

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of  
the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): October 3, 2024

Trevi Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware  
(State or Other Jurisdiction  
of Incorporation)

001-38886  
(Commission  
File Number)

45-0834299  
(IRS Employer  
Identification No.)

195 Church Street, 16th Floor  
New Haven, Connecticut  
(Address of Principal Executive Offices)

06510  
(Zip Code)

Registrant's telephone number, including area code: (203) 304-2499

Not applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class                       | Trading<br>symbol(s) | Name of each exchange<br>on which registered |
|-------------------------------------------|----------------------|----------------------------------------------|
| Common stock, \$0.001 par value per share | TRVI                 | The Nasdaq Stock Market LLC                  |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

## **Item 8.01 Other Events**

On October 3, 2024, Trevi Therapeutics, Inc. (the “Company”) announced the following updates on its clinical development programs.

The Company's Phase 2b CORAL trial for the treatment of chronic cough in patients with idiopathic pulmonary fibrosis has enrolled 50% of the targeted study enrollment, which is the number of patients needed for the pre-specified sample size re-estimation ("SSRE"). The SSRE will be performed once the last of these patients complete the six weeks of treatment. The outcome of the SSRE result is expected in December 2024. The three potential SSRE outcomes are: maintain current sample size (N=160), upsize within a pre-specified range, or evaluate for futility. Assuming no adjustments are made to the sample size, topline results are expected in the first half of 2025.

The Company's Human Abuse Potential study completed dosing. Topline results are expected in December 2024.

The Company's Phase 2a RIVER trial for the treatment of refractory chronic cough has enrolled the planned sample size but remains open to allow for additional enrollment in both arms to approximate the stratification targets. Topline results are now expected in the first quarter of 2025.

## **Forward-Looking Statements**

Statements contained in this current report on Form 8-K 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 Company's business plans and objectives, including future plans or expectations for Haduvio and plans and timing with respect to clinical trials, 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 and timing of the Company's product candidate development activities, including its ongoing 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 the Company's ability to execute on its strategy; uncertainties with respect to regulatory authorities' views as to the data from the Company's clinical trials and next steps in the development path for Haduvio in the United States and foreign countries, uncertainties inherent in estimating the Company's cash runway, future expenses and other financial results, including the Company'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 June 30, 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 current report on Form 8-K speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TREVI THERAPEUTICS, INC.

Date: October 3, 2024

By: /s/ Lisa Delfini

Name: Lisa Delfini

Title: Chief Financial Officer

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