# Trevi Therapeutics Reports Second Quarter 2024 Financial Results and Provides Business Updates Reaffirming Clinical Trial Guidance

August 8, 2024

Topline results expected in the fourth quarter of 2024 in the Phase 2a RIVER trial in refractory chronic cough (RCC)

Sample size re-estimation milestone is expected in the fourth quarter of 2024 in the Phase 2b CORAL trial in chronic cough in idiopathic pulmonary fibrosis (IPF)

Ended the second quarter of 2024 with $69.5 million in cash, cash equivalents and marketable securities with expected cash runway into 2026

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

NEW HAVEN, Conn., Aug. 8, 2024 /PRNewswire/ -- Trevi Therapeutics, Inc. (Nasdaq: TRVI), a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine ER) for the treatment of chronic cough in idiopathic pulmonary fibrosis (IPF) and refractory chronic cough (RCC), today announced financial results for the quarter ended June 30, 2024, as well as provided business updates.

"Recruitment in our clinical trials was strong during the quarter," said Jennifer Good, President and CEO of Trevi Therapeutics. "Our Phase 2a RIVER trial in RCC is now approximately 80% enrolled and we look forward to the topline data readout later this year. We also expect to complete the sample size re-estimation in our CORAL trial in the fourth quarter of this year. There is a significant unmet need for new therapies to help IPF and RCC patients. Chronic cough is a condition that is prevalent in 120,000 IPF patients and an estimated 2-3 million RCC patients in the U.S. and for which there are no approved therapies. We believe Haduvio's unique central and peripheral mechanism has the potential to provide a rapid, broad, and deep effect in those suffering from chronic cough."

**Second Quarter and Recent Business Highlights**

- In the Phase 2a RIVER trial for the treatment of RCC, approximately 80% of the planned 60 patients have been enrolled. The Company expects topline data in the fourth quarter of 2024.
- In the Phase 2b CORAL trial for the treatment of chronic cough in patients with IPF, in which the Company expects to enroll approximately 160 patients, the majority of the 60 planned sites have been initiated. The Company expects to conduct the sample size re-estimation (SSRE) in the fourth quarter of this year when 50% of the patients are evaluable for the primary endpoint. Assuming no adjustments are made to the sample size, topline results are expected in the first half of 2025.
- Other supportive studies:
    - The Human Abuse Potential (HAP) study is now approximately 95% enrolled and the last patient visit is expected by the end of September. Topline data is expected in the fourth quarter of 2024.
    - The Phase 1b TIDAL respiratory physiology study is approved to be conducted in the UK and US and we have initiated screening. The study will evaluate the effect of Haduvio on respiratory physiology in patients with IPF of varying disease severity. TIDAL is a randomized, single-blind, placebo-controlled study. We expect to enroll approximately 25 patients who will be in-patient for ten days. The primary endpoint of the study is the effect of escalating doses of Haduvio on respiratory function, as measured by minute ventilation. Secondary endpoints of additional respiratory functions will also be measured. The goal of this study is to define the patient population for any Phase 3 studies that we may conduct in IPF chronic cough.
- The Company also announced during the quarter the appointment of Margaret Garin, MD, MSCR, as Vice President of Clinical Development. Dr. Garin brings unique and relevant experience from her previous lead role in clinical development at Bellus Health.
- The Company ended the second quarter of 2024 with $69.5 million in cash, cash equivalents and marketable securities with expected cash runway into 2026.

**Second Quarter 2024 Financial Highlights**

**Research and development (R&D) expenses:** R&D expenses for the second quarter of 2024 increased to $10.0 million from $5.8 million in the same period in 2023, primarily due to increased clinical development expenses for our Phase 2b CORAL trial, our Phase 2a RIVER trial, our HAP study and our recently initiated Phase 1b TIDAL study, as well as increases in personnel and related expenses and stock-based compensation expense. These increases were partially offset by decreased clinical development expenses for our Phase 2b/3 PRISM trial.

**General and administrative (G&A) expenses:** G&A expenses for the second quarter of 2024 increased to $3.3 million from $2.5 million in the same period in 2023, primarily due to increases in personnel and related expenses, stock-based compensation expense, market research costs, as well as information technology services.

