Trevi Therapeutics Announces Fourth Quarter and Year End 2021 Financial Results and Business Update

March 17, 2022

Interim Analysis in Phase 2 CANAL Trial Showed Primary Efficacy Endpoint of Cough Reduction in Idiopathic Pulmonary Fibrosis was Highly Statistically Significant (p-value less than 0.0001)
Enrollment Ended Early

Trevi to host a KOL call "Understanding the Seriousness of Chronic Cough in IPF Patients" on March 30, 2022, from 8:00 to 9:00 am EDT

Phase 2b/3 PRISM Trial (Chronic Pruritus in PN) Completed Enrollment
Top-Line Data Readout Expected Second Quarter of 2022

Management to Host Conference Call and Webcast Today at 4:30 p.m. EDT

NEW HAVEN, Conn., March 17, 2022 /PRNewswire/ -- Trevi Therapeutics, Inc. (Nasdaq: TRVI) is a clinical-stage biopharmaceutical company developing an investigational therapy Haduvio™ (nalbuphine ER). Today, Trevi announced financial results for the quarter and year ended December 31, 2021, as well as provided business updates.

Positive interim results in P2 CANAL and top-line data expected in PRISM in 2Q with enrollment concluded in both trials

"We have made considerable progress on our two development programs with positive interim analysis results from our Phase 2 CANAL study for the treatment of chronic cough in idiopathic pulmonary fibrosis (IPF) and the completion of enrollment in our Phase 2b/3 PRISM study for the treatment of pruritus due to prurigo nodularis (PN)," said Jennifer L. Good, President and CEO of Trevi Therapeutics. "We were very pleased to see the strong magnitude of response and consistent results of Haduvio in the interim analysis for chronic cough in IPF. These results further support our belief in the overall mechanism of Haduvio and the potential to treat both chronic cough and chronic pruritus in various conditions. Chronic cough in IPF and pruritus in PN are both serious and debilitating conditions with no currently approved therapies and each of them potentially represents a significant opportunity to address an unmet need in the market."

Key Business Updates

- **Positive interim analysis results from the Phase 2 CANAL trial of Haduvio for chronic cough in patients with IPF**
  - The interim analysis was statistically significant on the primary endpoint demonstrating a 52% placebo-adjusted reduction in the geometric mean percent change in daytime cough events ($p<0.0001$) for Haduvio
  - Due to the magnitude of response in the interim analysis, enrollment concluded early and top-line data for the full set of approximately 40 subjects is expected in the third quarter of 202
- **Phase 2b/3 PRISM trial of Haduvio for severe pruritus in patients with PN**
  - Completed enrollment on January 31, 2022
  - Top-line data readout expected in the second quarter of 2022

Fourth Quarter 2021 Financial Highlights

Research and development (R&D) expenses: R&D expenses for the fourth quarter of 2021 were $6.2 million compared to $6.6 million in the same period in 2020. The decrease was primarily due to decreased purchases of clinical trial supplies. This decrease was partially offset by increased activity in the Company's Phase 2 CANAL clinical trial as well as an increase in personnel-related expenses due to increased employee headcount.

General and administrative (G&A) expenses: G&A expenses for the fourth quarter of 2021 were $2.1 million compared to $2.6 million in the same period in 2020. The decrease was primarily due to decreased market research costs.

Net loss: For the fourth quarter of 2021, the Company reported a net loss of $8.5 million, compared to a net loss of $9.5 million in the same period in 2020.

Year End 2021 Financial Highlights

Cash position: As of December 31, 2021, the Company had total cash and cash equivalents of $36.8 million.

R&D expenses: R&D expenses for the year ended December 31, 2021 were $23.0 million compared to $22.3 million for the year ended December 31, 2020. The increase was primarily due to an increase in personnel-related expenses due to increased employee headcount, including a related increase in stock-based compensation. Costs associated with clinical trials also increased along with consulting and professional fees. These increases were partially offset by decreased purchases of clinical trial supplies.

G&A expenses: G&A expenses for the year ended December 31, 2021 were $9.5 million compared to $10.2 million for the year ended December 31, 2020. The decrease was primarily due to decreased market research costs as well as lower stock-based compensation expense as a result of employee turnover, which was partially offset by higher legal and other professional fees.

Net loss: For the year ended December 31, 2021, Trevi reported a net loss of $33.9 million compared to a net loss of $32.8 million for the year ended December 31, 2020.

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 9674297. 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:

- March 30, 8:00 a.m. – 9:00 a.m. ET: "Understanding the Seriousness of Chronic Cough in IPF Patients and Trevi's Latest Data." A webinar featuring Trevi management, along with insights from an IPF expert.
- April 12, 8:00 – 8:45 am Fireside Chat: 21st Annual Needham Virtual Healthcare Conference

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 patients 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 classified 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 (Haduvio) is an investigational therapy that has been granted Fast Track designation by the FDA for the proposed indication of reduction of moderate to severe pruritus in patients 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 Trevi's ability to maintain its listing on the Nasdaq Global Market; 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, 2021 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, 2021	December 31, 2020
Cash and cash equivalents	$ 36,830	$ 45,001
Working capital	25,233	40,714
Total assets	38,475	47,131
Total debt	14,485	13,954
Stockholders' equity	17,075	27,282

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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 6,178	$ 6,560	$ 22,984	$ 22,328
General and administrative	2,094	2,633	9,492	10,161
Total operating expenses	8,272	9,193	32,476	32,489
Loss from operations	(8,272)	(9,193)	(32,476)	(32,489)
Other expense, net	(254)	(313)	(1,485)	(287)
Loss before income taxes	(8,526)	(9,506)	(33,961)	(32,776)
Income tax benefit (expense)	5	(17)	21	18
Net loss	$ (8,521)	$ (9,523)	$ (33,940)	$ (32,758)
Basic and diluted net loss per common share outstanding	$ (0.28)	$ (0.52)	$ (1.49)	$ (1.81)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	30,113,457	18,425,770	22,841,481	18,059,011

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