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

Initiated Phase 2a RIVER trial of Haduvio in refractory chronic cough (RCC) patients and expect topline data in the second half of 2024

Expect to initiate Phase 2b dose-ranging trial of Haduvio for the treatment of chronic cough in idiopathic pulmonary fibrosis (IPF) patients in the fourth quarter of 2023

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

NEW HAVEN, Conn., Nov. 9, 2023 /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), refractory chronic cough (RCC), and prurigo nodularis, today announced financial results for the quarter ended September 30, 2023, as well as provided business updates.

Haduvio is well-positioned in IPF chronic cough and RCC based on its ability to target cough centrally and peripherally

"We are thrilled to have initiated our Phase 2a RIVER trial of Haduvio in patients with refractory chronic cough, which builds on the strength of the clinical data seen with Haduvio in IPF chronic cough," said Jennifer Good, President and CEO of Trevi Therapeutics. "Refractory chronic cough impacts up to 10% of the adult population globally. We believe Haduvio is well-positioned in IPF chronic cough, as well as in RCC, based on its ability to target cough centrally and peripherally which potentially supports the ability to work across a wide range of cough conditions."

Key Business Updates

- Initiated the Phase 2a RIVER trial in patients with refractory chronic cough and expect topline data in the second half of 2024. The RIVER trial is a double-blind, randomized, placebo-controlled, 2-period crossover study evaluating the safety and efficacy of Haduvio in reducing chronic cough in RCC subjects. Approximately 60 RCC subjects are expected to be randomized with a 1:1 stratification between those with 10-19 coughs/hour (moderate 24-hour cough frequency) and those with ≥ 20 coughs/hour (high 24-hour cough frequency).
- Expect to initiate the Phase 2b dose-ranging trial of Haduvio for the treatment of chronic cough in IPF in the fourth quarter of 2023 and the Phase 1b trial to evaluate the effect of Haduvio on respiratory physiology in patients with IPF in the first quarter of 2024.
- Secured IV butorphanol supply for the human abuse potential study and expect to initiate dosing in the first quarter of 2024, with topline data expected in the second half of 2024.
- Announced preliminary results from the open-label extension portion of the Phase 2b/3 PRISM trial in prurigo nodularis in which 151 subjects completed the open label extension portion of the trial. The safety data over 52 weeks of treatment demonstrated that Haduvio was well-tolerated and consistent with the 14-week blinded safety data. In addition, there was a continued reduction in Worst Itch Numerical Rating Scale, or WI-NRS, scores observed among participants who remained in the study through 52 weeks of treatment.
- Ended the third quarter of 2023 with $88.9 million in cash, cash equivalents and marketable securities.

Third Quarter 2023 Financial Highlights

Research and development (R&D) expenses: R&D expenses for the third quarter of 2023 increased to $6.3 million from $5.8 million in the same period in 2022. The increase was primarily due to higher startup costs and consultant services associated with our chronic cough programs as well as an increase in personnel-related expenses. These increases were partially offset by a decline in clinical development expenses related to our completed Phase 2b/3 PRISM trial and our Phase 2 CANAL trial as well as decreased purchases of clinical trial supplies, among other factors.

General and administrative (G&A) expenses: G&A expenses were $2.7 million in the third quarter of 2023 compared to $2.6 million in the same period in 2022.

Other income, net: Other income, net was $1.3 million in the third quarter of 2023 compared to other income,

net of $0.1 million in the same period in 2022. The change was primarily due to an increase in interest income and reduced interest expense due to the payoff of the SVB Term Loan in May 2023.

Net loss: For the third quarter of 2023, the Company reported a net loss of $7.7 million, compared to a net loss of $8.3 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 5615817. 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 conference:

- Nov 14-15: Stifel 2023 Healthcare Conference – New York, NY

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine ER) for patients with chronic cough in idiopathic pulmonary fibrosis (IPF), refractory chronic cough (RCC), and 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 or Europe.

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 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, 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 September 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)

	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 25,965	$ 12,589
Marketable securities	62,903	107,921
Working capital	88,780	109,216
Total assets	95,896	123,015
Total debt	—	9,151
Stockholders' equity	89,610	107,459

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,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 6,323	$ 5,769	$ 17,165	$ 15,517
General and administrative	2,722	2,636	7,825	7,733
Total operating expenses	9,045	8,405	24,990	23,250
Loss from operations	(9,045)	(8,405)	(24,990)	(23,250)
Other income (expense), net	1,334	132	3,696	(413)
Loss before income taxes	(7,711)	(8,273)	(21,294)	(23,663)
Income tax benefit	13	7	50	16
Net loss	$ (7,698)	$ (8,266)	$ (21,244)	$ (23,647)
Basic and diluted net loss per common share outstanding	$ (0.08)	$ (0.12)	$ (0.21)	$ (0.44)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	99,325,540	68,898,810	98,880,882	53,221,949

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