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): August 16, 2021

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))

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. ☐

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**

Item 8.01 Other Events.

On August 16, 2021, Travere Therapeutics, Inc. (the “Company”) announced positive topline interim results from the ongoing pivotal Phase 3 PROTECT Study of sparsentan, an investigational product candidate for the treatment of IgA nephropathy (IgAN). The PROTECT Study met its pre-specified interim primary efficacy endpoint with statistical significance. 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 from the interim analysis suggest that to date in the study, sparsentan has been generally well-tolerated and consistent with the observed safety profile to date. Based on the results of the interim analysis, the Company plans to submit an application for accelerated approval in the United States in the first half of 2022 and also plans to submit an application for conditional marketing authorization in Europe.

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 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 current plan regarding, and expectations around the timeline for, submitting an application for accelerated approval of sparsentan for IgAN; references to the efficacy, safety and tolerability profile of sparsentan based on the preliminary data from the PROTECT Study interim analysis; and the Company’s belief that preliminary eGFR data available at the time of the interim analysis from the PROTECT Study are indicative of a potential clinically meaningful treatment effect after two years of treatment. Such forward-looking statements are based on current information available to the Company and involve inherent risks and uncertainties, including factors that could delay, divert or change any such forward-looking statements, 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 Subpart H accelerated approval pathway in the United States and the conditional marketing authorization (CMA) pathway in the Europe Union, including the risk that the FDA and/or EMA could disagree with the Company’s submission of an NDA under Subpart H for accelerated approval, or a Marketing Approval Application (“MAA”) under the CMA pathway. There is no guarantee that the FDA will accept for filing the Company’s planned NDA for sparsentan for IgAN under the Subpart H approval pathway, that the FDA will grant accelerated approval of sparsentan for IgAN or that sparsentan will be approved at all. The Company faces the risk that the Phase 3 PROTECT Study of sparsentan in IgAN will not demonstrate that sparsentan is safe or effective or serve as a basis for accelerated approval of sparsentan as planned and risk that ongoing clinical trials may not succeed or may be delayed for safety, regulatory or other reasons. In addition, such risks and uncertainties may include those described in the Company’s annual, quarterly and current reports (i.e., Form 10-K, Form 10-Q and Form 8-K) as filed or furnished with the SEC, which are 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 our control. Except to the extent required by law, the Company undertakes no obligation to publicly update any forward-looking statement.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

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: August 16, 2021

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