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): September 26, 2024

TRAVERE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36257**	**27-4842691**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

3611 Valley Centre Drive, Suite 300
San Diego, CA 92130
(Address of Principal Executive Offices, including Zip Code)

(888) 969-7879
(Registrant's Telephone Number, including Area Code)

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:

☐ 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
Common Stock, par value $0.0001 per share	**TVTX**	**The Nasdaq Global Market**

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 September 26, 2024, Travere Therapeutics, Inc. (the "Company") announced a voluntary pause of enrollment in the Phase 3 HARMONY Study evaluating pegtibatinase for the treatment of classical homocystinuria (HCU). The voluntary enrollment pause enables the Company to work to address necessary process improvements in manufacturing scale-up to support commercial scale manufacturing as well as full enrollment in the HARMONY Study. Patients currently enrolled in pegtibatinase studies continue to receive study medication from small scale batches which are unaffected by the scale-up process. Currently enrolled patients will be able to continue on study medication as scheduled for the duration of the trials they are participating in.

The voluntary enrollment pause was enacted following the Company's determination that the desired drug substance profile was not achieved in the recent scale-up process. The Company is in the process of notifying all study investigators of the decision to pause enrollment of new patients into the study until additional material is available.

The Company expects to further evaluate the necessary commercial process improvements to enable the continuation of the Phase 3 program and anticipates the earliest date to restart enrollment in the Phase 3 HARMONY Study will be in 2026.

Forward-Looking Statements

This report contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. Without limiting the foregoing, these statements are often identified by the words "on-track," "positioned," "look forward to," "will," "would," "may," "might," "believes," "anticipates," "plans," "expects," "intends," "potential," or similar expressions. In addition, expressions of strategies, intentions or plans are also forward-looking statements. Such forward-looking statements include, but are not limited to, references to: statements and expectations regarding future process improvements in manufacturing scale-up to support commercial scale manufacturing as well as full enrollment in the HARMONY Study, and related timing expectations; and statements regarding ongoing clinical trials, including statements regarding medication for patients currently enrolled in such trials. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties associated with manufacturing processes and improvements, and risks related to the regulatory review and approval process, as well as risks and uncertainties associated with the Company's business and finances in general, the success of its commercial products and risks and uncertainties associated with its preclinical and clinical stage pipeline. Specifically, the Company faces risks associated with the challenges of manufacturing scale-up, the ongoing commercial launch of FILSPARI, market acceptance of its commercial products including efficacy, safety, price, reimbursement, and benefit over competing therapies, as well as risks associated with the successful development and execution of commercial strategies for such products. The risks and uncertainties the Company faces with respect to its preclinical and clinical stage pipeline include risk that the Company's clinical candidates will not be found to be safe or effective and that current or anticipated future clinical trials will not proceed as planned. The Company also faces the risk that its cash runway might not last as long as currently anticipated and the risk that it will be unable to raise additional funding that may be required to complete development of any or all of its product candidates, including as a result of macroeconomic conditions; risks relating to the Company's dependence on contractors for clinical drug supply and commercial manufacturing; uncertainties relating to patent protection and exclusivity periods and intellectual property rights of third parties; risks associated with regulatory interactions; and risks and uncertainties relating to competitive products, including current and potential future generic competition with certain of the Company's products, and technological changes that may limit demand for the Company's products. The Company also faces additional risks associated with global and macroeconomic conditions, including health epidemics and pandemics, including risks related to potential disruptions to clinical trials, commercialization activity, supply chain, and manufacturing operations. You are cautioned not to place undue reliance on these forward-looking statements as there are important factors that could cause actual results to differ materially from those in forward-looking statements, many of which are beyond the Company's control. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Investors are referred to the full discussion of risks and uncertainties, including under the heading "Risk Factors", as included in the Company's most recent Form 10-K, Form 10-Q and other filings with the Securities and Exchange Commission.

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

TRAVERE THERAPEUTICS, INC.

Dated: September 26, 2024

By: /s/ Eric Dube
Name: Eric Dube
Title: Chief Executive Officer