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 17, 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 February 17, 2023, Travere Therapeutics, Inc. (the "Company") announced that the U.S. Food and Drug Administration (FDA) has granted accelerated approval to FILSPARI™ (sparsentan) to reduce proteinuria in adults with primary Immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.

This indication is granted under accelerated approval based on reduction in proteinuria. It has not been established whether FILSPARI slows kidney function decline in patients with IgAN. The continued approval of FILSPARI may be contingent upon confirmation of a clinical benefit in the ongoing Phase 3 PROTECT Study, which is designed to demonstrate whether FILSPARI slows kidney function decline. Topline results from the two-year confirmatory endpoints in the PROTECT Study are expected in the fourth quarter of 2023 and are intended to support traditional approval of FILSPARI.

FILSPARI, a once-daily oral medication, is designed to selectively target two critical pathways in the disease progression of IgAN (endothelin-1 and angiotensin II), and is the first and only non-immunosuppressive therapy approved for the treatment of this condition. IgAN is a rare kidney disease and a leading cause of kidney failure due to glomerular disease, affecting up to 150,000 people in the U.S., with approximately 30,000 to 50,000 of such patients estimated to be addressable under the indication approved via accelerated approval. The Company expects FILSPARI to be available beginning the week of February 27, 2023, and will be providing a comprehensive patient support program throughout the patient's treatment journey.

The approval of FILSPARI, granted under the FDA's accelerated approval pathway, is based on clinically meaningful and statistically significant improvements in proteinuria compared to an active comparator in the pivotal and ongoing Phase 3 PROTECT Study, the largest head-to-head interventional study to date in IgAN. The PROTECT Study is a global, randomized, multicenter, double-blind, active-controlled clinical trial evaluating the safety and efficacy of 400 mg of FILSPARI, compared to 300 mg of irbesartan, in 404 patients ages 18 years and up with IgAN and persistent proteinuria despite maximal tolerated ACE or ARB therapy.

In August 2021, the Company announced positive topline interim results that were based on the pre-specified, primary analyses set which showed that after 36 weeks of treatment, patients receiving FILSPARI achieved a mean reduction in proteinuria from baseline of 49.8%, compared to a mean reduction in proteinuria from baseline of 15.1% for irbesartan-treated patients ($p<0.0001$). Per request from the FDA, the efficacy data contained in the FDA-approved label is a post-hoc sensitivity analysis that evaluates the first 281 randomized patients, a subset of the full trial population. The mean reduction in proteinuria from baseline in the post-hoc sensitivity analysis is 45% for FILSPARI versus 15% for the active control, irbesartan. Both the pre-specified and post-hoc sensitivity analyses have demonstrated that FILSPARI achieves a rapid and sustained reduction in proteinuria, with statistically significant and clinically meaningful improvement compared to the active comparator irbesartan. Per the study protocol, patients continue in a blinded manner in the PROTECT Study to fully assess the treatment effect on eGFR slope over 110 weeks in the confirmatory endpoint analysis. Results from the confirmatory endpoint analysis are expected in the fourth quarter of 2023.

Results from the interim assessment in the PROTECT Study showed that FILSPARI was well tolerated with a clearly defined safety profile that has been consistent across all clinical trials conducted to date. In PROTECT, the most common adverse reactions (≥ 5%) are peripheral edema, hypotension (including orthostatic hypotension), dizziness, hyperkalemia, and anemia. Because of the risks of liver injury and birth defects, FILSPARI is available only through a Risk Evaluation and Mitigation Strategy (REMS) approved by the FDA.

In the second half of 2023, the Company together with its collaborator Vifor (International) Ltd., anticipates a review decision by the European Medicines Agency (EMA) on the potential approval of the Conditional Marketing Authorization (CMA) application for sparsentan for the treatment of IgAN in Europe.

In the second quarter of 2023, the Company expects to report topline results from the two-year confirmatory endpoints in the ongoing Phase 3 DUPLEX Study of sparsentan in focal segmental glomerulosclerosis (FSGS). Pending supportive data, the Company anticipates submitting a supplemental NDA for traditional approval for an FSGS indication in the second half of 2023 and a subsequent variation to the CMA of sparsentan for the treatment of patients with FSGS in Europe is targeted for submission by the end of 2023. Sparsentan has been granted Orphan Drug Designation for the treatment of IgAN and FSGS in the U.S. and Europe.

