Trevi Therapeutics Announces Second Quarter 2022 Financial Results and Business Update

Reported positive results from the Phase 2b/3 PRISM trial of Haduvio™ in the treatment of Prurigo Nodularis

Completed a $55 million private placement

Data from the full set of subjects in the completed Phase 2 CANAL trial in chronic cough in idiopathic pulmonary fibrosis (IPF) expected in the third quarter of 2022

Management to host a conference call and webcast today at 4:30 p.m. EDT

NEW HAVEN, Conn., Aug. 11, 2022 /PRNewswire/ -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company developing an investigational therapy Haduvio™ (oral nalbuphine ER) for the treatment of prurigo nodularis and chronic cough in adults with idiopathic pulmonary fibrosis (IPF), today announced financial results for the quarter ended June 30, 2022, as well as provided business updates.

Trevi's topline data expected for Ph2b/3 PRISM study this quarter and full results for Ph2 CANAL study in Q3

"The positive trial results reported this quarter in the treatment of prurigo nodularis not only further support the continued development of Haduvio in another therapeutic indication with a high unmet need, but also reaffirms the mechanism of action and the importance of having both a peripheral and centrally active therapy," said Jennifer Good, President and CEO of Trevi Therapeutics. "As a next step in our prurigo nodularis program, we plan to request an end of phase 2 meeting with the FDA. In our chronic cough in IPF program, we are looking forward to providing topline efficacy and safety data on the full set of subjects enrolled in the completed Phase 2 CANAL study this quarter. We are actively preparing for the next trial in chronic cough in IPF and are looking forward to discussing the program and trial plan with the FDA at a meeting scheduled for this quarter."

Key Business Updates

Phase 2b/3 PRISM trial of Haduvio in the treatment of Prurigo Nodularis

As previously announced in the Phase 2b/3 PRISM trial, results comparing subjects randomized to Haduvio (n=168) or placebo (n=176) achieved the primary and two key secondary endpoints. In addition, the Company has received the analysis on the final key secondary endpoint, the PROMIS sleep scale, which also achieved that endpoint with statistical significance at week 14. Below is a summary of the primary and all key secondary endpoints:

- 25% of Haduvio subjects evaluated at week 14 met the primary endpoint of a 4-point reduction in the Worst Itch Numerical Rating Scale from baseline compared to 14% of placebo subjects (p=0.0157).
- Haduvio subjects experienced significantly greater improvements in ItchyQoL vs. placebo (p=0.0002) at week 14, which was statistically significant across each of the three domains (symptoms, functional limitations, and emotions). ItchyQoL is used to measure how pruritus impacts a subject's quality of life.
- 55% of Haduvio subjects had at least a 1-category improvement in the 5-point scale in their Prurigo Activity Score (PAS) (pruriginous lesions with excoriations), vs. 38% on placebo (p=0.006) as evaluated at week 14.
- Haduvio subjects experienced significantly greater improvements in the PROMIS sleep disturbance short form 8a vs. placebo (p=0.0002) at week 14. The first assessment of PROMIS was made at week 6 of the trial and results at week 6 also demonstrated a statistically significant improvement.

Private Placement

- Completed a $55 million private placement in April 2022 to further the clinical development of Haduvio.

Second Quarter 2022 Financial Highlights

Cash position: As of June 30, 2022, the Company had total cash, cash equivalents and marketable securities of $78.9 million.

Research and development (R&D) expenses: R&D expenses for the second quarter of 2022 were $5.1 million compared to $6.5 million in the same period in 2021. The decrease was primarily due to reduced purchases of clinical trial supplies and clinical trial subject recruitment costs, a reduction in our use of consulting services and the non-recurrence of professional recruiting fees related to hirings in the prior year period.

General and administrative (G&A) expenses: G&A expenses were $2.7 million in the second quarter of 2022

and the second quarter of 2021.

Net loss: For the second quarter of 2022, the Company reported a net loss of $8.1 million, compared to a net loss of $9.8 million in the same period in 2021. The decrease was primarily due to the decrease in R&D expenses.

Conference Call
To participate in the live conference call on Thursday, August 11, by phone, please dial (888) 317-6003 (domestic) or (412) 317-6061 (international) and provide access code 9437525. 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.

Upcoming Meetings
The Company plans to present at the following upcoming conferences and events:

- August 15-17: Stifel Biotech Executive Summer Summit
- August 29: 6th Annual IPF Summit
- September 12-14: H.C. Wainwright 24th Annual Global Investment Conference

About Trevi Therapeutics, Inc.
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of the investigational therapy Haduvio for the treatment of prurigo nodularis and chronic cough in adults with idiopathic pulmonary fibrosis. 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 scheduled as a controlled substance by the DEA in the United States or by regulatory authorities in most of Europe. Trevi intends to propose Haduvio as the trade name for nalbuphine ER. Nalbuphine ER has been granted Fast Track designation by the FDA for the treatment of itch 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 expected timing of reporting top-line data from the full set of subjects' data from Trevi's Phase 2 CANAL trial of Haduvio in chronic cough in adults with IPF; Trevi's business plans and objectives, including future plans or expectations for Haduvio; 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, including with respect to the timing of reporting top-line data from the Phase 2 CANAL trial; uncertainties regarding Trevi's ability to execute on its strategy; the risk that positive interim or top-line results from a clinical trial may not necessarily be predictive of the results of the completed trial or other 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, comply with its obligations under its loan facility and fund future operations; 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; as well as other risks and uncertainties set forth in the quarterly report on Form 10-Q for the quarter ended June 30, 2022 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, 2022	December 31, 2021
Cash and cash equivalents	$ 24,698	$ 36,830
Marketable securities	54,157	—
Working capital	64,452	25,233
Total assets	81,414	38,475
Total debt	12,428	14,485
Stockholders' equity	60,515	17,075

Trevi Therapeutics, Inc.
Selected Statement of Operations Data
(unaudited)
(amounts in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 5,103	$ 6,498	$ 9,748	$ 12,087
General and administrative	2,717	2,669	5,097	5,169
Total operating expenses	7,820	9,167	14,845	17,256
Loss from operations	(7,820)	(9,167)	(14,845)	(17,256)
Other expense, net	(236)	(629)	(545)	(926)
Loss before income taxes	(8,056)	(9,796)	(15,390)	(18,182)
Income tax benefit	4	2	9	17
Net loss	$ (8,052)	$ (9,794)	$ (15,381)	$ (18,165)
Basic and diluted net loss per common share outstanding	$ (0.14)	$ (0.49)	$ (0.34)	$ (0.92)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	59,542,628	20,123,461	45,253,599	19,772,201

Investor Contact
Katie McManus
Trevi Therapeutics, Inc.
203-304-2499
k.mcmanus@trevitherapeutics.com

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

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