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 15, 2025

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 15, 2025, Travere Therapeutics, Inc. (the "Company") announced that the U.S. Food and Drug Administration ("FDA") has accepted its supplemental New Drug Application ("sNDA") for traditional approval of FILSPARI® (sparsentan) for the treatment of focal segmental glomerulosclerosis ("FSGS"). The FDA has assigned a Prescription Drug User Fee Act ("PDUFA") target action date of January 13, 2026, and has indicated that it is currently planning to hold an advisory committee meeting to discuss the application. The sNDA submission is supported by results from the Phase 3 DUPLEX Study and the Phase 2 DUET Study.

If approved, FILSPARI could become the first and only FDA-approved medicine indicated for FSGS, a rare kidney condition and leading cause of kidney failure.

About Focal Segmental Glomerulosclerosis

Focal segmental glomerulosclerosis (FSGS) is a rare proteinuric kidney disorder in both children and adults that is estimated to affect more than 40,000 patients in the U.S. with similar prevalence in Europe. The disorder is defined by progressive scarring of the kidney and often leads to kidney failure. FSGS is characterized by proteinuria, where protein leaks into the urine due to a breakdown of the normal filtration mechanism in the kidney. Once in the urine, protein is considered to be toxic to other parts of the kidney, especially the tubules, and is believed to contribute to further disease progression. Other common symptoms include swelling in parts of the body, known as edema, as well as low blood albumin levels, abnormal lipid profiles and hypertension. There is currently no approved pharmacologic indicated for the treatment of FSGS.

About the DUPLEX and DUET Studies

The Phase 3 DUPLEX Study is the largest interventional study to date in FSGS, and the only study in FSGS against a maximally dosed active comparator. While DUPLEX achieved its pre-specified interim FSGS partial remission of proteinuria (FPRE) endpoint with statistical significance at 36 weeks, it did not achieve the primary efficacy eGFR slope endpoint over 108 weeks of treatment. The two-year results from the study were published in the New England Journal of Medicine and showed that sparsentan delivered clinically meaningful benefit at 108 weeks with significant proteinuria reduction, higher rates of partial and complete remission, and a lower rate of end-stage kidney disease compared to the active control. The Phase 2 DUET Study of sparsentan in FSGS met the primary efficacy endpoint for the combined treatment group, demonstrating a greater than two-fold reduction in proteinuria compared to irbesartan. Sparsentan was well-tolerated with a safety profile that was consistent across all clinical trials conducted to date and comparable to the active control, irbesartan, including no drug-induced liver injury and no fluid overload. Patients who completed the DUPLEX and DUET double-blind portions of the studies on treatment were eligible to participate in the open-label extension of the trials.

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," "will," "would," "may," "might," "believes," "anticipates," "plans," "expects," "intends," "potential," 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 FDA's review of the Company's sNDA for FILSPARI in FSGS, and expectations regarding the timing and outcome thereof; statements and expectations regarding whether there will be a need for an advisory committee to discuss the application; statements regarding the potential for FILSPARI to become the first and only FDA-approved medicine indicated for FSGS; and references to the estimated size of the patient population. 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 related to the Company's sNDA for FILSPARI in FSGS, including the timing and outcome thereof. There is no guarantee that the FDA will grant approval of FILSPARI for FSGS on the anticipated timeline, or at all. The Company also faces risks and uncertainties related to its business and finances in general, the success of its commercial products, risks and uncertainties associated with its preclinical and clinical stage pipeline, risks and uncertainties associated with the regulatory review and approval process, risks and uncertainties associated with enrollment of clinical trials for rare diseases, and risks that ongoing or planned clinical trials may not succeed or may be delayed for safety, regulatory or other reasons. Specifically, the Company faces risks associated with the ongoing commercial launch of FILSPARI in IgAN, the timing and potential outcome of its and its partners' clinical studies, market acceptance of its commercial products including efficacy, safety, price, reimbursement, and benefit over competing therapies, risks related to the challenges of manufacturing scale-up, risks associated with the successful development and execution of commercial strategies for such products, including FILSPARI, and risks and uncertainties related to the new administration, including but not limited to risks and uncertainties related to tariffs and the funding, staffing and prioritization of resources at government agencies including the FDA. 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. 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 the Company's 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.

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 15, 2025

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