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): November 30, 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 2.05 Costs Associated with Exit or Disposal Activities.

On December 4, 2023, Travere Therapeutics, Inc. (the "Company") issued a press release announcing the completion of a successful pre-NDA meeting for FILSPARI® (sparsentan) in IgA nephropathy (IgAN) and provided regulatory updates for both IgAN and focal segmental glomerulosclerosis (FSGS), as described in more detail in Item 8.01 of this current report on Form 8-K. To further align the Company's resources for the ongoing FILSPARI launch and its planned Phase 3 program advancing the development of pegtibatinase as the first potential disease modifying treatment for HCU, the Company approved a strategic reorganization (the "Strategic Reorganization"). The Strategic Reorganization was approved by the Company on November 30, 2023 and is expected to be completed by the second quarter of 2024.

As part of the Strategic Reorganization, the Company is implementing an approximate 20% workforce reduction focused on non-field-based employees. The Company estimates that it will incur aggregate non-recurring charges of approximately $12-14 million in connection with the Strategic Reorganization, primarily consisting of employee severance related costs, substantially all which are expected to result in future cash expenditures. The Company expects that the majority of the restructuring charges will be incurred in Q4 2023 and that the implementation of the workforce reduction, including cash payments, will be substantially complete by the end of Q1 2024. Potential position eliminations are subject to legal requirements that vary by jurisdiction, which may extend this process beyond Q1 2024 in certain cases. The charges that the Company expects to incur are subject to a number of assumptions, including legal requirements in various jurisdictions, and actual expenses may differ materially from the estimates disclosed above. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the Strategic Reorganization.

Item 8.01 Other Events.

On December 4, 2023, the Company issued a press release announcing the completion of a successful pre-NDA meeting with the U.S. Food and Drug Administration ("FDA") for FILSPARI in IgAN. The Company plans to submit a supplemental New Drug Application (sNDA) in the first quarter of 2024 for conversion of the existing U.S. accelerated approval of FILSPARI to full approval. Following engagement with the FDA on focal segmental glomerulosclerosis (FSGS), the Company also provided an update that the two-year results from the Phase 3 DUPLEX Study alone were not sufficient to support an sNDA submission. The Company is conducting additional analyses of FSGS data and plans to re-engage FDA in 2024. The Company also announced that it is implementing the Strategic Reorganization to focus near-term resources on the ongoing FILSPARI launch in IgAN and the advancement of pegtibatinase in classical homocystinuria (HCU).

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 "anticipate," "believe," "expect," "intend," "may," "might," "objective," "plan," "will" 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 planned submission of an sNDA for full approval of FILSPARI in IgAN, and the anticipated timing and outcome thereof; planned additional analyses of FSGS data and plans and timing for re-engaging with FDA; the potential for pegtibatinase to be the first potential disease modifying treatment for HCU; statements regarding the planned Strategic Reorganization, the expected impact thereof, the number of employee positions that will be impacted, and the estimated amounts and timing of the anticipated charges related thereto. 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 the regulatory review and approval process, as well as risks and uncertainties associated with the Strategic Reorganization, the Company's business and finances in general, success of its commercial products and risks and uncertainties associated with the Company's preclinical and clinical stage pipeline. Specifically, the Company faces risks associated with 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, including FILSPARI. 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. Specifically, the Company faces risks related to the timing and potential outcome of its planned sNDA submission for full approval of sparsentan in IgAN, and the risk that the results from the Phase 3 DUPLEX Study of sparsentan in FSGS will not serve as a basis for a regulatory submission for approval of sparsentan for FSGS. There is no guarantee that regulators will grant full approval of sparsentan for IgAN or FSGS. 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 our 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.

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: December 4, 2023

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