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 1, 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 1, 2023, Travere Therapeutics, Inc. (the “Company”) announced topline primary efficacy results from the pivotal Phase 3 DUPLEX Study of sparsentan, a Dual Endothelin Angiotensin Receptor Antagonist (DEARA), in focal segmental glomerulosclerosis (FSGS). At the end of the 108-week double-blind period, sparsentan was observed to have a 0.3 mL/min/1.73m^2 per year (95% CI: -1.74, 2.41) favorable difference on eGFR total slope and a 0.9 mL/min/1.73m^2 per year (95% CI: -1.27, 3.04) favorable difference on eGFR chronic slope compared to the active control irbesartan, which was not statistically significant. After 108 weeks of treatment, sparsentan achieved a mean reduction in proteinuria from baseline of 50%, compared to 32% for irbesartan. Results from the two-year analysis demonstrated that sparsentan was well-tolerated and has shown a comparable safety profile to irbesartan.

The Company will engage with regulators to explore a potential path forward for a supplemental New Drug Application (sNDA) in the U.S. Together with its collaborator CSL Vifor, the Company also plans to engage with the European Medicines Agency (EMA) to determine the potential for a subsequent variation to the Conditional Marketing Authorization (CMA) of sparsentan for the treatment of FSGS, subject to a review decision on the pending application for CMA of sparsentan in IgA nephropathy.

In the DUPLEX Study, a total of 371 patients were randomized 1:1 to receive either sparsentan or irbesartan, the active control.

eGFR Primary Efficacy Endpoints:

a. **Total slope** (primary endpoint in US)**:** From day one to week 108, the difference in eGFR total slope was 0.3 mL/min/1.73m^2 per year in favor of sparsentan (-5.4 mL/min per 1.73 m^2 per year; 95% CI: -6.89, -3.93) versus the active control irbesartan (-5.7 mL/min per 1.73 m^2 per year; 95% CI: -7.20, -4.29), p=0.7491.
b. **Chronic slope** (primary endpoint in Europe): From week 6 to week 108 of treatment, following the initial acute effect of randomized treatment, the difference in eGFR chronic slope was 0.9 mL/min/1.73m^2 per year in favor of sparsentan (-4.8 mL/min per 1.73 m^2 per year; 95% CI: -6.34, -3.27) versus the active control irbesartan (-5.7 mL/min per 1.73 m^2 per year; 95% CI:-7.20, -4.18), p=0.4203.

The secondary and topline exploratory endpoints, including renal outcomes, trended favorably for sparsentan in the study.

Proteinuria Two-Year Exploratory Endpoints:

a. **Urine protein-to-creatinine ratio** (**UP/C):** After 108 weeks of treatment, the change from baseline UP/C was 50% for sparsentan versus 32% for irbesartan.
b. **FSGS partial remission of proteinuria endpoint (FPRE):** At week 108, 38% of patients on sparsentan achieved FPRE compared with 23% on irbesartan.
c. **Complete remission:**18% of patients on sparsentan versus 7% on irbesartan achieved complete remission of proteinuria (UP/C <0.3 g/g) at some time during the double-blind period.

A preliminary review of the safety results through 108 weeks of treatment indicate sparsentan has been generally well-tolerated and the overall safety profile in the study to date has been generally consistent between treatment groups.

The Company believes the results from DUPLEX will be instrumental in helping to inform the medical community’s understanding of FSGS, and is committed to further exploring the data to understand the potential role sparsentan could play in the treatment of FSGS. The Company intends to complete a full evaluation of the data from the DUPLEX Study and work with study investigators on future presentations and publication of the results at an upcoming medical meeting and/or in a peer-reviewed publication.

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 “on-track”, “positioned”, “look forward to”, "may", "might", "believes", "anticipates", "plans", "expects", "intends," “potential” 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 sparsentan based on the topline data from the DUPLEX Study which is based on a preliminary analysis of the data and subject to more comprehensive analyses, including with respect to secondary, and topline exploratory endpoints, including renal outcomes; the Company’s plan and timing for engaging with regulators to explore a potential path for a regulatory submission of sparsentan for FSGS; expectations regarding the ability to present the results from the DUPLEX Study at an upcoming medical meeting and/or in a peer-reviewed journal; the potential ability to submit a supplemental NDA for sparsentan for FSGS in the U.S. and the potential for a submission for a subsequent variation to the Conditional Marketing Authorization (CMA) of sparsentan for the treatment of FSGS in Europe, subject to a review decision on the pending application for CMA of sparsentan in IgA nephropathy; the Company’s belief that the results from DUPLEX will be instrumental in helping to inform the medical community’s understanding of FSGS, and its plan to further explore the data to understand the potential role sparsentan could play in the treatment of FSGS. 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, including the traditional and Subpart H accelerated approval pathways in the United States and the CMA pathway in the European Union, as well as risks and uncertainties associated with 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 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; the risk that the Phase 3 PROTECT Study of sparsentan in IgAN will not demonstrate that sparsentan is safe or effective or serve as the basis for further approval of sparsentan; the risk that sparsentan will not be approved further 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 or abandoned for safety, regulatory, program assessment or other reasons. There is no guarantee that the Company will be able to establish a pathway to a potential submission of sparsentan for FSGS based on the results from the DUPLEX Study, that the FDA and/or EMA will support an application for sparsentan in FSGS, or that sparsentan will be approved for FSGS. The Company faces 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; 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 as included under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on February 23, 2023.

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 1, 2023

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