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

Raised $70 Million in Gross Proceeds from Initial Public Offering and Concurrent Private Placement

Initiated Phase 2 Clinical Trial for Chronic Cough in Patients with Idiopathic Pulmonary Fibrosis (IPF)

NEW HAVEN, Conn., June 13, 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 March 31, 2019, as well as recent business highlights.

“The successful completion of our IPO enables Trevi to continue development of 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,” said Jennifer L. Good, President and CEO of Trevi Therapeutics. “We plan to report top-line data from our Phase 2b/3 PRISM trial of nalbuphine ER in patients with prurigo nodularis 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. We expect the re-estimation analysis will occur in early 2020. We are also pleased to announce the initiation of our Phase 2 trial for chronic cough in patients with IPF, a serious condition for IPF patients for which there are no approved therapies.”

First Quarter 2019 Highlights and Recent Events

- Activated clinical sites in Europe for the PRISM trial: During the first quarter of 2019 Trevi commenced activation of clinical sites in Europe and have begun enrolling patients in the PRISM trial in Europe.
- Initiated Phase 2 trial of nalbuphine ER for chronic cough in patients with IPF in June 2019: 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. The primary endpoint for the study is the mean change in daytime cough frequency as measured by a cough monitor. The study will also examine various secondary endpoints. Trevi plans to report top-line data from this trial in the first half of 2020.
- Completed initial public offering (IPO): In May 2019, Trevi announced it had 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 net proceeds to the Company of approximately $62.6 million after deducting underwriting discounts and commissions and estimated offering expenses. Shares outstanding immediately after the IPO and private placement were approximately 17.8 million.
- Licensed patents for use of nalbuphine ER for treatment of LID in Parkinson’s disease: In February 2019, Trevi announced it had entered into exclusive license agreements with Rutgers, The State University of New Jersey and MentiNova, Inc. for intellectual property and data supporting the development of nalbuphine ER for LID in patients with Parkinson’s disease. Based on feedback from the Food and Drug Administration (FDA) in a pre-IND meeting earlier this year, Trevi plans to submit an IND in preparation for a Phase 2 trial of nalbuphine ER in this indication expected to commence in the second half of 2019.

First Quarter 2019 Financial Highlights

Cash position: As of March 31, 2019, Trevi reported total cash and cash equivalents of $12.9 million, compared to $7.2 million as of December 31, 2018. Subsequent to the quarter, in May 2019, Trevi received approximately $62.6 million of net proceeds from its IPO and concurrent private placement.

Research and development (R&D) expenses: R&D expenses for the first quarter of 2019 were $3.3 million compared to $2.4 million in the same period in 2018. The increase was primarily due to initiation of the Phase 2b/3 PRISM trial in the third quarter of 2018 and an increase in personnel.

General and administrative (G&A) expenses: G&A expenses for the first quarter of 2019 were $1.5 million compared to $0.8 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 consulting and professional fees.

Net loss: For the first quarter of 2019, Trevi reported a net loss of $4.8 million, compared to a net loss of $4.1 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 or 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 commencement of Trevi's planned Phase 2 clinical trial of nalbuphine ER for treatment of LID in Parkinson's disease; 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; risks with respect to Trevi's ability to fund its operations on a continuing basis; as well as the other risks and uncertainties set forth in the final prospectus related to Trevi's initial public offering 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)

	March 31, 2019	December 31, 2018
Cash and cash equivalents	$ 12,946	$ 7,202
Working capital	11,099	6,148
Total assets	17,185	10,526
Stockholders' deficit	(115,476)	(109,494)

Trevi Therapeutics, Inc.

Selected Statement of Operations Data

(unaudited)

(amounts in thousands)

	Three Months Ended March 31,	
	2019	2018
Operating expenses:		
Research and development	$ 3,338	$ 2,363
General and administrative	1,474	779
Total operating expenses	4,812	3,142
Loss from operations	(4,812)	(3,142)
Other income (expense), net:	6	(934)
Loss before income tax benefit	(4,806)	(4,076)
Income tax benefit	4	25
Net loss	$ (4,802)	$ (4,051)

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