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

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**CURRENT REPORT**

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

**Date of report (Date of earliest event reported): December 12, 2024**

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**Trevi Therapeutics, Inc.**

(Exact Name of Registrant as Specified in Charter)

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**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)

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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 symbol(s)	Name of each exchange on which registered
<b>Common stock, \$0.001 par value per share</b>	<b>TRVI</b>	<b>The Nasdaq Stock Market LLC</b>

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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.

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### **Item 8.01 Other Events**

On December 12, 2024, Trevi Therapeutics, Inc., a Delaware corporation (the “Company”), announced the positive outcome from the planned sample size re-estimation (the “SSRE”) for the ongoing Phase 2b CORAL trial in idiopathic pulmonary fibrosis patients with chronic cough, which requires no change to the current sample size for the trial (N=160). The trial has reached 75% of the targeted enrollment, and topline results from the full trial continue to be expected in the first half of 2025.

The SSRE analysis was conducted on the highest dose (108mg twice daily) in the trial after 50% of the initial targeted trial enrollment, or 80 patients, completed the six weeks of treatment. Based on the SSRE analysis, it was recommended that the CORAL trial should continue as planned to maintain the pre-specified conditional power of 80% or greater. The other two potential pre-specified outcomes of the SSRE analysis were an increase in the sample size or futility.

### **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 clinical data, 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 Company’s product candidate development activities and ongoing clinical trials; the risk that positive data from a clinical trial, or from the SSRE analysis announced in this Current Report on Form 8-K, 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, as well as other risks and uncertainties set forth in the Company’s quarterly report on Form 10-Q for the quarter ended September 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: December 12, 2024

By: /s/ Lisa Delfini

Name: Lisa Delfini

Title: Chief Financial Officer

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