Trevi Therapeutics Announces First Quarter 2022 Financial Results and Business Update

Accelerated planning for next phase of development of Haduvio for the treatment of chronic cough in IPF based on results from statistically significant interim analysis of Phase 2 CANAL Trial

Completed enrollment for Phase 2b/3 PRISM study in chronic pruritus in PN with data expected Q2 2022

Completed $55 million private placement in April 2022, proceeds will be used to fund clinical development of Haduvio for the treatment of chronic cough in IPF patients

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

NEW HAVEN, Conn., May 12, 2022 /PRNewswire/ -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company developing an investigational therapy Haduvio™ (nalbuphine ER) for pruritus in prurigo nodularis (PN) and chronic cough in idiopathic pulmonary fibrosis (IPF), today announced financial results for the quarter ended March 31, 2022, as well as provided business updates.

Trevi's topline data expected for Ph2b/3 PRISM study this quarter and full results for Ph2 CANAL study in Q3

"We are delighted with the significant progress made this year in achieving Trevi's clinical development goals and the advancement of Haduvio," said Jennifer Good, President and CEO of Trevi Therapeutics. "The interim analysis results of the Phase 2 CANAL study allowed us to end enrollment early in the trial and begin preparations to accelerate development for this indication."

Ms. Good added, "Additionally, the successful closing of a $55 million private placement on April 11, 2022, allows us to fund the next phase of development for Haduvio in chronic cough in IPF. We look forward to our expected data readout for the Phase 2b/3 PRISM study this quarter and the data readout from the full set of subjects for the Phase 2 CANAL study in the third quarter of this year."

Key Business Updates

- **Phase 2 CANAL trial of Haduvio for chronic cough in patients with IPF**
  - Concluded enrollment early for its Phase 2 Cough And NALbuphine (CANAL) trial for the treatment of chronic cough in IPF patients
  - Statistically significant efficacy results from the interim analysis (N=26) were announced:
    - The primary efficacy endpoint demonstrated a 77.3% reduction in daytime cough frequency from baseline with the use of Haduvio compared to a 25.7% reduction with placebo, demonstrating a 52% placebo-adjusted reduction in the geometric mean percent change in the daytime cough frequency ($p<0.0001$)
  - Expect to report efficacy and safety data on the full set of subjects in the third quarter of 2022
- **Phase 2b/3 PRISM trial of Haduvio for severe pruritus in patients with PN**
  - Completed enrollment in Phase 2b/3 PRISM trial in January 2022
  - Expect to report top-line data in the second quarter of 2022
- **$55 million private placement completed in April**
  - Proceeds will fund ongoing clinical development of Haduvio as well as for working capital and other general corporate purposes

First Quarter 2022 Financial Highlights

Cash position: As of March 31, 2022, the Company had total cash and cash equivalents of $29.1 million. The Company's gross proceeds from the April 2022 private placement were $55.0 million.

Research and development (R&D) expenses: R&D expenses for the first quarter of 2022 were $4.6 million compared to $5.6 million in the same period in 2021. The decrease was primarily due to decreased clinical trial subject recruitment costs. Our consulting expenses and professional fees declined as well due to a reduction in consulting work and the non-recurrence of professional recruiting fees related to hirings in the prior year period.

General and administrative (G&A) expenses: G&A expenses for the first quarter of 2022 were $2.4 million compared to $2.5 million in the same period in 2021. The decrease was primarily due to lower legal fees as a result of the timing of certain intellectual property filings.

Net loss: For the first quarter of 2022, the Company reported a net loss of $7.3 million, compared to a net loss of $8.4 million in the same period in 2021.

Conference Call
To participate in the live conference call by phone, please dial (888) 317 6003 (domestic) or (412) 317 6061 (international) and provide access code 5008663. 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 present at the following upcoming conferences and events:

- May 23-26: H.C. Wainwright Global Investment Conference
- June 13-16: BIO International Convention

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of the investigational therapy Haduvio to treat serious neurologically mediated conditions. Trevi is conducting a Phase 2b/3 clinical trial of Haduvio for the treatment of chronic pruritus associated with prurigo nodularis (PN) and a Phase 2 trial for chronic cough in adults with idiopathic pulmonary fibrosis (IPF). These conditions share a common pathophysiology that is mediated through opioid receptors in the central and peripheral nervous systems.

Founded in 2011, Trevi Therapeutics is headquartered in New Haven, CT.

About Haduvio
Haduvio, an investigational therapy, is an oral extended-release (ER) formulation of nalbuphine. Nalbuphine is a mixed κ-opioid receptor agonist and μ-opioid receptor antagonist that has been approved and marketed as an injectable for pain indications for more than 20 years in the United States and Europe. The κ- and μ-opioid receptors are known to be critical mediators of itch, cough and certain movement disorders. Nalbuphine's mechanism of action may also mitigate the risk of abuse associated with μ-opioid agonists because it antagonizes, or blocks, μ-opioid receptors. Parenteral nalbuphine is not currently scheduled as a controlled substance 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. Nalbuphine ER has been granted Fast Track designation by the FDA for the proposed indication of reduction of moderate to severe pruritus in adults with prurigo nodularis. Its safety and efficacy have not been evaluated by any regulatory authority.

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 the expected timing of reporting top-line data from Trevi's Phase 2b/3 PRISM trial of Haduvio in subjects with PN and the expected timing of reporting top-line data from the full set of subjects' data from Trevi's Phase 2 CANAL trial of Haduvio in IPF subjects with chronic cough; Trevi's business plans and objectives, including future plans or expectations for Trevi's product candidates; 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, including with respect to the timing of reporting top-line data from both Trevi's Phase 2b/3 PRISM trial and Phase 2 CANAL trial; uncertainties regarding Trevi's ability to execute on its strategy; the risk that positive interim or top-line results from a clinical trial may not necessarily be predictive of the results of the completed trial or other future or ongoing clinical trials; potential regulatory developments in the United States and foreign countries; uncertainties regarding fast track designation and the effect such status could have on the regulatory review or approval process; uncertainties inherent in estimating Trevi's cash runway, future expenses and other financial results, including Trevi's ability to continue as a going concern, comply with its obligations under its loan facility and fund future operations; 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, 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)

	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 29,113	$ 36,830
Working capital	16,972	25,233
Total assets	30,386	38,475
Total debt	14,056	14,485
Stockholders' equity	10,463	17,075

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

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	$ 4,645	$ 5,589
General and administrative	2,380	2,500
Total operating expenses	7,025	8,089
Loss from operations	(7,025)	(8,089)
Other expense, net	(309)	(297)
Loss before income taxes	(7,334)	(8,386)
Income tax benefit	5	15
Net loss	$ (7,329)	$ (8,371)
Basic and diluted net loss per common share outstanding	$ (0.24)	$ (0.43)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	30,805,804	19,417,038

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