Trevi Therapeutics Announces Second Quarter 2021 Financial Results and Business Update

Phase 2b/3 PRISM (Chronic Pruritus in PN) Trial Approximately 80% Enrolled, Top-Line Data Readout Expected First Half of 2022
Phase 2 CANAL (Chronic Cough in IPF) Trial Recruiting, Top-Line Data Readout Expected First Half of 2022

NEW HAVEN, Conn., Aug. 12, 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 June 30, 2021, as well as business updates.

Pruritus in PN (PRISM) Trial 80% enrolled and top-line data readout expected in 1H 2022

"We continue to advance both our pruritus in prurigo nodularis (PN) and chronic cough in idiopathic pulmonary fibrosis (IPF) trials," said Jennifer L. Good, President and CEO of Trevi Therapeutics. "We are particularly pleased to see recruitment and enrollment activity resume in our CANAL trial with the lifting of COVID-19 restrictions in the UK. As a result of this activity, we have announced guidance for reporting top-line data on the CANAL trial in the first half of 2022."

In addition, Trevi recently announced two new additions to its management team. "Trevi is pleased to have welcomed Lisa Delfini as our Chief Financial Officer and Danine Summers who joined us full time as our VP of Medical Affairs. We look forward to utilizing their deep experience as we grow the Company," added Ms. Good.

Key Business Updates

- **Phase 2b/3 PRISM trial of Haduvio for severe pruritus in patients with PN**
  - Approximately 285, or 80%, of planned subjects have enrolled
    - Enrollment expected to be completed by the end of 2021
  - Top-line data readout expected in the first half of 2022
- **Phase 2 CANAL trial of Haduvio for chronic cough in patients with IPF**
  - Ongoing recruitment and screening taking place at multiple sites in the UK
  - Top-line data readout expected in the first half of 2022
- Expanded leadership team to support the growth of the Company

Second Quarter 2021 Financial Highlights

Cash position: As of June 30, 2021, the Company had total cash and cash equivalents of $36.4 million, compared to $45.0 million as of December 31, 2020.

Research and development (R&D) expenses: R&D expenses for the second quarter of 2021 were $6.5 million compared to $4.9 million in the same period in 2020. The increase was primarily due to an increase in personnel-related expenses due to increased employee headcount, increased costs associated with higher activity and enrollment in the Company's ongoing Phase 2b/3 PRISM trial, increased purchases of clinical trial supplies and an increase in consulting and professional fees. These increases were partially offset by decreased expenses relating to the Company's Phase 1b clinical trial in patients with chronic liver disease which was completed in the first half of 2020.

General and administrative (G&A) expenses: G&A expenses for the second quarter of 2021 were $2.7 million compared to $2.5 million in the same period in 2020. The increase was primarily due to increased legal and professional fees partially offset by a reduction in personnel-related expenses.

Net loss: For the second quarter of 2021, the Company reported a net loss of $9.8 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, August 12th at 4:30 p.m. ET, please dial (888) 317-6003 (domestic) or (412) 317-6061 (international) and provide access code 0833159. 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 prurigo nodularis (PN) and a Phase 2 trial for chronic cough in patients with idiopathic pulmonary fibrosis (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 June 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)

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 36,425	$ 45,001
Working capital	29,070	40,714
Total assets	39,149	47,131
Total debt	14,245	13,954
Stockholders' equity	17,736	27,282

Trevi Therapeutics, Inc.

Selected Statement of Operations Data
(unaudited)
(amounts in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 6,498	$ 4,921	$ 12,087	$ 10,940
General and administrative	2,669	2,492	5,169	5,112
Total operating expenses	9,167	7,413	17,256	16,052
Loss from operations	(9,167)	(7,413)	(17,256)	(16,052)
Other (expense) income, net	(629)	14	(926)	171
Loss before income taxes	(9,796)	(7,399)	(18,182)	(15,881)
Income tax benefit	2	15	17	24
Net loss	$ (9,794)	$ (7,384)	$ (18,165)	$ (15,857)

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