Trevi Therapeutics Reports Fourth Quarter and Year End 2025 Financial Results and Provides Business Updates

March 17, 2026

Following the End-of-Phase 2 meeting with the FDA, the Company gained alignment on its Phase 3 program for the treatment of patients with idiopathic pulmonary fibrosis-related chronic cough

On track to initiate a Phase 2b clinical trial for the treatment of patients with refractory chronic cough in the second quarter of 2026

Company ended 2025 with $188.3 million in cash, cash equivalents and marketable securities, with expected cash runway into 2028

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

NEW HAVEN, Conn., March 17, 2026 (GLOBE NEWSWIRE) -- 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), non-IPF interstitial lung disease (non-IPF ILD), and refractory chronic cough (RCC), today announced financial results for the fourth quarter and year ended December 31, 2025, and provided business updates.

"Our progress in 2025 marked a major inflection point for Trevi's growth trajectory, driven by positive Phase 2 data across our chronic cough programs," said Jennifer Good, President and CEO of Trevi Therapeutics. "These results provide a strong foundation as we pursue our goal of becoming a leader in treating chronic cough. We've carried this momentum into 2026 as we gained overall alignment with the FDA during our End-of-Phase 2 meeting for patients with IPF-related chronic cough. We are now focused on initiating the first of our two pivotal Phase 3 IPF-related chronic cough trials, as well as our Phase 2b RCC trial in the second quarter of this year. Looking ahead, Trevi is well positioned to execute on its clinical programs and help address the high unmet need for patients who are burdened by chronic cough in our target indications, where there are no FDA-approved therapies."

Recent Business Highlights

IPF-Related Chronic Cough

- The Company had its End-of-Phase 2 meeting with the FDA and gained overall alignment on the plan for the remaining development program of nalbuphine ER (NAL ER) for the treatment of IPF-related chronic cough. The Company plans to conduct two pivotal Phase 3 clinical trials and obtained agreement on the remaining Phase 1 clinical studies that the Company expects to conduct to support a New Drug Application (NDA) submission. The Company plans to conduct the two Phase 3 trials in parallel and is on track to initiate the first Phase 3 trial in the second quarter of 2026 and the second Phase 3 trial in the second half of 2026.
- The first of the two Phase 3 trials is planned to enroll approximately 300 patients and have 52 weeks of fixed dosing with NAL ER 54 mg twice-a-day (BID), with the primary endpoint at 24 weeks of fixed dosing. The second Phase 3 trial is planned to enroll approximately 130 patients and have 12 weeks of fixed dosing with NAL ER 54 mg BID. The primary efficacy endpoint for both trials will be the relative change from Baseline in 24-hour cough frequency (coughs per hour), as determined by an objective cough monitor, for nalbuphine ER compared with placebo. These trial designs are subject to final review of the protocols by the FDA.
- Key Phase 2b CORAL trial results in patients with IPF-related chronic cough were published in the Journal of the American Medical Association (JAMA) in January 2026.

Refractory Chronic Cough

- The Company plans to initiate a Phase 2b trial of nalbuphine ER for the treatment of patients with RCC in the second quarter of 2026. The Company expects the primary efficacy endpoint of the trial will be the mean change in 24-hour cough frequency, as determined by an objective cough monitor. The trial is subject to final review of the protocol by regulatory authorities.

Non-IPF ILD-Related Chronic Cough

- The Company plans to initiate an adaptive design Phase 2b trial of nalbuphine ER for the treatment of patients with non-IPF ILD-related chronic cough in the second half of 2026, subject to review of the protocol for the trial by the FDA.

Corporate

- The Company plans to host an Investor and Analyst Day on May 7, 2026, from 10:00 a.m. to 12:00 p.m. ET, to discuss the Company's clinical and commercial strategy and will be joined by esteemed KOLs. The in-person event will take place in New York City. To register for the webcast, please visit Trevi's website or register here.

Fourth Quarter 2025 Financial Highlights

Cash, cash equivalents and marketable securities: The Company ended 2025 with $188.3 million with expected cash runway into 2028.

Research and development (R&D) expenses: R&D expenses for the fourth quarter of 2025 decreased to $6.2 million from $9.3 million in the same period in 2024, primarily due to decreased clinical development expenses for the Company's Phase 2a RIVER trial and Phase 2b CORAL trial, which were actively enrolling patients in the prior year period.

