Trevi Therapeutics Announces Third Quarter 2020 Financial Results and Business Update

November 11, 2020

PRISM Trial of Haduvio ™ for Severe Pruritus in Patients with Prurigo Nodularis

Exceeds Halfway Enrollment Milestone

Phase 2 Chronic Cough Trial in Patients with IPF Enrolled First New Subject Post-COVID-19 Restrictions

Cash Position Expected to Fund Operations into the First Half of 2022

NEW HAVEN, Conn., Nov. 11, 2020 (GLOBE NEWSWIRE) -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company focused on the development and commercialization of Haduvio™ (nalbuphine ER) to treat serious neurologically mediated conditions, today announced financial results for the quarter ended September 30, 2020, as well as business updates.

"We are pleased with the continued progress of our clinical development programs," said Jennifer L. Good, President and CEO of Trevi Therapeutics. "We recently announced significant developments in both of our ongoing clinical trials by surpassing halfway enrollment in our PRISM trial and enrolling the first new subject in our chronic cough trial in IPF since the study resumed after pausing due to COVID restrictions. We are focused on completing enrollment in both trials and preparing for the next steps in the development of Haduvio."

Key Business Updates

- **Phase 2b/3 PRISM trial of Haduvio for severe pruritus in patients with prurigo nodularis:** The Company has enrolled approximately 190 subjects in the trial and reaffirms its guidance that it expects to complete enrollment in the third quarter of 2021 and to report top-line data in the fourth quarter of 2021.

- **Phase 2 trial of Haduvio for chronic cough in patients with idiopathic pulmonary fibrosis (IPF):** The Company resumed screening and enrolling patients in the trial following the pause in the trial due to COVID-19. The Company amended the study protocol to require fewer in-person visits by subjects as well as fewer procedures in order to facilitate the completion of the trial in an at-risk patient population for COVID-19. Additionally, the Company is assessing additional study sites in Germany which could potentially accelerate enrollment and reduce the risks inherent with single-country recruitment during the COVID-19 pandemic.

Third Quarter 2020 Financial Highlights

Cash position: As of September 30, 2020, the Company had total cash and cash equivalents of $53.3 million, compared to $57.3 million as of December 31, 2019. During the third quarter of 2020, the Company received $14.0 million in proceeds from a term loan with Silicon Valley Bank and sold approximately $2.5 million of common stock under the Company's ATM program. The Company expects its cash position will fund operations into the first half of 2022.

Research and development (R&D) expenses: R&D expenses for the third quarter of 2020 were $4.8 million compared to $5.7 million in the same period in 2019. The decrease was primarily due to decreased activity in the Company's Phase 2 trial in chronic cough in patients with IPF due to the pausing of enrollment and treatment of patients as a result of the COVID-19 pandemic as well as decreased activity with the completion of the Company's Phase 1b trial in patients with chronic liver disease.

General and administrative (G&A) expenses: G&A expenses for the third quarter of 2020 were $2.4 million compared to $2.0 million in the same period in 2019. The increase was primarily due to an increase in stock-based compensation expenses and an increase in consulting fees.

Net loss: For the third quarter of 2020, the Company reported a net loss of $7.4 million, compared to a net loss of $7.4 million in the same period in 2019.

Conference Call
As previously announced, the Company will host a conference call and webcast today, November 11, 2020 at 4:30 p.m. ET. To participate in the live conference call by phone, please dial (866) 360-5746 (domestic) or (602) 563-8605 (international) and provide access code 9375955. 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 Haduvio to treat serious neurologically mediated conditions. Trevi is currently developing Haduvio for the treatment of chronic pruritus, chronic cough in patients with idiopathic pulmonary fibrosis (IPF) and 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. Trevi is currently conducting a Phase 2b/3 clinical trial of Haduvio, referred to as the PRISM trial, in patients with severe pruritus associated with prurigo nodularis.

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

About HADUVIO
Haduvio is an oral extended release 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 also mitigates the risk of abuse associated with μ-opioid agonists because it antagonizes, or blocks, μ-opioid receptors. Nalbuphine is currently the only opioid approved for marketing that is not classified as a controlled substance in the United States and most of Europe. Trevi intends to propose Haduvio as the trade name for the nalbuphine ER investigational product. Haduvio is an investigational drug product and its safety and efficacy have not been fully 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 prurigo nodularis; Trevi's business plans and objectives, including future plans or expectations for Trevi's product candidates and 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 inherent in estimating Trevi's cash runway, future expenses and other financial results; as well as other risks and uncertainties set forth in the quarterly report on Form 10-Q for the quarter ended June 30, 2020 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, 2020	December 31, 2019
Cash and cash equivalents	$ 53,293	$ 57,313
Working capital	49,106	54,353
Total assets	55,879	60,001
Total debt	13,798	—
Stockholders' equity	35,618	54,545

Trevi Therapeutics, Inc.

Selected Statement of Operations Data

(unaudited)

(amounts in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 4,828	$ 5,650	$ 15,768	$ 14,516
General and administrative	2,416	2,000	7,528	5,363
Total operating expenses	7,244	7,650	23,296	19,879
Loss from operations	(7,244)	(7,650)	(23,296)	(19,879)
Other income (expense), net	(145)	280	26	352
Loss before income tax benefit	(7,389)	(7,370)	(23,270)	(19,527)
Income tax benefit	11	5	35	14
Net loss	$ (7,378)	$ (7,365)	$ (23,235)	$ (19,513)

Investor Contact
Chris Seiter, Chief Financial Officer
Trevi Therapeutics, Inc.
203-304-2499

chris.seiter@trevitherapeutics.com

Media Contact
Rosalia Scampoli
914-815-1465
rscampoli@marketcompr.com

Source: Trevi Therapeutics