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 21, 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 September 21, 2023, Travere Therapeutics, Inc. (the "Company") announced topline two-year confirmatory secondary endpoint results from the Company's pivotal head-to-head Phase 3 PROTECT Study of FILSPARI® (sparsentan) in IgA nephropathy (IgAN) versus irbesartan. FILSPARI demonstrated long-term kidney function preservation and achieved a clinically meaningful difference in estimated glomerular filtration rate (eGFR) total and chronic slope versus irbesartan, narrowly missing statistical significance in eGFR total slope while achieving statistical significance in eGFR chronic slope for purposes of regulatory review in the EU. FILSPARI is currently available under accelerated approval in the U.S. The Company will engage with regulators and expects to submit a supplemental New Drug Application (sNDA) in the first half of 2024 for full approval in the U.S.

In the PROTECT Study, a total of 404 patients with persistent proteinuria despite active angiotensin-converting enzyme (ACE) inhibitor or angiotensin-receptor blocker (ARB) treatment, were randomized 1:1 to receive once daily oral doses of either FILSPARI or irbesartan, the active control. eGFR total and chronic slope are the secondary confirmatory endpoints for the U.S. and the EU, respectively. All topline efficacy endpoints favored FILSPARI as compared to irbesartan.

	FILSPARI (N=202)	Irbesartan (N=202)	Difference (FILSPARI - Irbesartan)
eGFR total slope, mL/min/1.73m² per year[a]	-2.9	-3.9	**1.0,** p=0.058 (-0.03, 1.94)
eGFR chronic slope, mL/min/1.73m² per year[b]	-2.7	-3.8	**1.1,** p=0.037 (0.07, 2.12)
UP/C (g/g) Mean % change from baseline at week 110[c]	-42.8	-4.4	**GMR: 0.60** (0.50, 0.72)
Absolute change in eGFR Mean change from baseline at week 110[d]	-5.8	-9.5	**3.7** (1.45, 5.99)
Absolute change in eGFR Mean change from baseline at week 114[e] following 4 weeks post treatment (Patients who completed blinded treatment period)	-6.1	-9.0	**2.9** (0.45, 5.25)
Confirmed 40% Reduction in eGFR, ESRD, or Death during the Study n (%)	**18** (8.9)	**26** (12.9)	**RR: 0.68** (0.37, 1.24)[f]

[a]LS Means and 95% CI from a random coefficient analysis including available on-treatment eGFR data from Week 6 through Week 110 with multiple imputation; mL/min/1.73m² per year
[b]LS Means and 95% CI from a random coefficient analysis including available on-treatment eGFR data through Week 110 with multiple imputation; mL/min/1.73m² per year
[c]Geometric LS Means, Geometric LS Mean Ratio (GMR), and 95% CI from MMRM analysis including on-treatment data through Week 110 with multiple imputation
[d]LS Means and 95% CI from MMRM analysis including on-treatment data through Week 110; mL/min/1.73m²
[e]ANCOVA adjusted for eGFR at baseline; mL/min/1.73m²
[f]Relative risk (RR) of events and 95% CI from Poisson regression model

A preliminary review of the safety results through 110 weeks of treatment indicates FILSPARI was generally well-tolerated and the overall safety profile in the study has been consistent between treatment groups.

The Company will complete a full evaluation of the data from the PROTECT Study and work with the study investigators on future presentations and publications of the results at an upcoming medical meeting and in a peer-reviewed publication.

In August 2022, the European Medicines Agency (EMA) accepted for review the Conditional Marketing Authorization (CMA) application of sparsentan for the treatment of IgAN. Together with its partner CSL Vifor, the Company anticipates a review opinion by the Committee for Medicinal Products for Human Use (CHMP) on the CMA application for sparsentan for the treatment of IgAN in the EU around the end of 2023.

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 "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 Company’s expectations regarding planned future engagement with FDA regarding the filing of an sNDA for full approval of FILSPARI for patients with IgAN in the U.S. and the timing and outcome thereof; statements regarding the Company’s further evaluation of the data from the PROTECT Study and work with the study investigators on future presentations and publications; and statements regarding expectations related to the regulatory approval pathway in the US and Europe. 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 commercial launch of a new product, the regulatory review and approval process, including traditional approval in the United States and the CMA and subsequent variation pathway in the European Union, the Company’s business and finances in general, success of its commercial products and the Company’s preclinical and clinical stage pipeline. Specifically, the Company faces risks associated with market acceptance of FILSPARI and its other products, including efficacy, safety, price, reimbursement and benefit over competing therapies; and the risk that the results of the Phase 3 PROTECT Study of sparsentan in IgAN will not be deemed sufficient by the FDA to serve as the basis for an sNDA submission for traditional approval of sparsentan. There is no guarantee that the FDA will grant full approval of sparsentan for IgAN. The Company faces risk 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; 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.

SIGNATURES

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 21, 2023

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