients.

Refractory chronic cough affects approximately 2-3 million adults in the U.S. and is caused by cough reflex hypersensitivity in both the central and peripheral nerves. It is highly disruptive and accompanied by a wide range of complications, ranging from urinary incontinence in females to sleep disruption and social embarrassment that causes significant social and economic burdens for patients and those around them. Haduvio is being developed for the treatment of moderate to severe RCC. There are also no approved therapies for RCC in the U.S.

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 and clinical data, 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 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, 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 June 30, 2024 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)

	September 30, 2024	December 31, 2023
Cash and cash equivalents	$ 16,052	$ 32,397
Marketable securities	49,441	50,574
Working capital	58,213	81,723
Total assets	68,908	89,403
Stockholders' equity	58,969	82,547

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 11,224	$ 6,323	$ 30,049	$ 17,165
General and administrative	2,863	2,722	9,232	7,825
Total operating expenses	14,087	9,045	39,281	24,990
Loss from operations	(14,087)	(9,045)	(39,281)	(24,990)
Other income, net	814	1,334	2,739	3,696
Loss before income taxes	(13,273)	(7,711)	(36,542)	(21,294)
Income tax benefit	31	13	46	50
Net loss	$ (13,242)	$ (7,698)	$ (36,496)	$ (21,244)
Basic and diluted net loss per common share outstanding	$ (0.13)	$ (0.08)	$ (0.36)	$ (0.21)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	101,282,228	99,325,540	100,616,111	98,880,882

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