Trevi Therapeutics Announces Third Quarter 2021 Financial Results and Business Update

Phase 2b/3 PRISM (Chronic Pruritus in PN) Trial Approximately 90% Enrolled, Top-Line Data Readout Expected First Half of 2022
Phase 2 CANAL (Chronic Cough in IPF) Actively Enrolling, Top-Line Data Readout Expected First Half of 2022
Management to Host Conference Call at 4:30 pm ET

NEW HAVEN, Conn., Nov. 10, 2021 /PRNewswire/ -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company focused on the development and commercialization of an investigational therapy Haduvio™ (nalbuphine ER) to treat serious neurologically mediated conditions, today announced financial results for the quarter ended September 30, 2021, as well as provided business updates.

Pruritus in PN (PRISM) Trial ~90% enrolled and top-line data readout expected 1H 2022

"We continue to execute on enrollment for both of our trials, with PRISM, our Phase 2b/3 in chronic pruritus in prurigo nodularis (PN) now being 90% enrolled. Haduvio is the most advanced oral compound in clinical development for both pruritus in PN and chronic cough in patients with idiopathic pulmonary fibrosis (IPF)," said Jennifer L. Good, President and CEO of Trevi Therapeutics. "With large commercial market opportunities in our first two indications, we are excited to conclude these trials and report topline data in the first half of 2022. The potential for indication expansion in both pruritus and chronic cough is significant, and we continue to focus on completing these trials while preparing for further clinical development, future regulatory filings, and the commercial launch of Haduvio. There continues to be a high unmet need in these two patient populations."

Key Business Updates

- **Phase 2b/3 PRISM trial of Haduvio for severe pruritus in patients with PN**
  - Approximately 90% of the planned 360 subjects have enrolled
  - Approximately 90% of eligible subjects continued into the open label extension study
  - Top-line data readout expected in the first half of 2022
- **Phase 2 CANAL trial of Haduvio for chronic cough in patients with IPF**
  - Enrollment steadily progressing with top-line data readout expected in the first half of 2022

Upcoming Meetings
The Company plans to present at the following upcoming conferences:

- Stifel 2021 Virtual Healthcare Conference, November 15-17, 2021
- 5th Annual Dermatology Drug Development Summit for Inflammatory Skin Diseases, November 16-18, 2021
- 11th Annual LifeSci Partners Corporate Access Event, January 5-7, 2022
- H.C. Wainwright BioConnect Virtual Conference, January 10-13, 2022

Third Quarter 2021 Financial Highlights

Cash position: As of September 30, 2021, the Company had total cash and cash equivalents of $29.3 million. In addition, subsequent to the end of the quarter, the Company raised $14.8M through the sale of common stock and warrants to fund Company operations and the development of Haduvio in both of our clinical trials.

Research and development (R&D) expenses: R&D expenses for the third quarter of 2021 were $4.7 million compared to $4.8 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 an increase in personnel-related expenses due to increased employee headcount.

General and administrative (G&A) expenses: G&A expenses for the third quarter of 2021 were $2.2 million compared to $2.4 million in the same period in 2020. The decrease was primarily due to decreased market research costs as well as lower stock-based compensation expense which were partially offset by higher legal and other professional fees.

Net loss: For the third quarter of 2021, the Company reported a net loss of $7.3 million, compared to a net loss of $7.4 million in the same period in 2020.

Conference Call
To participate in the live conference call today, November 10th at 4:30 pm ET, please dial (888) 317-6003 (domestic) or (412) 317-6061 (international) and provide access code 6938277. 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.

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 PN and a Phase 2 trial for chronic cough in patients with IPF. Trevi is also developing Haduvio for the treatment of levodopa-induced dyskinesia (LID) in patients with Parkinson's disease. 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 and by regulatory authorities in most of Europe. Trevi intends to propose Haduvio as the trade name for 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 impact of the COVID-19 pandemic on Trevi's clinical trials, business and operations; the expected timing of enrollment and for reporting top-line data from Trevi's Phase 2b/3 PRISM trial of Haduvio in patients with PN and Phase 2 CANAL trial of Haduvio for chronic cough in patients with IPF; 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; 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; uncertainties regarding Trevi's ability to execute on its strategy; the risk that positive results from a clinical trial may not necessarily be predictive of the results of 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 and its obligations under its loan facility; 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)

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 29,318	$ 45,001
Working capital	20,794	40,714
Total assets	31,596	47,131
Total debt	14,328	13,954
Stockholders' equity	11,380	27,282

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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 4,718	$ 4,828	$ 16,805	$ 15,768
General and administrative	2,229	2,416	7,398	7,528
Total operating expenses	6,947	7,244	24,203	23,296
Loss from operations	(6,947)	(7,244)	(24,203)	(23,296)
Other (expense) income, net	(306)	(145)	(1,232)	26
Loss before income taxes	(7,253)	(7,389)	(25,435)	(23,270)
Income tax (expense) benefit	(2)	11	15	35
Net loss	$ (7,255)	$ (7,378)	$ (25,420)	$ (23,235)
Basic and diluted net loss per common share outstanding	$ (0.34)	$ (0.41)	$ (1.25)	$ (1.30)

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