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

August 7, 2025

Announced positive topline results from its Phase 2b CORAL trial of Haduvio for the treatment of chronic cough in patients with IPF

Closed $115 million underwritten offering with expected cash runway into 2029

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

NEW HAVEN, Conn., Aug. 7, 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 June 30, 2025, and provided business updates.

"The recently received full data set from our CORAL trial for chronic cough in patients with IPF bolsters the statistically-significant topline results presented in June. This data marks a major milestone for Trevi as it shows consistency and clinically meaningful benefit for these patients," said Jennifer Good, President and CEO of Trevi Therapeutics. "Chronic cough is a debilitating and underserved condition for patients with IPF, and these results, along with the positive RCC data from our RIVER trial announced earlier this year, reinforce our belief in Haduvio's potential to transform care of chronic cough and the lives of these patients. We expect our current cash and investments to provide us with cash runway into 2029, giving us the financial strength to advance Haduvio through late-stage development and several key clinical milestones, as well as enabling pre-commercial planning activities."

Second Quarter 2025 Financial Results and Recent Business Highlights

- Positive topline results from the Phase 2b CORAL trial evaluating Haduvio for the treatment of chronic cough in patients with IPF (N=165) were announced in June 2025. Haduvio met the primary endpoint with statistically-significant reductions in 24-hour cough frequency across all dose groups. The 108 mg BID, 54 mg BID, and 27 mg BID dose groups achieved statistically-significant reductions from Baseline of 60.2% ($p<0.0001$), 53.4% ($p<0.0001$), and 47.9% ($p<0.01$), respectively, compared to a placebo reduction from Baseline of 16.9%.[1] The Company plans to request an End-of-Phase 2 meeting with the FDA in the fourth quarter of 2025 to align on the Phase 3 program. The Company is preparing to initiate the Phase 3 program in the first half of 2026.
- Additional analyses from the Phase 2b CORAL trial showed positive results with Haduvio on the Leicester Cough Questionnaire (LCQ) Total Score for the 108 mg BID and 54 mg BID dose groups, increasing the LCQ score by 3.4 points ($p=0.01$) and 3.7 points ($p=0.01$), respectively. A 1.3-point increase from Baseline is considered clinically meaningful. The LCQ is considered an important measure of quality of life for patients suffering from chronic cough.
- Completed a $115 million underwritten offering in June 2025, enabling continued advancement of Haduvio's clinical programs. The Company ended the second quarter of 2025 with $203.9 million in cash, cash equivalents and marketable securities, with expected cash runway into 2029.

Second Quarter 2025 Financial Highlights
Research and development (R&D) expenses: R&D expenses for the second quarter of 2025 decreased to $9.4 million from $10.0 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 (HAP) 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 initiated Phase 1 drug-drug interaction study, and personnel and related expenses.

General and administrative (G&A) expenses: G&A expenses for the second quarter of 2025 increased to $4.3 million from $3.3 million in the same period in 2024, primarily due to an increase in professional fees, and personnel and related expenses.

Other Income, net: Other Income, net for the second quarter of 2025 increased to $1.4 million from $0.9 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 second quarter of 2025, the Company reported a net loss of $12.3 million compared to the net loss of $12.4 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:

- August 11-13: Stifel's 2025 Biotech Summer Summit
- September 3-5: Wells Fargo 2025 Healthcare Conference
- September 3-5: Cantor Global Healthcare Conference 2025
- September 8-10: H.C. Wainwright & Co. 27th Annual Global Investment Conference
- September 8-10: Morgan Stanley 23rd Annual Global Healthcare Conference
- September 17-19: 2025 Leerink Partners Biopharma Summit
- September 27-October 1: European Respiratory Society (ERS) Congress

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 chronic cough patients with IPF 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 is a highly prevalent condition, impacting up to 85% of patients with IPF. There are ~150,000 patients in the U.S. with IPF. 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 March 31, 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)

	June 30, 2025	December 31, 2024
Cash and cash equivalents	$ 117,058	$ 34,097

Marketable securities	86,827	73,525
Working capital	197,987	98,919
Total assets	208,339	110,900
Stockholders' equity	198,493	99,644

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 9,389	$ 10,021	$ 17,200	$ 18,825
General and administrative	4,333	3,268	7,992	6,370
Total operating expenses	13,722	13,289	25,192	25,195
Loss from operations	(13,722)	(13,289)	(25,192)	(25,195)
Other income, net	1,400	929	2,519	1,925
Loss before income taxes	(12,322)	(12,360)	(22,673)	(23,270)
Income tax benefit	21	8	32	16
Net loss	$ (12,301)	$ (12,352)	$ (22,641)	$ (23,254)
Basic and diluted net loss per common share outstanding	$ (0.09)	$ (0.12)	$ (0.18)	$ (0.23)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	130,350,391	101,041,573	124,015,763	100,279,393

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

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

[1] One placebo patient with an extreme outlier value at Week 6 was excluded from the modified intent-to-treat (mITT) population. Inclusion of the patient in the placebo group would have resulted in an increased cough frequency from Baseline in the placebo group and much greater placebo-adjusted differences.

SOURCE Trevi Therapeutics, Inc.