Trevi Therapeutics Reports Third Quarter 2026 Financial Results and Provides Business Updates

November 9, 2026

Initiated Phase 3 OCEAN-2 trial for patients with IPF-related chronic cough in the third quarter; both Phase 3 OCEAN trials actively recruiting

Positive meeting with the FDA on the non-IPF ILD-related chronic cough program held in October 2026; Phase 2 dose-ranging trial expected to initiate in the first quarter of 2027

Notice of Allowance from the USPTO for patent application covering nalbuphine ER dosing in hepatically impaired patients with non-IPF ILD-related chronic cough, with patent expected to expire in 2041

Cash runway into 2030 funding key clinical milestones

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

NEW HAVEN, Conn., Nov. 09, 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 quarter ended September 30, 2026, and provided business updates.

"This is an important time of clinical execution for Trevi as we actively open sites globally and enroll patients across all three active trials," said Jennifer Good, President and CEO of Trevi Therapeutics. "We also recently aligned with the FDA on our non-IPF ILD-related chronic cough program and expect to initiate a Phase 2 dose-ranging trial in the first quarter of 2027. Chronic cough remains a significant unmet need, and we believe our dual central and peripheral mechanism may be important for the treatment of these patients. The associated respiratory hospitalizations and potential higher risk of lung transplant results in higher cost for IPF and ILD patients, where no FDA-approved therapies exist."

Recent Business Highlights
IPF-Related Chronic Cough

- The Company is actively recruiting patients with IPF-related chronic cough in both Phase 3 OCEAN trials. The 12-week fixed-dose OCEAN-2 trial, was initiated in the third quarter of 2026, and topline results are expected in the second half of 2027. The 52-week fixed-dose OCEAN-1 trial was initiated in the second quarter of 2026, and topline results are expected in the first half of 2028.

Non-IPF ILD-Related Chronic Cough

- The Company had a positive meeting with the FDA on the non-IPF ILD-related chronic cough program and gained overall alignment on the development path forward, including on the Phase 2 dose-ranging trial design. The Phase 2 trial will evaluate two doses, 54 mg BID and 27 mg BID, of nalbuphine ER versus placebo, with the primary efficacy endpoint of relative change from Baseline in 24-hour cough frequency (coughs per hour), as determined by an objective cough monitor, to be evaluated at 12 weeks of fixed dosing. The trial is expected to enroll approximately 120 patients. The Company expects to initiate the trial in the first quarter of 2027, subject to review of the trial protocol by the FDA, and topline results are expected in the first half of 2028.
- The Company received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for a patent application with claims covering dosing nalbuphine ER in hepatically impaired patients with non-IPF ILD-related chronic cough. Once issued, the patent is expected to expire in 2041. Based on our projected product labeling, the Company believes this patent will be listable on the Orange Book for the non-IPF ILD-related chronic cough indication.

Refractory Chronic Cough

- The Company initiated the Phase 2b LAKE trial in patients with RCC in the second quarter of 2026 and enrollment is progressing. The trial provides for a sample size re-estimation (SSRE) analysis once 50% of the patients complete treatment. Based on projected enrollment, the Company now expects to report the outcome of the SSRE analysis early in the first quarter of 2027. The Company continues to expect topline results from the full trial in the second half of 2027.

Third Quarter 2026 Financial Highlights
Cash, cash equivalents and marketable securities: The Company ended the third quarter of 2026 with $299.4 million in cash, cash equivalents and marketable securities.

The Company expects its current cash, cash equivalents and marketable securities will provide cash runway into 2030 and fund

the development of Haduvio for the treatment of patients with IPF-related chronic cough, through potential FDA approval. The Company also expects these cash resources will enable the Company to fund the clinical development program through Phase 2 for the treatment of patients with non-IPF ILD-related chronic cough, and the ongoing Phase 2b LAKE trial for the treatment of patients with RCC.

Research and development (R&D) expenses: R&D expenses for the third quarter of 2026 increased to $19.1 million from $10.1 million in the same period in 2025, primarily due to increased clinical development expenses associated with the Phase 3 OCEAN-1 trial, the Phase 2b LAKE trial, and the Phase 3 OCEAN-2 trial as well as increases in stock-based compensation and personnel-related expenses. These increases were partially offset by decreased costs for the Phase 1 NDA supportive studies and the Phase 2b CORAL trial.

General and administrative (G&A) expenses: G&A expenses for the third quarter of 2026 increased to $5.4 million from $3.8 million in the same period in 2025, primarily due to an increase in stock-based compensation and personnel-related expenses.

Other Income, net: Other Income, net for the third quarter of 2026 increased to $3.0 million from $2.1 million in the same period in 2025, primarily due to an increase in interest income from higher invested cash equivalents and marketable securities balances.

Net loss: For the third quarter of 2026, the Company reported a net loss of $21.5 million, compared to a net loss of $11.8 million in the same period in 2025.

Conference Call and Webcast
The Company plans to hold a conference call and webcast to discuss the Company's financial results and business highlights. 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). In clinical trials, Haduvio showed a statistically-significant reduction in cough frequency, consistent across baseline cough frequencies, and showed improvements in patient-reported outcomes, in both patients with IPF-related chronic cough and in patients with RCC. Haduvio is believed to act on the cough reflex arc both centrally and peripherally as a dual acting kappa opioid receptor agonist and a mu opioid receptor antagonist ("KAMA"), hypothesized to reduce cough hypersensitivity by modulating both central neural pathways and peripheral airway nerves. Nalbuphine has been approved and marketed as an injectable for pain indications for decades in the United States ("U.S.") and Europe. Parenteral nalbuphine is not currently scheduled by the U.S. Drug Enforcement Administration and in most of Europe.

Chronic cough in patients with IPF and non-IPF ILD is a condition with high unmet need and no FDA-approved therapies. There are ~140,000 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.

The FDA has conditionally accepted Haduvio as the trade name for 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, Trevi's estimated cash runway, 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, statements regarding FDA guidance and approval, statements regarding Trevi's uses and sufficiency of capital, and other statements containing the words "believes," "anticipates," "plans," "expects," "may," and similar expressions. Risks that contribute to the uncertain nature of the forward-looking statements include: 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; uncertainties regarding the success, cost and timing of Trevi's product candidate development activities and clinical trials, including with respect to the timing of the initiation of

and generation of data from 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; as well as other risks and uncertainties set forth in the annual report on Form 10-K for the year ended December 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)

	September 30, 2026	December 31, 2025
Cash and cash equivalents	$ 27,849	$ 18,914
Marketable securities	271,559	169,346
Working capital	297,928	181,907
Total assets	310,812	193,439
Stockholders' equity	302,756	183,244

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 19,064	$ 10,085	$ 44,157	$ 27,285
General and administrative	5,422	3,831	15,751	11,823
Total operating expenses	24,486	13,916	59,908	39,108
Loss from operations	(24,486)	(13,916)	(59,908)	(39,108)
Other income, net	3,015	2,099	7,408	4,617
Loss before income taxes	(21,471)	(11,817)	(52,500)	(34,491)
Income tax benefit	(19)	(15)	(59)	(48)
Net loss	$ (21,452)	$ (11,802)	$ (52,441)	$ (34,443)
Basic and diluted net loss per common share outstanding	$ (0.13)	$ (0.08)	$ (0.34)	$ (0.26)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	159,727,489	145,104,986	154,025,958	131,122,754

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