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): December 15, 2021

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))

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. ☐

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**

Item 8.01 Other Events.

On December 15, 2021, Travere Therapeutics, Inc. (the “Company”) announced positive topline results from the ongoing Phase 1/2 COMPOSE Study of pegtibatinase, a novel investigational enzyme replacement therapy being evaluated for the treatment of classical homocystinuria (HCU). To date in the COMPOSE Study, a total of 19 patients with HCU have been randomized 3:1 to receive either pegtibatinase or placebo in independent ascending subcutaneous dose cohorts, ranging from 0.33mg/kg once weekly to 1.5mg/kg BIW. The study protocol provided for an unblinded assessment to evaluate safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD) and clinical effects after twelve weeks of treatment had been completed in the fifth cohort (1.5mg/kg BIW).

Key findings from the topline results are as follows:

- To date in the COMPOSE Study, pegtibatinase has been generally well-tolerated.
- There were no discontinuations due to treatment-related adverse events. There was one serious adverse event, moderate acute urticaria (hives), that was categorized by the treating physician to be likely related to pegtibatinase treatment but did not lead to treatment discontinuation and resolved following a single dose interruption.
- Pegtibatinase demonstrated dose-dependent reductions in tHcy after 12 weeks of treatment.
- At the two highest doses, pegtibatinase appeared to reduce tHcy regardless of starting baseline tHcy levels or background therapy.
- In the highest dose cohort to date of 1.5mg/kg dosed twice weekly (BIW), treatment with pegtibatinase resulted in rapid and sustained reductions in tHcy, resulting in a maintenance of tHcy below a clinically meaningful threshold of 100 µmol from week 2 through week 12 of treatment.
- In the 1.5mg/kg BIW dose cohort, treatment with pegtibatinase resulted in a mean relative reduction from baseline of 55.1% (n=3, mean baseline tHcy = 187.0 µmol), compared to a mean relative reduction from baseline of 4.8% for all patients receiving placebo in the study (n=5, mean baseline tHcy = 131.1 µmol).
- In a dose-dependent manner in the study to date, 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.

Based on these results, the Company is preparing to engage with regulators to establish next steps for a pivotal development program to ultimately support the potential approvals of pegtibatinase for the treatment of HCU. In parallel, the Company has initiated one additional cohort in the COMPOSE Study to inform and refine formulation work for future development and commercial purposes and to further evaluate the dose response curve for pegtibatinase. Patients enrolled in the COMPOSE Study are eligible to enter into an open-label extension and receive the 1.5mg/kg dose of pegtibatinase.

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 the Compose Study interim analysis; the Company’s plan to engage with regulators to establish next steps for a pivotal development program to ultimately support the potential approvals of pegtibatinase for the treatment of HCU; and the Company’s plans to enroll one additional dose cohort in the COMPOSE Study to inform and refine formulation work for future development and commercial purposes and to further evaluate the dose response curve for pegtibatinase. 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. 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 the Compose Study or a planned 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 September 30, 2021, as filed with the SEC on October 29, 2021, 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

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: December 15, 2021

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