Trevi Therapeutics Announces First Quarter 2023 Financial Results and Provides Business Update

Initiating three clinical studies in chronic cough indications later this year

Received Notice of Allowance for key U.S. patent for the use of oral nalbuphine ER for the treatment of chronic cough in idiopathic pulmonary fibrosis

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

NEW HAVEN, Conn., May 11, 2023 /PRNewswire/ -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine ER) for difficult to treat patients with chronic cough in idiopathic pulmonary fibrosis (IPF), other chronic cough indications and prurigo nodularis (PN), today announced financial results for the quarter ended March 31, 2023, as well as provided business updates.

"We have been focused on progressing our clinical development plans as we work to initiate clinical trials in both chronic cough in IPF and in refractory chronic cough as well as advance our human abuse potential study," said Jennifer Good, President and CEO of Trevi Therapeutics. "Our efforts remain on track with the completion of the open-label extension trial for PN and part 1 of the human abuse potential study in the first quarter, as well as advancing key activities to initiate the trials in each of the chronic cough indications in the second half of this year."

Key Business Updates

- Chronic cough trials:
  - Phase 2b dose ranging trial for the treatment of chronic cough in IPF is expected to initiate in the second half of 2023.
  - Phase 1b trial to evaluate the effect on respiratory physiology in IPF patients is expected to initiate in the second half of 2023.
  - Phase 2a trial in refractory chronic cough is expected to initiate in the third quarter of 2023.
- Completed part 1 of the human abuse potential study characterizing butorphanol and selected a butorphanol dose for part 2.
- Received Notice of Allowance for U.S. patent application covering the use of nalbuphine ER for the treatment of chronic cough in IPF. Trevi expects the resulting patent will be eligible for listing in the Orange Book with an anticipated expiration in 2039.
- Completed the open-label extension portion of the Phase 2b/3 PRISM trial for the treatment of prurigo nodularis during the first quarter of 2023. Data from the extension study is being analyzed and the Company will request an End of Phase 2 meeting with the FDA to discuss the program.
- The Company ended the first quarter of 2023 with $111.3 million in cash, cash equivalents and marketable securities.

First Quarter 2023 Financial Highlights

Research and development (R&D) expenses: R&D expenses for the first quarter of 2023 increased to $5.0 million from $4.6 million in the same period in 2022. The increase was primarily due to increased consulting and professional fees related to startup activities for the three planned chronic cough trials. This increase was partially offset by a decrease in clinical development expenses reflecting the completion prior to the first quarter of 2023 of both the blinded portion of the Phase 2b/3 PRISM trial and the Phase 2 CANAL trial for the treatment of chronic cough in IPF.

General and administrative (G&A) expenses: G&A expenses were $2.6 million in the first quarter of 2023 compared to $2.4 million in the same period in 2022. The increase was primarily due to an increase in personnel-related expenses and higher tax professional fees.

Other income (expense), net: Other income, net was $1.2 million in the first quarter of 2023 compared to other expense, net of $0.3 million in the same period in 2022. The change was primarily due to an increase in interest income.

Net loss: For the first quarter of 2023, the Company reported a net loss of $6.4 million, compared to a net loss of $7.3 million in the same period in 2022.

Conference Call/Webcast
To participate in today's live conference call by phone, please dial (888) 317 6003 (domestic) or (412) 317 6061 (international) and provide access code 0161285. 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 upcoming conferences and events:

- May 19-20: American Thoracic Society's (ATS) 2023 Respiratory Innovation Summit
- May 19-24: ATS 2023 International Conference
- May 31-June 1: Yale Innovation Summit 2023
- June 5-8: 2023: BIO International Convention
- June 9-10: 2023: American Cough Conference

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine ER) for difficult to treat patients with chronic cough in IPF, other chronic cough indications, and PN. Haduvio is a dual κ-opioid receptor agonist and μ-opioid receptor antagonist that works both centrally as well as peripherally in the lungs and has the potential for a synergistic anti-tussive 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. There are no approved therapies for the treatment of chronic cough in IPF and current treatment options provide minimal relief to patients. In IPF, chronic cough may lead to worsening fibrosis and may be associated with a higher risk of progression, death, or need for lung transplant.

Parenteral nalbuphine is not scheduled by the US Drug and Enforcement Agency. Trevi intends to propose 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 the Company on 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 future 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 future 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, including Trevi's ability to submit and get clearance of an IND and other regulatory filings on a timely basis; 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 scope, timing and severity of the COVID-19 pandemic, the impact of the COVID-19 pandemic on Trevi's clinical operations and actions taken in response to the pandemic; as well as other risks and uncertainties set forth in the quarterly report on Form 10-Q for the quarter ended March 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, 2023	December 31, 2022
Cash and cash equivalents	$ 11,651	$ 12,589
Marketable securities	99,607	107,921
Working capital	101,000	109,216
Total assets	116,205	123,015
Total debt	7,482	9,151
Stockholders' equity	101,732	107,459

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

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	$ 5,000	$ 4,645
General and administrative	2,563	2,380
Total operating expenses	7,563	7,025
Loss from operations	(7,563)	(7,025)
Other income (expense), net	1,155	(309)
Loss before income taxes	(6,408)	(7,334)
Income tax benefit	7	5
Net loss	$ (6,401)	$ (7,329)
Basic and diluted net loss per common share outstanding	$ (0.06)	$ (0.24)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	98,610,671	30,805,804

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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