Trevi Therapeutics Reports First Quarter 2024 Financial Results and Provides Business Updates

Reaffirms guidance for the Phase 2a RIVER trial in refractory chronic cough and Human Abuse Potential (HAP) Study with topline data for each expected in the second half of 2024

Topline results continue to be expected in the first half of 2025 for the Phase 2b CORAL trial in chronic cough in IPF

IND cleared with the FDA for planned Phase 1b trial to evaluate respiratory physiology in IPF patients with varying disease severity

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

NEW HAVEN, Conn., May 7, 2024 /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 idiopathic pulmonary fibrosis (IPF) and refractory chronic cough (RCC), today announced financial results for the quarter ended March 31, 2024, as well as provided business updates.

Trevi reaffirms guidance for clinical development milestones, progressing Haduvio in chronic cough indications

"I am pleased with the progress across all our clinical trials, which continue to remain on track with our guidance," said Jennifer Good, President and CEO of Trevi Therapeutics. "During the quarter, we continued site activations and recruitment across our clinical trials and, with the clearance of our IND, we are moving towards initiating our planned respiratory physiology trial. We look forward to reporting data from our ongoing trials beginning in the second half of this year. The chronic cough markets in both IPF and refractory chronic cough are significant and currently have no approved therapies in the U.S. We believe our differentiated central and peripheral mechanism of action has the potential to offer an important therapy for these patients."

Key Business Updates

- Phase 2a RIVER trial for the treatment of RCC, in which we expect to enroll approximately 60 patients, now has all sites activated and enrollment is progressing. In line with our current guidance, we expect topline data in the second half of 2024.
- Phase 2b CORAL trial for the treatment of chronic cough in IPF, in which we expect to enroll approximately 160 patients, continues enrollment, and we expect the sample size re-estimation to occur in the second half of 2024 when 50% of the patients are evaluable for the primary endpoint. Assuming no adjustments are made to the sample size, topline results are expected in the first half of 2025.
- Other supportive studies:
  - The second part of the human abuse potential (HAP) study, in which we expect to enroll approximately 56 patients, is 75% enrolled and we continue to expect topline data in the second half of 2024.
  - With the clearance of our IND, we expect to initiate our planned Phase 1b respiratory physiology study in the United States in the third quarter of 2024. This trial is designed to assist us in defining the IPF population for a pivotal program.
- The Company ended the first quarter of 2024 with $72.8 million in cash, cash equivalents and marketable securities with expected cash runway into 2026.

First Quarter 2024 Financial Highlights

Research and development (R&D) expenses: R&D expenses for the first quarter of 2024 increased to $8.8 million from $5.0 million in the same period in 2023, primarily due to increased clinical development expenses for our Phase 2b CORAL trial, our Phase 2a RIVER trial and our HAP trial. These increases were partially offset by decreased clinical development expenses for our Phase 2b/3 PRISM.

General and administrative (G&A) expenses: G&A expenses were $3.1 million in the first quarter of 2024 compared to $2.6 million in the same period in 2023, primarily due to increases in information technology and finance staffing and activities as well as professional fees.

Other income, net: Other income, net was $1.0 million in the first quarter of 2024 compared to $1.2 million in the same period in 2023.

Net loss: For the first quarter of 2024, the Company reported a net loss of $10.9 million, compared to a net loss of $6.4 million in the same period in 2023.

Conference Call/Webcast
To participate in today's live conference call by phone, please dial (888) 317 6003 (domestic) or (412) 317 6061 (international). 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:

- May 13-14: The Citizens JMP Life Sciences Conference
- May 17-22: ATS 2024 International Conference
- May 20: Life Science Education Series: Chronic Cough – KOL Panel Discussion
- June 3-6: 2024 BIO International Convention
- June 26-28: Oppenheimer's 2024 Montauk Life Sciences Summit

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine ER) for the treatment of chronic cough in idiopathic pulmonary fibrosis (IPF) and refractory chronic cough (RCC). Trevi is also developing Haduvio for prurigo nodularis. Haduvio is a dual κ-opioid receptor agonist and μ-opioid receptor antagonist that works both centrally in the brain as well as peripherally in the lungs and has the potential for a synergistic antitussive effect to treat chronic cough.

The impact of chronic cough is significant and often leads to a decline in patients' social, physical, and psychological quality of life. In IPF, chronic cough may lead to worsening disease and may be associated with a higher risk of progression, death, or need for lung transplant. There are no approved therapies for the treatment of chronic cough in IPF and current treatment options provide minimal relief to patients. RCC affects up to 10% of the adult population, and Haduvio's expansion into RCC has the potential to reach patients suffering from moderate to severe chronic cough. There are also no approved therapies for RCC in the US.

Parenteral nalbuphine is not scheduled by the U.S. Drug Enforcement Agency. 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, 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 ongoing and planned 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 annual report on Form 10-K for the fiscal year ended December 31, 2023 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, 2024	December 31, 2023
Cash and cash equivalents	$ 13,811	$ 32,397
Marketable securities	59,009	50,574
Working capital	71,490	81,723
Total assets	78,559	89,403
Stockholders' equity	72,334	82,547

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

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 8,804	$ 5,000
General and administrative	3,102	2,563
Total operating expenses	11,906	7,563
Loss from operations	(11,906)	(7,563)
Other income, net	996	1,155
Loss before income taxes	(10,910)	(6,408)
Income tax benefit	8	7
Net loss	$ (10,902)	$ (6,401)
Basic and diluted net loss per common share outstanding	$ (0.11)	$ (0.06)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	99,517,212	98,610,671

Investor Contact
Katie McManus
Trevi Therapeutics, Inc.
203-304-2499
k.mcmanus@trevitherapeutics.com

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

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