# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

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## FORM 8-K

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## Current Report
**Pursuant to Section 13 or 15(d)of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): October 13, 2022

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## TRAVERE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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| **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 October 13, 2022, Travere Therapeutics, Inc. (the “Company”) announced that following late-cycle review interactions with the U.S. Food and Drug Administration (FDA), the Company expects the previously assigned Prescription Drug User Fee Act (PDUFA) target action date of November 17, 2022 for its New Drug Application (NDA) under Subpart H for accelerated approval of sparsentan for the treatment of IgA nephropathy to be extended by three months.

As part of its late-cycle review, the FDA has requested that the Company update its proposed Risk Evaluation Mitigation Strategy (REMS) to include liver monitoring for sparsentan consistent with certain other approved products in the endothelin receptor antagonist class. The Company anticipates submitting an updated REMS plan in the coming days. Based upon feedback from the FDA, the updated submission is likely to be considered a major amendment to the NDA which is expected to result in a three-month extension of the PDUFA target action date to allow sufficient time to review the information. No additional clinical data or studies have been requested as part of the application review process.

**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 “likely to be, "anticipates", "expects" 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 expectation that the updated submission will be considered a major amendment to the NDA and that the PDUFA target action date will be extended by three months and the Company’s anticipated timing for submitting an updated REMS plan. 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. Specifically, 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 the basis for accelerated approval of sparsentan as planned; and the risk that sparsentan will not be approved for efficacy, safety, regulatory or other reasons. There is no guarantee that the updated PDUFA target date, once assigned by the FDA, will be three months from the original PDUFA target action date or that the review process for the sparsentan IgAN NDA will remain on track for the FDA’s updated target action date, once assigned, or that the FDA will grant accelerated approval of sparsentan for IgAN within the assigned target action date, or at all. 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, as filed with the Securities and Exchange Commission on August 4, 2022, and other filings with the Securities and Exchange Commission.

## 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: October 13, 2022

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