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): January 9, 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 2.02 Results of Operations and Financial Condition.

On January 9, 2023, Travere Therapeutics, Inc. (the "Company") issued a press release announcing certain preliminary financial results for the fourth quarter and year ended December 31, 2022. A copy of the press release is attached as Exhibit 99.1 to this current report.

The information in this Item 2.02, and Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 2.02, and Exhibit 99.1 attached hereto, shall not be incorporated by reference into any registration statement or other document filed with the Securities and Exchange Commission, whether filed before or after the date hereof regardless of any general incorporation language in any such filing, unless the registrant expressly sets forth in such filing that such information is to be considered "filed" or incorporated by reference therein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Travere Therapeutics, Inc. dated January 9, 2023.
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: January 9, 2023

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

Exhibit 99.1

Contact:
Naomi Eichenbaum
Vice President, Investor Relations
IR@travere.com
888-969-7879

Travere Therapeutics Provides Corporate Update and 2023 Outlook

Company well-positioned for potential FDA Subpart H approval and commercial launch of sparsentan for IgA nephropathy (IgAN) in 1Q23, followed by potential EMA approval in second half of 2023

Preliminary net product sales of $201 million for the full year 2022

SAN DIEGO, January 9, 2023 – Travere Therapeutics, Inc. (NASDAQ: TVTX) today announced that, based on preliminary and unaudited financial data, the Company expects net product sales for the fourth quarter of 2022 to be approximately $52 million. For the fiscal year 2022, the Company expects total revenue of $212 million, inclusive of approximately $201 million in net product sales and approximately $11 million in licensing and collaboration revenue. The Company ended 2022 with approximately $450 million in cash, cash equivalents and marketable securities. The Company also provided a general update on its development programs, including anticipated milestones for 2023.

"This is a very exciting year for Travere and the rare disease community, with the first potential approvals from our development pipeline of therapies targeting rare diseases with significant unmet needs. We are focused and ready to execute on a successful U.S. commercial launch of sparsentan for IgAN in the first quarter, pending FDA approval following our upcoming PDUFA target action date of February 17, 2023," said Eric Dube, Ph.D., president and chief executive officer of Travere Therapeutics. "We also look forward to additional data from our Phase 3 DUPLEX Study of sparsentan which has the potential to support a supplemental NDA for FSGS, a condition that is currently lacking effective treatment options. Beyond sparsentan, we anticipate the initiation of a Phase 3 program for pegtibatinase, which continues to advance in clinical development with the goal of becoming the first disease-modifying therapy for people living with classical homocystinuria. We anticipate that 2023 will be a pivotal year for us as we pursue our mission of delivering life-changing therapies to people living with rare disease."

Program Updates and Anticipated 2023 Milestones

In 2023, the Company anticipates the first regulatory approvals in the U.S. and Europe for sparsentan, the first and only Dual Endothelin Angiotensin Receptor Antagonist (DEARA) in development for rare kidney disorders. If approved, sparsentan would also become the only non-immunosuppressive treatment indicated for IgAN.

Sparsentan – IgAN

- The U.S. Food and Drug Administration (FDA) is reviewing a New Drug Application (NDA) under Subpart H for accelerated approval of sparsentan for the treatment of IgAN. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of February 17, 2023, and if approved, the Company is well-positioned for commercial launch in the first quarter of 2023.

- In the second half of 2023, the Company together with its collaborator CSL Vifor, 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. If approved, sparsentan would receive CMA in all member states of the European Union, as well as in Iceland, Liechtenstein and Norway.
- In the fourth quarter of 2023, the Company expects to report topline results from the two-year confirmatory endpoints in the ongoing Phase 3 PROTECT Study, which are designed to support traditional approval of sparsentan in IgAN.
- In 2023, the Company plans to expand data generation through a sub study in the open-label extension of the ongoing PROTECT Study, as well as an open-label clinical study to investigate the safety and efficacy of sparsentan in combination with sodium glucose cotransporter-2 inhibitors (SGLT2i) for the treatment of IgAN.

Sparsentan – FSGS

- 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 data supportive of approval, the Company anticipates submitting a supplemental NDA for traditional approval for FSGS in the second half of 2023.
- Pending completion of the DUPLEX Study of sparsentan in FSGS and data supportive of approval, a subsequent variation to the CMA of sparsentan for the treatment of FSGS in Europe is targeted for submission by the end of 2023.

