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

November 13, 2025

Company preparing to initiate comprehensive Phase 3 program for chronic cough in patients with idiopathic pulmonary fibrosis in first half of 2026

Company ended the third quarter of 2025 with $194.9 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. EST

NEW HAVEN, Conn., Nov. 13, 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), non-IPF interstitial lung disease (non-IPF ILD), and refractory chronic cough (RCC), today announced financial results for the quarter ended September 30, 2025, and provided business updates.

"Following positive clinical data for both IPF chronic cough and RCC earlier this year, our strong progress continues. We have been executing on the studies necessary to advance our IPF chronic cough program and are on track to submit our End-of-Phase 2 meeting request to the FDA in the fourth quarter," said Jennifer Good, President and CEO of Trevi Therapeutics. "We look forward to discussing our development program with the FDA and are building a robust and comprehensive package for those discussions. Our overall corporate strategy is built on a clear path for growth, focused on specialty indications in chronic cough that currently have no approved therapies in the U.S. and have significant negative impacts on the quality of life of the patients with these conditions."

Third Quarter 2025 Financial Results and Recent Business Highlights

Chronic Cough in IPF

- The Company is preparing to request an End-of-Phase 2 meeting in the fourth quarter of 2025 and to initiate its Phase 3 program in the first half of 2026.
- The safety review committee for the Phase 1 respiratory function and safety study in patients with IPF, which is referred to as TIDAL, met to review data for the sentinel cohort of patients and concluded there were no safety signals and gave approval to complete enrollment. The study is expected to be completed in the fourth quarter of 2025 and available data will be included in the End-of-Phase 2 meeting package.
- The Company successfully completed a Phase 1 drug-drug interaction study in healthy adult participants to evaluate the co-administration of nalbuphine ER with standard of care antifibrotic therapies, pirfenidone or nintedanib. The results of the study showed no clinically meaningful pharmacokinetic findings for nalbuphine ER or either of the antifibrotics when given in combination.
- Topline results from the Phase 2b CORAL trial were presented at the CHEST 2025 Annual Meeting.

Refractory Chronic Cough

- Following the positive Phase 2a RIVER trial results earlier this year, the Company is planning to initiate a Phase 2b RCC study in the first half of 2026.
- Results from the RIVER trial were presented at both the CHEST 2025 Annual Meeting as well as at the ERS Congress 2025.

Corporate

- The Company ended the third quarter of 2025 with $194.9 million in cash, cash equivalents and marketable securities, with expected cash runway into 2028.

Third Quarter 2025 Financial Highlights
Research and development (R&D) expenses: R&D expenses for the third quarter of 2025 decreased to $10.1 million from $11.2 million in the same period in 2024, primarily due to decreased clinical development expenses for the Company's Phase 2a RIVER trial, Human Abuse Potential study, and Phase 2b CORAL trial, all of which were actively enrolling patients in the prior year period. These decreases were partially offset by increased costs for the Company's recently completed Phase 1 drug-drug interaction study and personnel-related expenses.

General and administrative (G&A) expenses: G&A expenses for the third quarter of 2025 increased to $3.8 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 third quarter of 2025 increased to $2.1 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 third quarter of 2025, the Company reported a net loss of $11.8 million compared to the net loss of $13.2 million in the same period in 2024.

Conference Call and 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.

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, 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 June 30, 2025 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, 2025	December 31, 2024

Cash and cash equivalents	$ 56,869	$ 34,097
Marketable securities	138,058	73,525
Working capital	189,258	98,919
Total assets	199,356	110,900
Stockholders' equity	189,788	99,644

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

	Three Months Ended September 30,		Nine Months Ende September 30,	
	2025	**2024**	**2025**	**2**
Operating expenses:				
Research and development	$ 10,085	$ 11,224	$ 27,285	$
General and administrative	3,831	2,863	11,823	
Total operating expenses	13,916	14,087	39,108	
Loss from operations	(13,916)	(14,087)	(39,108)	
Other income, net	2,099	814	4,617	
Loss before income taxes	(11,817)	(13,273)	(34,491)	
Income tax benefit	15	31	48	
Net loss	$ (11,802)	$ (13,242)	$ (34,443)	$
Basic and diluted net loss per common share outstanding	$ (0.08)	$ (0.13)	$ (0.26)	$
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	145,104,986	101,282,228	131,122,754	10

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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