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 25, 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 May 25, 2021, Travere Therapeutics, Inc. (the “Company”) provided a regulatory update for its sparsentan program in focal segmental glomerulosclerosis (“FSGS”) following the receipt of final meeting minutes from its pre-NDA meeting interactions with the United States Food & Drug Administration (the “FDA”), including feedback from the FDA that the available data from the previously announced interim assessment of the DUPLEX Study would not be adequate to support an accelerated approval at this time. Based on this feedback, the Company does not plan to submit an application for accelerated approval for FSGS in the U.S. with the currently available data set. The FDA has indicated that it may be possible to submit an application for accelerated approval in FSGS after additional data accrue in the ongoing DUPLEX Study. The Company intends to continue the dialogue with the FDA with the objective of identifying a future path to providing sufficient additional estimated glomerular filtration (eGFR) data from the DUPLEX Study for a potential accelerated approval submission in the U.S. for sparsentan in FSGS in 2022.

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 related to the Company’s intentions to continue the dialogue with the FDA with the objective of identifying a future path to providing sufficient additional estimated glomerular filtration (eGFR) data from the DUPLEX Study for a potential accelerated approval submission in the U.S. for sparsentan in FSGS in 2022. 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. There is no guarantee that the Company will be able to reach alignment with the FDA around a future NDA submission for sparsentan for FSGS under the Subpart H approval pathway, including alignment on a pathway of providing additional eGFR data from the DUPLEX Study for a potential accelerated approval submission in the U.S. for sparsentan in FSGS in 2022; that the FDA will grant accelerated approval of sparsentan for FSGS or that sparsentan will be approved at all. The Company faces the risk that the Phase 3 DUPLEX Study of sparsentan in FSGS 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: May 25, 2021

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