About the PROTECT Study

The ongoing PROTECT Study is one of the largest interventional studies to date in IgAN. It is a global, randomized, multicenter, double-blind, parallel-arm, active-controlled clinical trial evaluating the safety and efficacy of 400mg of sparsentan, compared to 300mg of irbesartan, in 404 patients ages 18 years and up with IgAN and persistent proteinuria despite available ACE or ARB therapy. In August 2021, the Company announced the PROTECT Study met its pre-specified interim primary efficacy endpoint with statistical significance. Based on the pre-specified, primary analyses set, after 36 weeks of treatment, patients receiving sparsentan achieved a mean reduction in proteinuria from baseline of 49.8 percent, compared to a mean reduction in proteinuria from baseline of 15.1 percent for irbesartan-treated patients ($p<0.0001$). The Company believes that preliminary eGFR data available at the time of the interim analysis are indicative of a potential clinically meaningful treatment effect after two years of treatment. Preliminary results at the time of the interim assessment suggested that sparsentan had been generally well-tolerated to date in the study and consistent with its overall observed safety profile. The PROTECT Study is fully enrolled and is scheduled to continue as planned on a blinded basis to assess the treatment effect on eGFR slope over 110 weeks in the confirmatory endpoint analysis. Topline results from the confirmatory endpoint analysis are expected in the fourth quarter of 2023.

Milestone Payment

Pursuant to the Company's sublicense agreement with Ligand Pharmaceuticals, Inc. ("Ligand"), dated February 16, 2012, the Company expects to make a $23 million milestone payment to Ligand and Bristol Myers Squibb Company ("BMS") in the first quarter of 2023, as a result of the accelerated approval granted to FILSPARI (sparsentan). The Company remains obligated to make payments to Ligand and BMS upon achievement of certain other regulatory and sales milestones, as well as an escalating annual royalty between 15 percent and 17 percent of global net product sales of FILSPARI.

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 when FILSPARI will be available; the expected timing for reporting topline results from the confirmatory endpoint analysis of the PROTECT Study; the Company's belief that preliminary eGFR data from the PROTECT Study available at the time of the interim analysis are indicative of a potential clinically meaningful treatment effect after two years of treatment; the potential traditional regulatory approval of sparsentan for IgAN; the estimated addressable U.S. patient population for FILSPARI under the indication approved via accelerated approval; the anticipated review decision by the EMA on the potential approval of the CMA application for sparsentan for the treatment of IgAN, and the timing thereof; the timing for reporting topline results from the confirmatory endpoints in the ongoing DUPLEX Study in FSGS; the Company's plan to submit a supplemental NDA for traditional approval for FSGS in the second half of 2023 and a subsequent variation to the CMA of sparsentan for the treatment of FSGS in Europe by the end of 2023, pending supportive data; and timing of the expected milestone payment to Ligand and BMS. 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 both traditional approval and the accelerated approval pathway in the United States and the CMA 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 commercial products, including efficacy, safety, price, reimbursement and benefit over competing therapies; the risk that the confirmatory endpoint analysis from the Phase 3 PROTECT Study will not serve as a basis for traditional approval of FILSPARI; the risk that the Phase 3 DUPLEX Study of sparsentan in FSGS will not demonstrate that sparsentan is safe or effective or serve as the basis for traditional approval of sparsentan; the risk that sparsentan for FSGS 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. There is no guarantee that the FDA will grant traditional approval of sparsentan for IgAN or FSGS. The Company faces risk that it will be unable to raise additional funding that may be required to successfully launch FILSPARI in the United States or complete development of any or all of its product candidates; 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 faces additional risks associated with the potential impacts that a resurgence of COVID-19 or other health epidemic or pandemic may have on its business, including, but not limited to the Company's ability to continue its ongoing development activities and clinical trials, the timing of such clinical trials and the release of data from those trials, the Company's and its suppliers' ability to successfully manufacture its commercial products and product candidates, and the market for and sales of its commercial products. 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 "Risk Factors" heading of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, as filed with the Securities and Exchange Commission ("SEC") on October 27, 2022, and other filings with the SEC.

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 17, 2023

By: /s/ Elizabeth E. Reed
Name: Elizabeth E. Reed
Title: Senior Vice President, General Counsel and Secretary