UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): May 5, 2026

Trevi Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-38886**	**45-0834299**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

195 Church Street, 16th Floor **New Haven, Connecticut** **(Address of Principal Executive Offices)**	**06510** **(Zip Code)**

Registrant's telephone number, including area code: (203) 304-2499
Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value per share	**TRVI**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On May 5, 2026, Trevi Therapeutics, Inc., a Delaware corporation (the "Company"), announced its financial results for the quarter ended March 31, 2026. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information provided under Item 2.02 of this Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by the Company on May 5, 2026*
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* The exhibit shall be deemed to be furnished, and not filed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TREVI THERAPEUTICS, INC.

Date: May 5, 2026

By: /s/ David C. Hastings
Name: David C. Hastings
Title: Chief Financial Officer

Exhibit 99.1

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

Completed follow-on common stock offering with net proceeds of ~$162 million, extending expected cash runway into 2030 through potential FDA approval of Haduvio in IPF-related chronic cough and continued pipeline advancement

Clinical development plans remain on track across all chronic cough indications

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

New Haven, Conn., May 5, 2026 – 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 March 31, 2026, and provided business updates.

“We are entering an important phase of execution for Trevi, with study initiations anticipated across our chronic cough programs,” said Jennifer Good, President and CEO of Trevi Therapeutics. “Following a very productive End-of-Phase 2 meeting with the FDA on our lead program in IPF-related chronic cough, we are excited to initiate multiple clinical trials this quarter, including our first Phase 3 in IPF-related chronic cough and our Phase 2b in RCC. With an expected cash runway into 2030, we are well-positioned to execute on our development strategy and advance towards a potential FDA submission in IPF-related chronic cough. We believe successful execution of our strategy would establish Trevi as the leader in providing best-in-class therapy in chronic cough indications with significant unmet needs and no FDA-approved therapies.”

Recent Business Highlights

IPF-Related Chronic Cough

- Completed an End-of-Phase 2 meeting with the FDA and gained overall alignment on the clinical development plan for the treatment of IPF-related chronic cough. Execution plans remain on track to conduct two Phase 3 trials in parallel with the first trial expected to initiate in the second quarter of 2026 and the second trial in the second half of 2026. The Company expects to have topline results from the first Phase 3 trial in the first half of 2028 and from the second Phase 3 trial in the second half of 2027.
- The Company received a notice to grant a European patent covering nalbuphine ER for the treatment of IPF-related chronic cough, with expected expiration in 2039, further strengthening its global intellectual property portfolio.

Non-IPF ILD-Related Chronic Cough

- The Company plans to initiate an adaptive design Phase 2b clinical trial for the treatment of patients with non-IPF ILD-related chronic cough in the second half of 2026, subject to a meeting with the FDA which includes review of the trial protocol. If the trial is initiated when anticipated, the Company would expect topline results from the Phase 2b trial in the second half of 2027.

Refractory Chronic Cough

- The Company plans to initiate a Phase 2b trial in patients with RCC in the second quarter of 2026, subject to final protocol review by regulatory authorities. The protocol will provide for a sample size re-estimation, or SSRE, analysis, which is expected to occur in the fourth quarter of 2026. The Company expects topline results from the trial in the second half of 2027.

Corporate

- In April 2026, the Company completed an underwritten common stock offering, resulting in net proceeds of approximately $162 million, after deducting underwriting discounts and commissions and estimated offering expenses.
- 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 its clinical and commercial strategy, with participation from key opinion leaders. To register for the webcast, please visit Trevi's website or register here.
- The Company plans to host an investor and analyst event in-person on May 18, 2026, from 11:30 a.m. to 1:15 p.m., during the American Thoracic Society (ATS) 2026 International Conference to present data highlights from Trevi's 2026 ATS presentations. To register for the event, email IR@trevitx.com.

First Quarter 2026 Financial Highlights

Cash, cash equivalents and marketable securities: The Company ended the first quarter of 2026 with $171.8 million. After completion of its underwritten common stock offering in April 2026, the Company expects current cash resources to extend its cash runway into 2030.

The Company expects its current cash, cash equivalents and marketable securities to fund the development of Haduvio for the treatment of patients with IPF-related chronic cough, potentially through FDA approval. The Company also expects these cash resources will enable the Company to fund and report topline data from the planned Phase 2b clinical trial and potentially a subsequent Phase 3 trial for the treatment of patients with non-IPF ILD-related chronic cough, and the planned Phase 2b trial for the treatment of patients with RCC. The planned spending of these resources does not include any commercial expenses related to the commercial launch of Haduvio or any other clinical trials.

Research and development (R&D) expenses: R&D expenses for the first quarter of 2026 increased to $9.9 million from $7.8 million in the same period in 2025, primarily due to increased clinical development expenses for the Company's Phase 1 NDA supportive studies, Phase 3 IPF-related chronic cough trials and Phase 2b RCC trial, partially offset by a decrease in clinical development expenses for the Company's Phase 2b CORAL trial and Phase 2a RIVER trial.

General and administrative (G&A) expenses: G&A expenses for the first quarter of 2026 increased to $5.0 million from $3.7 million in the same period in 2025, primarily due to higher legal fees associated with intellectual property filings as well as an increase in non-cash stock option expense and other personnel-related expenses.

Other Income, net: Other Income, net for the first quarter of 2026 increased to $1.7 million from $1.1 million in the same period in 2025, primarily due to an increase in interest income from higher invested cash equivalent and marketable securities balances.

Net loss: For the first quarter of 2026, the Company reported a net loss of $13.2 million, compared to a net loss of $10.3 million in the same period in 2025.

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.

Upcoming Meetings
The Company plans to participate in the following events:

- May 7: Trevi Therapeutics Investor and Analyst Day
- May 12-13: Bank of America Global Healthcare Conference 2026
- May 15-20: American Thoracic Society (ATS) 2026 International Conference
- May 18: Trevi Therapeutics - Data Highlights from Trevi's ATS 2026 Presentations

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-related 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 ~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.

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, 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, as well as regulatory submissions, statements regarding FDA guidance and approval, and expectations 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; 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)

	March 31, 2026	December 31, 2025
Cash and cash equivalents	$ 19,412	$ 18,914
Marketable securities	152,371	169,346
Working capital	169,006	181,907
Total assets	179,606	193,439
Stockholders' equity	172,127	183,244

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

	Three Months Ended March 31,	
	2026	2025
Operating expenses:		
Research and development	$ 9,941	$ 7,811
General and administrative	4,971	3,659
Total operating expenses	14,912	11,470
Loss from operations	(14,912)	(11,470)
Other income, net	1,700	1,119
Loss before income taxes	(13,212)	(10,351)
Income tax benefit	(20)	(11)
Net loss	$ (13,192)	$ (10,340)
Basic and diluted net loss per common share outstanding	$ (0.09)	$ (0.09)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	145,592,901	117,610,750

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