Trevi Therapeutics Announces Second Quarter 2020 Financial Results and Business Update

Announced Positive Outcome of Sample Size Re-Estimation Analysis for PRISM Trial

Strong Enrollment in PRISM Trial After Lifting of COVID-19 Restrictions

Announces $14 Million Term Loan - Cash Position Expected to Fund Operations into the First Half of 2022

NEW HAVEN, Conn., Aug. 13, 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 June 30, 2020, as well as recent business updates.

“We are pleased with how the Trevi team was able to manage the continued execution of the PRISM trial in the face of the COVID-19 pandemic restrictions. The Company announced the positive outcome of the sample size re-estimation analysis and continued to activate clinical sites virtually,” said Jennifer L. Good, President and CEO of Trevi Therapeutics. “Once the screening and enrollment restrictions were lifted in the PRISM trial, we were able to rapidly restart screening and enrollment in most of our sites. We now have approximately 80% of our sites screening patients and have had our strongest two months of enrollment thus far in the trial. In addition, we are pleased to announce the execution of a non-dilutive $14 million term loan which we expect will extend our cash runway into the first half of 2022, past the anticipated top-line results from the PRISM trial which are expected in the fourth quarter of 2021.”

Key Business Updates

- Phase 2b/3 PRISM trial of Haduvio for severe pruritus in patients with prurigo nodularis: The Company completed the pre-specified sample size re-estimation (SSRE) analysis in July and based on the recommendation of the independent Data Monitoring Committee, we increased the trial size from the initial target enrollment of 240 to 360 subjects to maintain statistical power for the primary endpoint. The pace of enrollment has accelerated since the removal of most COVID-19 screening and enrollment restrictions and approximately 155 subjects have been enrolled in the study. We expect to complete enrollment in the third quarter of 2021 and 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 is amending the study protocol to reduce the number of in-person visits to facilitate this study being completed in an at-risk patient population for COVID-19. The Company is planning for a restart of this trial in the second half of 2020.
- Entered into $14 million term loan with Silicon Valley Bank: The Company entered into a $14 million term loan with Silicon Valley Bank on August 13, 2020 which will bolster our balance sheet and extends our cash runway into the first half of 2022. The term loan requires monthly interest-only payments through February 28, 2022, followed by monthly payments of principal and interest until February 1, 2024. Interest on the term loan initially accrues at a floating per annum rate of the greater of (i) the prime rate plus 1.0% and (ii) 4.25%. Other material terms related to the term loan can be found in the Company’s Form 10-Q.

Second Quarter 2020 Financial Highlights

Cash position: As of June 30, 2020, the Company had total cash and cash equivalents of $44.2 million, compared to $57.3 million as of December 31, 2019.

Research and development (R&D) expenses: R&D expenses for the second quarter of 2020 were $4.9 million compared to $5.5 million in the same period in 2019. The decrease was primarily due to decreased activity in our Phase 2 trial in chronic cough in patients with IPF due to the halting of enrollment and treatment of patients as a result of the COVID-19 pandemic.

General and administrative (G&A) expenses: G&A expenses for the second quarter of 2020 were $2.5 million compared to $1.9 million in the same period in 2019. The increase was primarily due to an increase in stock-based compensation expenses and an increase in expenses related to being a public company.

Net loss: For the second quarter of 2020, the Company reported a net loss of $7.4 million, compared to a net loss of $7.3 million in the same period in 2019.

Conference Call
As previously announced, the Company will host a conference call and webcast today, August 13, 2020 at 4:30 p.m. ET. To participate in the live conference call by phone, please dial 866-360-5746 (domestic) or 270-833-1418 (international) and provide access code 8162375. 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 our 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; the expected timing of milestones for the Company's other ongoing and planned clinical trials; 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 our cash runway, future expenses and other financial results; as well as other risks and uncertainties set forth in the annual report on Form 10-Q for the quarter ended March 31, 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)

	June 30, 2020	December 31, 2019
Cash and cash equivalents	$ 44,180	$ 57,313
Working capital	39,573	54,353
Total assets	47,009	60,001
Stockholders' equity	40,037	54,545

Trevi Therapeutics, Inc.

Selected Statement of Operations Data

(unaudited)

(amounts in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 4,921	$ 5,528	$ 10,940	$ 8,866
General and administrative	2,492	1,889	5,112	3,363
Total operating expenses	7,413	7,417	16,052	12,229
Loss from operations	(7,413)	(7,417)	(16,052)	(12,229)
Other income (expense), net	14	66	171	72
Loss before income tax benefit	(7,399)	(7,351)	(15,881)	(12,157)
Income tax benefit	15	5	24	9

Net loss	$ (7,384)	$ (7,346)	$ (15,857)	$ (12,148)

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