Trevi Therapeutics Reports First Quarter 2025 Financial Results and Provides Business Updates

Completed enrollment and last patient last visit in the Phase 2b CORAL trial in IPF patients with chronic cough; topline results continue to be expected in the second quarter of 2025

Announced positive topline results from the Phase 2a RIVER trial in patients with refractory chronic cough

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

NEW HAVEN, Conn., May 8, 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 in patients with refractory chronic cough (RCC), today announced financial results for the quarter ended March 31, 2025, and provided business updates.

"The RIVER data in patients with RCC demonstrated the clinical significance of Haduvio's centrally and peripherally acting mechanism and its potential across a broad range of chronic cough patients and cough counts," said Jennifer Good, President and CEO of Trevi Therapeutics. "Building on that positive momentum, we look forward to the topline results from the Phase 2b CORAL trial expected this quarter for the treatment of IPF patients with chronic cough. Chronic cough is a significant burden to IPF patients and there are no approved therapies. Trevi is at a pivotal moment with promising data, a dedicated development team advancing trials, and a strong balance sheet to support the continued development of Haduvio."

First Quarter 2025 Financial Results and Recent Business Highlights

- Enrollment was completed in February 2025 in the Phase 2b CORAL trial of Haduvio in chronic cough patients with IPF and the last patient last visit was completed in April 2025. Topline results for the CORAL trial remain on track for the second quarter of 2025.
- In March, Trevi announced positive topline results from its Phase 2a RIVER trial of Haduvio in patients with RCC (N=66). Haduvio met the primary endpoint with a statistically significant reduction in objective 24-hour cough frequency of 67% from baseline and 57% on a placebo-adjusted basis ($p<0.0001$). Planned analyses of all pre-specified secondary endpoints at the end of treatment were also statistically significant. The Company is now reviewing the full data set and is in the process of designing the next planned trial of Haduvio in patients with RCC.
- Ended the first quarter of 2025 with $103.3 million in cash, cash equivalents and marketable securities, with expected cash runway into the fourth quarter of 2026.

First Quarter 2025 Financial Highlights
Research and development (R&D) expenses: R&D expenses for the first quarter of 2025 decreased to $7.8 million from $8.8 million in the same period in 2024, primarily due to decreased clinical development expenses for the Company's Human Abuse Potential study, which was actively enrolling patients in the prior year, partially offset by an increase in personnel related expenses due to increased headcount.

General and administrative (G&A) expenses: G&A expenses for the first quarter of 2025 increased to $3.7 million from $3.1 million in the same period in 2024, primarily due to an increase in personnel-related expenses.

Net loss: For the first quarter of 2025, the Company reported a net loss of $10.3 million, compared to a net loss of $10.9 million in the same period in 2024.

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:

- May 16-21: American Thoracic Society 2025 International Conference
- June 6-7: 10th American Cough Conference
- June 16-19: BIO International Convention

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 in patients with refractory chronic cough (RCC). Haduvio is the first and only investigational therapy to show a statistically significant reduction in cough frequency in clinical trials with IPF chronic cough patients and RCC patients. Haduvio acts on the cough reflex arc both centrally and peripherally as a kappa agonist and a mu antagonist (KAMA), targeting opioid receptors that play a key role in controlling chronic cough. 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 ~150,000 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 annual report on Form 10-K for the year ended December 31, 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)

	March 31, 2025	December 31, 2024

Cash and cash equivalents	$ 19,374	$ 34,097
Marketable securities	83,883	73,525
Working capital	98,755	98,919
Total assets	107,004	110,900
Stockholders' equity	99,457	99,644

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

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 7,811	$ 8,804
General and administrative	3,659	3,102
Total operating expenses	11,470	11,906
Loss from operations	(11,470)	(11,906)
Other income, net	1,119	996
Loss before income taxes	(10,351)	(10,910)
Income tax benefit	11	8
Net loss	$ (10,340)	$ (10,902)
Basic and diluted net loss per common share outstanding	$ (0.09)	$ (0.11)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	117,610,750	99,517,212

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