**Net loss:** For the second quarter of 2024, the Company reported a net loss of $12.4 million, compared to a net loss of $7.1 million in the same period in 2023.

**Conference Call/Webcast**
To participate in the live conference call by phone, please dial (877) 870 4263 (domestic) or (412) 317 0790 (international) and ask to join the Trevi Therapeutics call. No code is necessary for access. 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 participate in the following events:

- August 12-14: Stifel 2024 Biotech Summer Summit
- September 4-6: 2024 Wells Fargo Healthcare Conference
- September 7-11: European Respiratory Society (ERS) Congress 2024
- September 9-11: H.C. Wainwright 26th Annual Global Investment Conference
- September 17-19: 2024 Cantor Global Healthcare Conference
- September 24-26: 2024 Leerink Partners Biopharma Summit

**About Trevi Therapeutics, Inc.**
Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine ER) for the treatment of chronic cough in idiopathic pulmonary fibrosis (IPF) and refractory chronic cough (RCC). Haduvio is a dual κ-opioid receptor agonist and μ-opioid receptor antagonist that works both centrally in the brain as well as peripherally in the lungs and has the potential for a synergistic antitussive effect to treat chronic cough. Parenteral nalbuphine is not scheduled by the U.S. Drug Enforcement Agency.

The impact of chronic cough is significant and often leads to a decline in patients' social, physical, and psychological quality of life. In IPF, chronic cough may lead to worsening disease and may be associated with a higher risk of progression, death, or need for lung transplant. There are no approved therapies for the treatment of chronic cough in IPF and current treatment options provide minimal benefit to patients. Chronic cough affects up to 10% of the adult population, and Haduvio's expansion into RCC has the potential to reach patients suffering from moderate to severe refractory chronic cough. There are also no approved therapies for RCC in the U.S.

Trevi intends to propose Haduvio as the trade name for oral nalbuphine ER. Its safety and efficacy have not been evaluated by any regulatory authority.

For more information, visit www.TreviTherapeutics.com and follow Trevi on X (formerly Twitter) and LinkedIn.

**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 Trevi's business plans and objectives, including future plans or expectations for Haduvio and plans and timing with respect to clinical trials, 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; the risk that positive data from a clinical trial may not necessarily be predictive of the results of later clinical trials in the same or a different indication; uncertainties regarding Trevi's ability to execute on its strategy; uncertainties with respect to regulatory authorities' views as to the data from Trevi's clinical trials and next steps in the development path for Haduvio in the United States and foreign countries, uncertainties inherent in estimating Trevi's cash runway, future expenses and other financial results, including Trevi's ability to fund future operations, including clinical trials, as well as other risks and uncertainties set forth in the quarterly report on Form 10-Q for the quarter ended March 31, 2024 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, 2024 | December 31, 2023 |
|---|---|---|
| Cash and cash equivalents | $ 12,963 | $ 32,397 |
| Marketable securities | 56,532 | 50,574 |
| Working capital | 65,377 | 81,723 |

| | | |
|---|---|---|
| Total assets | 73,810 | 89,403 |
| Stockholders' equity | 66,174 | 82,547 |

**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, | |
|---|---|---|---|---|
| | **2024** | **2023** | **2024** | **20** |
| Operating expenses: | | | | |
| Research and development | $ 10,021 | $ 5,842 | $ 18,825 | $ |
| General and administrative | 3,268 | 2,540 | 6,370 | |
| Total operating expenses | 13,289 | 8,382 | 25,195 | |
| Loss from operations | (13,289) | (8,382) | (25,195) | ( |
| Other income, net | 929 | 1,207 | 1,925 | |
| Loss before income taxes | (12,360) | (7,175) | (23,270) | ( |
| Income tax benefit | 8 | 30 | 16 | |
| Net loss | $ (12,352) | $ (7,145) | $ (23,254) | $ ( |
| Basic and diluted net loss per common share outstanding | $ (0.12) | $ (0.07) | $ (0.23) | $ |
| Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted | 101,041,573 | 98,698,579 | 100,279,393 | 98,6 |

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