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

Plans to initiate three clinical studies in chronic cough indications for later this year remain on track

Data from Phase 2 CANAL trial of chronic cough in patients with idiopathic pulmonary fibrosis published in NEJM Evidence

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

NEW HAVEN, Conn., Aug. 10, 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, today announced financial results for the quarter ended June 30, 2023, as well as provided business updates.

Plans to initiate three clinical studies in chronic cough indications for later this year remain on track

"Our development plans remain on track in our chronic cough programs and we expect to initiate clinical trials in both chronic cough in IPF and refractory chronic cough in the second half of this year," said Jennifer Good, President and CEO of Trevi Therapeutics. "We are currently in the regulatory submission phase in various countries to support trial initiations. We were encouraged by the high degree of scientific and clinical interest at the medical meetings held this quarter surrounding our data generated in chronic cough in IPF and the potential of Haduvio's mechanism of action to broadly treat chronic cough."

Key Business Updates

- Preparation for the initiation of three chronic cough trials (Phase 2b dose ranging trial for treatment of chronic cough in patients with IPF, Phase 1b trial to evaluate respiratory physiology in patients with IPF, and Phase 2a trial in refractory chronic cough (RCC)) continues to advance as we work through the regulatory submission process in multiple countries. All trials are expected to be initiated in the second half of this year.
- Announced publication of positive data from the Phase 2 CANAL trial of Haduvio for the treatment of chronic cough in IPF in NEJM Evidence.
- Working on securing supply of the comparator drug IV butorphanol to complete the final part of the Human Abuse Potential study. There was an identified shortage of IV butorphanol due to a single supplier and recent tornado damage to their manufacturing plant. This will delay our anticipated year-end results.
- Repaid the outstanding indebtedness under our term loan with a payment of $6.5 million on May 9, 2023. The Company ended the second quarter of 2023 with $94.2 million in cash, cash equivalents and marketable securities.

Second Quarter 2023 Financial Highlights

Research and development (R&D) expenses: R&D expenses for the second quarter of 2023 increased to $5.8 million from $5.1 million in the same period in 2022. The increase was primarily due to higher consulting and professional fees related to startup activities for the Company's three planned chronic cough trials as well as an increase in personnel-related expenses.

General and administrative (G&A) expenses: G&A expenses were $2.5 million in the second quarter of 2023 compared to $2.7 million in the same period in 2022. The decrease was primarily due to a reduction in market research costs.

Other income (expense), net: Other income, net was $1.2 million in the second quarter of 2023 compared to other expense, net of $0.2 million in the same period in 2022. The change was primarily due to an increase in interest income.

Net loss: For the second quarter of 2023, the Company reported a net loss of $7.1 million, compared to a net loss of $8.1 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 6064699. 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:

- Aug 14-16: Stifel Biotech Executive Summit – Newport, RI
- Sep 9-13: ERS International Congress 2023 – Milan, Italy
- Sep 19-21: Cantor Fitzgerald Global Healthcare Conference 2023 – New York, NY
- Sep 20-22: 2023 SVB Securities Biopharma Summit – Montecito, CA

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 idiopathic pulmonary fibrosis (IPF), other chronic cough indications, and prurigo nodularis. 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 disease 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 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 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 as well as other risks and uncertainties set forth in the quarterly report on Form 10-Q for the quarter ended June 30, 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)

	June 30, 2023	December 31, 2022
Cash and cash equivalents	$ 13,752	$ 12,589
Marketable securities	80,400	107,921
Working capital	94,502	109,216

Total assets	100,977	123,015
Total debt	—	9,151
Stockholders' equity	95,073	107,459

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,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 5,842	$ 5,103	$ 10,842	$ 9,748
General and administrative	2,540	2,717	5,103	5,097
Total operating expenses	8,382	7,820	15,945	14,845
Loss from operations	(8,382)	(7,820)	(15,945)	(14,845)
Other income (expense), net	1,207	(236)	2,362	(545)
Loss before income taxes	(7,175)	(8,056)	(13,583)	(15,390)
Income tax benefit	30	4	37	9
Net loss	$ (7,145)	$ (8,052)	$ (13,546)	$ (15,381)
Basic and diluted net loss per common share outstanding	$ (0.07)	$ (0.14)	$ (0.14)	$ (0.34)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	98,698,579	59,542,628	98,654,868	45,253,599

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