Trevi Therapeutics Announces Fourth Quarter and Year End 2022 Financial Results and Provides Business Update

March 16, 2023

Multiple trial initiations planned for 2023 to progress Haduvio in chronic cough indications

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

NEW HAVEN, Conn., March 16, 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 adults with idiopathic pulmonary fibrosis (IPF) and other chronic cough indications, and for the treatment of prurigo nodularis, today announced financial results for the quarter and year ended December 31, 2022, as well as provided business updates.

Trevi has multiple trial initiations planned for 2023 to progress Haduvio in chronic cough indications

"Following the very encouraging results from our Phase 2 CANAL trial in IPF chronic cough, we have entered a transformational period in the development of Haduvio for the treatment of serious chronic cough conditions," said Jennifer Good, President and CEO of Trevi Therapeutics. "With a strong balance sheet and cash runway expected into 2026, we are well-positioned to develop Haduvio as a pipeline in a product, supported by the differentiated central and peripheral mechanism of action of Haduvio."

2022 Fourth Quarter and Year End Business Highlights

- Presented final data from the Phase 2 CANAL Trial of Haduvio for the treatment of chronic cough in IPF at the British Thoracic Society's Winter Meeting.
- Appointed David Clark, MD, MRCP, as Chief Medical Officer.
- Initiated the Human Abuse Liability study for Haduvio.
- Ended 2022 with cash, cash equivalents, and marketable securities of $120.5 million.

Key Business Updates

IPF Chronic Cough Clinical Trials
The Company is planning to conduct a Phase 2b dose ranging trial of Haduvio for the treatment of chronic cough in IPF patients. The objective of the trial is to determine the dose response of Haduvio in this IPF patient population. The Company expects to initiate this dose ranging study in the second half of 2023.

The Company is also planning a Phase 1b study to evaluate the effect of Haduvio on respiratory physiology in IPF patients of varying disease severity. The Company is in discussions with the U.S. Food and Drug Administration (FDA) regarding the design of this trial and expects to start this trial in the second half of 2023.

Phase 2a Trial in Refractory Chronic Cough
The Company is preparing to conduct a Phase 2a study in refractory chronic cough which is expected to be initiated in the third quarter of 2023. The objective of this trial is to establish the potential of Haduvio across a broader range of chronic cough conditions and to further validate the importance of Haduvio's central and peripheral mechanism of action in a variety of chronic cough patient populations.

Phase 2b/3 PRISM Trial in Prurigo Nodularis
Dosing was completed in the open-label extension portion of our Phase 2b/3 PRISM trial for the treatment of prurigo nodularis in the first quarter of 2023 and full data are expected in the second quarter of 2023. Once data is received, the Company intends to request an end of phase 2 meeting with the FDA. The Company also plans to present the data from the open-label extension at a future medical meeting.

Human Abuse Liability Study
The Company initiated a human abuse liability study in the fourth quarter of 2022 to compare the abuse potential of oral nalbuphine to butorphanol. The injectable version of nalbuphine is currently unscheduled in the U.S. by the Drug Enforcement Agency (DEA). The study is a randomized, double-blind, active and placebo-controlled 5-way crossover design. The study is conducted in two parts, with the first part characterizing various butorphanol doses. One butorphanol dose will be selected to be studied in the second part of the protocol to determine the abuse potential of oral nalbuphine relative to butorphanol. The Company is currently completing Part 1 of the study and expects top-line data from the complete trial by the end of 2023.

Fourth Quarter 2022 Financial Highlights

Research and development (R&D) expenses: R&D expenses for the fourth quarter of 2022 decreased to $4.3 million from $6.2 million in the same period in 2021. The decrease was primarily due to decreased clinical trial costs reflecting the completion prior

to the fourth quarter of 2022 of both the blinded portion of the Phase 2b/3 PRISM trial and the Phase 2 CANAL trial, partially offset by an increase in trial costs related to the human abuse liability study.

General and administrative (G&A) expenses: G&A expenses were $2.3 million in the fourth quarter of 2022 compared to $2.1 million in the same period in 2021. The increase was primarily due to higher legal fees associated with intellectual property filings and other professional fees.

Other income (expense), net: Other income, net was $1.1 million in the fourth quarter of 2022 compared to other expense, net of $0.3 million in the same period in 2021. The change was primarily due to an increase in interest income.

Net loss: For the fourth quarter of 2022, the Company reported a net loss of $5.5 million, compared to a net loss of $8.5 million in the same period in 2021.

Full-Year 2022 Financial Highlights

R&D expenses: R&D expenses for the year ended December 31, 2022, were $19.8 million compared to $23.0 for the year ended December 31, 2021. The decrease was primarily due to decreased trial costs reflecting the completion of the blinded portion of the Phase 2b/3 PRISM trial and the Phase 2 CANAL trial in 2022, which were partially offset by an increase in startup activities for our planned trials including purchases of clinical trial supplies and increased consulting expenses and professional fees.

G&A expenses: G&A expenses for the year ended December 31, 2022, were $10.1 million compared to $9.5 million for the year ended December 31, 2021. The increase was primarily due to increased market research costs and professional fees.

Other income (expense), net: Other income, net for the year ended December 31, 2022, was $0.7 million compared to other expense, net of $1.5 million for the year ended December 31, 2021. The change was primarily due to an increase in interest income due to higher cash equivalent and marketable securities balances invested at higher interest rate yields and a decrease in expense related to the value of shares of common stock issued as a commitment fee under an equity credit facility which did not recur in 2022.

Net loss: For the year ended December 31, 2022, the Company reported a net loss of $29.2 million, compared to a net loss of $33.9 million for the year ended December 31, 2021.

Conference Call/Webcast
To participate in the live conference call by phone, please dial (888) 317 6003 (domestic) or (412) 317 6061 (international) and provide access code 1366506. 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:

- March 20-22: BIO-Europe Spring
- April 17-20: 22nd Annual Needham Virtual Healthcare Conference

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing Haduvio, an investigational therapy in an oral extended-release formulation of nalbuphine, for the treatment of chronic cough in IPF and other chronic cough indications. Haduvio is a mixed κ-opioid receptor agonist and μ-opioid receptor antagonist that works both centrally and peripherally. The κ and μ receptors are known critical mediators of cough. Parenteral nalbuphine has been approved and marketed for over 20 years for the treatment of acute pain indications and is not scheduled by the DEA in the United States or by regulatory authorities in most of Europe. 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 Trevi's Haduvio in the United States and foreign countries, including the Company's ability to submit and get clearance on an IND 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 September 30, 2022 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)

	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 12,589	$ 36,830
Marketable securities	107,921	—
Working capital	109,216	25,233
Total assets	123,015	38,475
Total debt	9,151	14,485
Stockholders' equity	107,459	17,075

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 4,317	$ 6,178	$ 19,834	$ 22,984
General and administrative	2,339	2,094	10,073	9,492
Total operating expenses	6,656	8,272	29,907	32,476
Loss from operations	(6,656)	(8,272)	(29,907)	(32,476)
Other income (expense), net	1,132	(254)	719	(1,485)
Loss before income taxes	(5,524)	(8,526)	(29,188)	(33,961)
Income tax benefit	20	5	36	21
Net loss	$ (5,504)	$ (8,521)	$ (29,152)	$ (33,940)
Basic and diluted net loss per common share outstanding	$ (0.06)	$ (0.28)	$ (0.45)	$ (1.49)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	98,132,668	30,113,457	64,541,911	22,841,481

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