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): February 23, 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 February 23, 2024, Travere Therapeutics, Inc. (the “Company”) and CSL Vifor announced that the European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended approval of the conditional marketing authorization (CMA) application for sparsentan for the treatment of adults with primary IgA nephropathy (IgAN) with a urine protein excretion >1.0 g/day (or urine protein-to-creatinine ratio ≥0.75 g/g). The positive CHMP opinion is based on results from the Company’s pivotal Phase 3 PROTECT Study of sparsentan in IgAN. The CHMP opinion provides the basis for the European Commission’s final decision regarding the potential CMA for sparsentan. If approved, sparsentan would receive CMA in all member states of the European Union, as well as in Iceland, Liechtenstein and Norway. Sparsentan is currently marketed in the U.S. under accelerated approval granted by the U.S. Food and Drug Administration under the brand name FILSPARI® to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio ≥1.5 g/g.

In August 2022, Travere Therapeutics and CSL Vifor announced they had submitted a Marketing Authorization Application (MAA) for CMA to the EMA. The European Commission previously granted Orphan Medicinal Product Designation to sparsentan for the treatment of IgAN. In 2021, Travere Therapeutics granted CSL Vifor exclusive commercialization rights for sparsentan in Europe, Australia and New Zealand.

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 strategies, intentions or plans are also forward-looking statements. Such forward-looking statements include, but are not limited to, references to: statements regarding the potential conditional marketing authorization of sparsentan for the treatment of IgAN in the European Union, Iceland, Liechtenstein and Norway and the anticipated timing thereof, including the potential timing and outcome of the European Commission’s decision; and the potential for sparsentan to be the first non-immunosuppressive, single-molecule, dual endothelin angiotensin receptor antagonist for the treatment of IgAN in the EU. 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 Company’s business and finances in general, the 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 the European Commission’s decision regarding conditional marketing authorization of sparsentan for IgAN. There is no guarantee that the European Commission will grant conditional marketing authorization of sparsentan for IgAN or that regulators will grant full approval of sparsentan for IgAN. The Company also faces 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.

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 annual report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on February 20, 2024, and other filings with the SEC, 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 the Company’s control. Except to the extent required by law, the Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise.

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: February 23, 2024

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