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): May 31, 2023

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 May 31, 2023, Travere Therapeutics, Inc. (the “Company”) announced positive topline results from cohort 6 in the Phase 1/2 COMPOSE Study of pegtibatinase, a novel investigational enzyme replacement therapy being evaluated for the treatment of classical homocystinuria (HCU). In cohort 6, five patients were randomized in a blinded fashion to receive 2.5 mg/kg of lyophilized pegtibatinase or placebo twice weekly (BIW) during the 12 week double-blind treatment period, with four patients assigned to the treatment group.

Key findings from the Cohort 6 topline results are as follows:

- To date in the study, pegtibatinase has been generally well-tolerated.
- There were no reports of treatment-related serious adverse events, anaphylaxis, or discontinuations in the highest dose cohort treated with the 2.5 mg/kg twice weekly dose of pegtibatinase. To date, no evidence of neutralizing antibody activity has been observed as determined by pharmacokinetic and pharmacodynamic monitoring.
- Two participants receiving 2.5 mg/kg BIW reported moderate injection site reactions (ISRs) associated with urticaria, which resulted in a temporary dose interruption. Both participants restarted treatment at a lower dose after resolution of the ISR and were able to titrate up to the intended dose which was subsequently well-tolerated. There was no persistence or reoccurrence of urticaria with dose titration.
- In cohort 6, treatment with pegtibatinase resulted in a mean relative reduction from baseline of 67.1% (n=4, mean baseline tHcy = 96.8 µM), compared to a 0.6% increase in tHcy levels from baseline for patients receiving placebo in the study (n=6, mean baseline tHcy = 124.8 µM), calculated as the geometric mean by averaging tHcy over weeks 6, 8, 10, and 12.
- All patients achieved a mean tHcy below the clinically meaningful threshold of 100 µM, over weeks 6 to 12 of treatment. Some patients achieved tHcy below 50 µM, including one patient with a lower tHcy level at baseline achieving normalization of tHcy.
- Methionine levels were substantially reduced and cystathionine levels were substantially elevated following treatment with pegtibatinase, suggesting that pegtibatinase acts in a manner similar to the native CBS enzyme.

The Company is engaging with regulators on the design of a potential pivotal Phase 3 study with the expectation of initiating a Phase 3 program by the end of 2023. The Company plans to present additional detailed study results at an upcoming medical meeting or in a peer-reviewed publication.

Forward-Looking Statements

This Current Report on Form 8-K 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 "may", "might", "believes", "thinks", "anticipates", "plans", "expects", "intends" or similar expressions. In addition, expressions of our strategies, intentions or plans are also forward-looking statements. Such forward-looking statements include, but are not limited to, references to the efficacy, safety and tolerability profile of pegtibatinase based on the preliminary data from Cohort 6 of the Compose Study; the Company’s engagement with regulators on the design of a potential pivotal Phase 3 study and the expectation of initiating a Phase 3 program by the end of 2023; as well as the Company’s plans to present additional detailed study results at an upcoming medical meeting or in a peer-reviewed publication. Such forward-looking statements are based on current information available to the Company and involve inherent risks and uncertainties, including factors that could delay, divert or change any such forward-looking statements, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. There is no guarantee that the Company will be able to align with regulators on the design of, or ultimately proceed with, a pivotal program for pegtibatinase for HCU or that the results of any such Phase 3 trial will be positive or support the future approval of pegtibatinase as a therapy for HCU. 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 clinical development, interactions with regulatory authorities and manufacturing of novel product candidates. Specifically, the Company faces risk that a potential future pivotal study of pegtibatinase will not proceed as planned, risks associated with the manufacturing of pegtibatinase, including reliance on third party contract manufacturers, and risks that pegtibatinase will not be approved for efficacy, safety, regulatory or other reasons, and for each of the Company’s programs, risk associated with enrollment of clinical trials for rare diseases and risk that ongoing or planned clinical trials may not succeed or may be delayed for safety, regulatory or other reasons. In addition, such risks and uncertainties may include those described in the Company’s filings with the SEC, including under the “Risk Factors” heading of the Company’s quarterly report on Form 10-Q for the quarter ended March 31, 2023, as filed with the SEC on May 4 2023, which are also available at the Company’s website (www.travere.com) under “Investors & Media”. You are cautioned not to place undue reliance on any forward-looking statements as there are important factors that could cause actual results to differ materially from those in any forward-looking statements, many of which are beyond our control. Except to the extent required by law, the Company undertakes no obligation to publicly update any forward-looking statement.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: May 31, 2023

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