Trevi Therapeutics Reports Fourth Quarter and Year End 2024 Financial Results and Provides Business Updates

March 18, 2025

Announced positive topline data from the Phase 2a RIVER trial in patients with refractory chronic cough (RCC), making Haduvio the first therapy in clinical development to show benefit in patients with chronic cough in idiopathic pulmonary fibrosis (IPF) and RCC

Completed enrollment in the Phase 2b CORAL trial in IPF patients with chronic cough in February 2025, with topline data expected in the second quarter of 2025

Announced positive outcome from sample size re-estimation in the Phase 2b CORAL trial, resulting in no change to study sample size

Ended 2024 with $107.6 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., March 18, 2025 /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 patients with idiopathic pulmonary fibrosis (IPF) and refractory chronic cough (RCC), today announced financial results for the quarter and year ended December 31, 2024, and provided business updates.

"Trevi had three positive and meaningful clinical data read-outs over the past few months validating the strategy of developing Haduvio as a potential best-in-class therapy for chronic cough conditions," said Jennifer Good, President and CEO of Trevi Therapeutics. "With Haduvio, we are looking to address a significant unmet need across chronic cough conditions where there are no therapies approved in the U.S. Haduvio has the unique potential to work across various chronic cough conditions due to its central and peripheral mechanism. We look forward to our expected readout of topline results for the Phase 2b CORAL trial in IPF chronic cough patients in the second quarter of this year."

Fourth Quarter and Recent Business Highlights

- Positive topline data in the Phase 2a RIVER trial for the treatment of patients with RCC (N=66) in March 2025. Haduvio met the primary endpoint with a statistically-significant reduction ($p<0.0001$) in 24-hour cough frequency with a 57% placebo-adjusted change from baseline and showed similar effects in patients with moderate or severe cough counts. The Company plans to discuss next steps and future study design with the FDA.
- Positive sample size re-estimation (SSRE) outcome for the Phase 2b CORAL trial for the treatment of chronic cough in patients with IPF in December 2024. The SSRE reaffirmed the conditional power assumptions and the original sample size (N=160). The trial completed enrollment in February 2025 and topline data is expected in the second quarter of 2025.
- Positive topline results from the Human Abuse Potential study of oral nalbuphine in December 2024. Oral nalbuphine had a statistically significant lower "Drug Liking" for the clinical dose range vs. the active comparator as well as secondary endpoint results that were consistent with the primary endpoint supporting the known profile of nalbuphine and its currently unscheduled status.
- Completed a $50 million underwritten offering in December 2024 to support the continued development of Haduvio.
- Ended 2024 with $107.6 million in cash, cash equivalents and marketable securities, with expected cash runway into the second half of 2026.

Fourth Quarter 2024 Financial Highlights

Research and development (R&D) expenses: R&D expenses for the fourth quarter of 2024 increased to $9.3 million from $6.5 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 fourth quarter of 2024 increased to $2.9 million from $2.4 million in the same period in 2023, primarily due to an increase in stock-based compensation expense and personnel-related expenses.

Other income, net: Other income, net was $0.8 million in the fourth quarter of 2024 compared to $1.1 million in the same period of 2023. The decrease was primarily due to lower cash equivalent and marketable securities balances and lower interest rate yields.

Net loss: For the fourth quarter of 2024, the Company reported a net loss of $11.4 million, compared to a net loss of $7.8 million in the same period in 2023.

Full Year 2024 Financial Highlights
R&D expenses: R&D expenses for the year ended December 31, 2024, were $39.4 million compared to $23.7 million in 2023. The increase was primarily due to increased clinical development expenses for the Phase 2b CORAL trial, the Phase 2a RIVER trial, the HAP study, and the Phase 1b TIDAL study, as well as an increase in personnel-related expenses and stock-based compensation expense. These increases were partially offset by decreased clinical development expenses for our Phase 2b/3 PRISM trial.

G&A expenses: G&A expenses for the year ended December 31, 2024, were $12.1 million compared to $10.2 million in 2023. The increase was primarily due to an increase in personnel-related expenses, stock-based compensation expense, information technology service costs and market research costs.

Other income, net: Other income, net was $3.6 million for the year ended December 31, 2024, compared to $4.8 million 2023. The decrease was primarily due to a decrease in interest income due to lower cash equivalent and marketable securities balances.

Net loss: For the year ended December 31, 2024, the Company reported a net loss of $47.9 million, compared to a net loss of $29.1 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:

- April 7-10: 24th Annual Needham Virtual Healthcare Conference
- April 8-10: Jones 2025 Healthcare & Technology Summit
- April 16-17: Piper Sandler Spring Biopharma Symposium

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine extended-release) for the treatment of chronic cough in patients with idiopathic pulmonary fibrosis (IPF) and refractory chronic cough (RCC). Haduvio is the first and only therapy in clinical development to show a statistically significant reduction in chronic cough across patients with both IPF and 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 a highly prevalent condition in IPF patients, impacting up to 85% of the IPF population. There are ~140,000 U.S. IPF patients and the impact of chronic cough is significant with patients coughing up to 1,500 times per day. This consistent cough and any associated damage 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 patients with IPF and current off-label treatment options provide minimal benefit to patients.

Refractory chronic cough has no approved therapies in the U.S. and is defined as a persistent cough lasting >8 weeks despite treatment for an underlying condition (i.e., asthma, gastroesophageal reflux disease, non-asthmatic eosinophilic bronchitis, and upper airway cough syndrome or post-nasal drip) and includes unexplained chronic cough. RCC affects ~2-3 million patients in the U.S. and is caused by cough reflex hypersensitivity in both the central and peripheral nerves. It is a highly debilitating disease 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.

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 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 September 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)

	December 31, 2024	December 31, 2023
Cash and cash equivalents	$ 34,097	$ 32,397
Marketable securities	73,525	50,574
Working capital	98,919	81,723
Total assets	110,900	89,403
Stockholders' equity	99,644	82,547

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,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 9,327	$ 6,519	$ 39,377	$ 23,683
General and administrative	2,916	2,415	12,147	10,240
Total operating expenses	12,243	8,934	51,524	33,923
Loss from operations	(12,243)	(8,934)	(51,524)	(33,923)
Other income, net	844	1,130	3,583	4,826
Loss before income taxes	(11,399)	(7,804)	(47,941)	(29,097)
Income tax (provision) benefit	(17)	(18)	30	32
Net loss	$ (11,416)	$ (7,822)	$ (47,911)	$ (29,065)
Basic and diluted net loss per common share outstanding	$ (0.11)	$ (0.08)	$ (0.47)	$ (0.29)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	106,009,686	99,485,873	101,971,873	99,033,373

Investor Contact
Jonathan Carlson
Trevi Therapeutics, Inc.
(203) 654 3286
carlsonj@trevitherapeutics.com

Media Contact
Rosalia Scampoli
914-815-1465
rscampoli@marketcompr.com

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