General and administrative (G&A) expenses: G&A expenses for the fourth quarter of 2025 increased to $4.0 million from $2.9 million in the same period in 2024, primarily due to an increase in professional fees and personnel-related expenses.

Other Income, net: Other Income, net for the fourth quarter of 2025 increased to $1.9 million from $0.8 million in the same period in 2024, primarily due to an increase in interest income from higher invested cash equivalent and marketable securities balances.

Net loss: For the fourth quarter of 2025, the Company reported a net loss of $8.3 million compared to the net loss of $11.4 million in the same period in 2024.

Full Year 2025 Financial Highlights
R&D expenses: R&D expenses for the year ended December 31, 2025, were $33.5 million compared to $39.4 million in 2024, primarily due to decreased clinical development expenses for the Company's human abuse potential study, Phase 2a RIVER trial, and Phase 2b CORAL trial, which were actively enrolling patients in 2024, partially offset by increased costs incurred associated with the recently completed Phase 1 drug-drug interaction study and personnel-related expenses.

G&A expenses: G&A expenses for the year ended December 31, 2025, were $15.9 million compared to $12.1 million in 2024, primarily due to an increase in professional fees and personnel-related expenses.

Other income, net: Other income, net was $6.5 million for the year ended December 31, 2025, compared to $3.6 million in 2024, primarily due to an increase in interest income from higher invested cash equivalent and marketable securities balances.

Net loss: For the year ended December 31, 2025, the Company reported a net loss of $42.8 million, compared to a net loss of $47.9 million in 2024.

Conference Call and Webcast
To register for the live conference call and webcast, please visit the 'Investors & News' section of the Company's website or access directly at ir.trevitherapeutics.com/news-events/events. Please note for phone participants: Once registered, you will receive an email with unique call-in details. An archived replay of the webcast will also be available for 30 days on the Company's website following the event.

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), non-IPF interstitial lung disease (non-IPF ILD), and refractory chronic cough (RCC). Haduvio is the first and only investigational therapy to show a statistically-significant reduction in cough frequency in clinical trials across both patients with IPF chronic cough and in patients with RCC. 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 in patients with IPF and non-IPF ILD is a condition with high unmet need and no FDA-approved therapies. There are ~150,000 U.S. patients with IPF, and two-thirds of these patients are faced with uncontrolled chronic cough. Additionally, there are ~228,000 U.S. patients with non-IPF ILD, with 50-60% having uncontrolled chronic cough. 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 a higher risk of morbidity and mortality, including worsening disease, a higher risk of progression, increased respiratory hospitalizations, and a decline in patients' quality of life.

RCC is a condition with high unmet need and no FDA-approved therapies. RCC 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, upper airway cough syndrome, or post-nasal drip) and includes unexplained chronic cough. There are ~2-3 million U.S. patients with RCC, and it is believed to be associated with cough reflex hypersensitivity involving both the central and peripheral nervous systems. RCC is highly debilitating and may impact patients physically, psychologically, and socially.

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, as well as regulatory submissions, statements regarding FDA guidance, 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, 2025 filed with the Securities and Exchange Commission and in subsequent filings made by the Company 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, 2025	December 31, 2024
Cash and cash equivalents	$ 18,914	$ 34,097
Marketable securities	169,346	73,525
Working capital	181,907	98,919
Total assets	193,439	110,900
Stockholders' equity	183,244	99,644

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,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 6,194	$ 9,327	$ 33,478	$ 39,377
General and administrative	4,026	2,916	15,850	12,147
Total operating expenses	10,220	12,243	49,328	51,524
Loss from operations	(10,220)	(12,243)	(49,328)	(51,524)
Other income, net	1,888	844	6,505	3,583
Loss before income taxes	(8,332)	(11,399)	(42,823)	(47,941)
Income tax (benefit) provision	(16)	17	(64)	(30)
Net loss	$ (8,316)	$ (11,416)	$ (42,759)	$ (47,911)
Basic and diluted net loss per common share outstanding	$ (0.06)	$ (0.11)	$ (0.32)	$ (0.47)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	145,502,344	106,009,686	134,747,198	101,971,873

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