Trevi Therapeutics Announces Second Quarter 2019 Financial Results and Recent Business Developments

August 12, 2019

Advancement of Nalbuphine ER Through Clinical Development in Multiple Indications

NEW HAVEN, Conn., Aug. 12, 2019 (GLOBE NEWSWIRE) -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company focused on the development and commercialization of nalbuphine ER to treat serious neurologically mediated conditions, today announced financial results for the quarter ended June 30, 2019, as well as recent business highlights.

“We are pleased with the progress we made during the first half of 2019 advancing the development of nalbuphine ER and positioning Trevi for several important clinical milestones later this year and in 2020,” said Jennifer L. Good, President and CEO of Trevi Therapeutics. “We remain on track to report top-line data from both our Phase 2b/3 PRISM trial of nalbuphine ER in patients with prurigo nodularis and from our Phase 2 trial of nalbuphine ER for the treatment of chronic cough in patients with idiopathic pulmonary fibrosis (IPF) in the first half of 2020. In addition, we remain on track to report data from our Phase 1b liver study of nalbuphine ER and initiate our Phase 2 study of nalbuphine ER for the treatment of levodopa-induced dyskinesia (LID) in patients with Parkinson’s disease in the second half of 2019.”

Second Quarter 2019 Highlights and Recent Events

- Continued patient enrollment in the Phase 2b/3 PRISM trial: The ongoing PRISM trial is a randomized, double-blind, placebo controlled, two-arm treatment study that is designed to evaluate the safety and anti-pruritic efficacy of nalbuphine ER in approximately 240 prurigo nodularis (PN) patients with severe pruritus from PN in approximately 50 centers in the U.S. and Europe. The Company plans to report topline data from the PRISM trial in the first half of 2020. Additionally, the protocol for the PRISM trial provides for a sample size re-estimation analysis once 50% of the patients in the trial are evaluable for the primary endpoint. Trevi expects the re-estimation analysis will occur in early 2020.

- Initiated Phase 2 trial of nalbuphine ER for chronic cough in patients with IPF: The Phase 2 clinical trial is a randomized, double-blind, placebo controlled, two-treatment, two-period, crossover study designed to evaluate the efficacy, safety, tolerability and dosing of nalbuphine ER for chronic cough in up to 56 patients with IPF in the United Kingdom. Trevi plans to report top-line data from this trial in the first half of 2020.

- Completed Pre-IND meeting with the FDA for LID in patients with Parkinson’s disease: Based on input from the FDA, Trevi plans to finalize a protocol for the planned Phase 2 trial for LID in patients with Parkinson’s disease, submit an IND and prepare to initiate the Phase 2 trial in the second half of 2019.

- Completed initial public offering (IPO): In May 2019, Trevi completed its IPO of 5,500,000 shares of common stock and a concurrent private placement of 1,500,000 shares of common stock, resulting in combined gross proceeds to the Company of $70.0 million.

Second Quarter 2019 Financial Highlights

Cash position: As of June 30, 2019, Trevi reported total cash and cash equivalents of $71.4 million, compared to $7.2 million as of December 31, 2018. Trevi believes this cash position will fund operations through the end of 2020.

Research and development (R&D) expenses: R&D expenses for the second quarter of 2019 were $5.5 million compared to $3.4 million in the same period in 2018. The increase was primarily due to increased activities of the Phase 2b/3 PRISM trial and the initiation of the Phase 2 trial for chronic cough in patients with IPF.

General and administrative (G&A) expenses: G&A expenses for the second quarter of 2019 were $1.9 million compared to $0.9 million in the same period in 2018. The increase was primarily due to an increase in personnel and associated stock-based compensation expense as well as expenses related to being a public company.

Net loss: For the second quarter of 2019, Trevi reported a net loss of $7.3 million, compared to a net loss of $4.9 million in the same period in 2018.

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of nalbuphine ER to treat serious neurologically mediated conditions. Trevi is currently developing nalbuphine ER 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 nalbuphine ER, 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 Nalbuphine ER
Nalbuphine ER 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.

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, 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 the re-estimation analysis for, and for reporting top-line data from, Trevi's Phase 2b/3 PRISM trial of nalbuphine ER 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 the Trevi's product candidate development activities and planned clinical trials; 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 future expenses, capital requirements and other financial results; as well as the other risks and uncertainties set forth in the quarterly report on Form 10-Q for the quarter ended March 31, 2019 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, 2019
Cash and cash equivalents	$ 71,387
Working capital	67,503
Total assets	75,116
Stockholders' equity (deficit)	67,703

Trevi Therapeutics, Inc.

Selected Statement of Operations Data

(unaudited)

(amounts in thousands)

	Three Months Ended June 30,	
	2019	2018
Operating expenses:		
Research and development	$ 5,528	$ 3,439
General and administrative	1,889	941
Total operating expenses	7,417	4,380
Loss from operations	(7,417)	(4,380)
Other income (expense), net	66	(503)
Loss before income tax benefit	(7,351)	(4,883)
Income tax benefit	5	25
Net loss	$ (7,346)	$ (4,858)

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