Pegtibatinase (TVT-058) – HCU

The Company continues to advance pegtibatinase, a novel investigational enzyme replacement therapy with the potential to become the first disease-modifying therapy for people living with classical homocystinuria (HCU). Following positive results from the first five cohorts of the ongoing Phase 1/2 COMPOSE Study, the Company is evaluating pegtibatinase in a final cohort in the COMPOSE Study to further inform its potential pivotal development program.

- In the fourth quarter of 2022, enrollment completed in the sixth and final cohort of the ongoing Phase 1/2 COMPOSE Study. The Company anticipates reporting additional data from COMPOSE in mid-2023.
- In parallel with completing the final cohort in the COMPOSE Study, the Company is preparing for the initiation of a pivotal Phase 3 clinical trial of pegtibatinase in patients with HCU in the second half of 2023.

CDCA – CTX

The Company's chenodeoxycholic acid (CDCA) program includes Chenodal (chenodiol), a commercially available product that is under clinical evaluation to include an indication for cerebrotendinous xanthomatosis (CTX), a rare, progressive, and underdiagnosed bile acid synthesis disorder, to its label.

- During 2023, the Company expects to complete the ongoing Phase 3 RESTORE Study in CTX. Pending supportive data, the Company anticipates being in position to subsequently submit an NDA for a CTX indication.

The Company expects to announce complete full year 2022 financial results and provide a corporate update in late February.

About Travere Therapeutics

At Travere Therapeutics, we are in rare for life. We are a biopharmaceutical company that comes together every day to help patients, families and caregivers of all backgrounds as they navigate life with a rare disease. On this path, we know the need for treatment options is urgent – that is why our global team works with the rare disease community to identify, develop and deliver life-changing therapies. In pursuit of this mission, we continuously seek to understand the diverse perspectives of rare patients and to courageously forge new paths to make a difference in their lives and provide hope – today and tomorrow. For more information, visit travere.com.

About Preliminary Financial Results

The preliminary results set forth above are unaudited, are based on management's initial review of the Company's results for the quarter and year ended December 31, 2022 and are subject to revision based upon the Company's year-end closing procedures and the completion and external audit of the Company's year-end financial statements. Actual results may differ materially from these preliminary unaudited results following the completion of year-end closing procedures, final adjustments or other developments arising between now and the time that the Company's financial results are finalized. In addition, these preliminary unaudited results are not a comprehensive statement of the Company's financial results for the year ended December 31, 2022, should not be viewed as a substitute for full, audited financial statements prepared in accordance with generally accepted accounting principles, and are not necessarily indicative of the Company's results for any future period.

Forward Looking Statements

This press release 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 expectations regarding net product sales for the fourth quarter of 2022 and total revenues for fiscal year 2022 based on preliminary and unaudited financial data; potential regulatory approvals of sparsentan for IgAN in 2023 in the U.S. and Europe; the Company's ability to execute on a successful launch of sparsentan in IgAN, if approved; the Company's plans to investigate the safety and efficacy of sparsentan in combination with sodium glucose cotransporter-2 inhibition (SGLT2i) in the treatment of IgAN; the ability to submit for approval of sparsentan in FSGS, pending supportive data; references to the Company's pipeline of potential first-in-class therapies and the Company's ability to deliver new life-changing therapies to people living with rare disease; future plans and timelines for the pegtibatinase program and the potential for the program to deliver the first therapy targeting the underlying deficiency in HCU; and the ability to add CTX to the CDCA label. 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, including the Subpart H accelerated approval pathway in the United States and the conditional marketing authorization (CMA) pathway in the Europe Union, as well as risks and uncertainties associated with the Company's business and finances in general, success of its commercial products and risks and uncertainties associated with the Company's preclinical and clinical stage pipeline. Specifically, the Company faces risks associated with market acceptance of its commercial products including efficacy, safety, price, reimbursement and benefit over competing therapies. The risks and uncertainties the Company faces with respect to its preclinical and clinical stage pipeline include risk that the Company's clinical candidates will not be found to be safe or effective and that current clinical trials will not proceed as planned. 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 a basis for accelerated approval of sparsentan as planned; 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 as planned; and risk that sparsentan 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 accelerated approval of sparsentan for IgAN by the PDUFA target action date, or at all, or that the FDA will grant traditional approval of sparsentan for FSGS. There is also no guarantee that the results from ongoing or future clinical studies of pegtibatinase will be positive or that a Phase 3 clinical program of pegtibatinase will proceed on the Company's anticipated timeline. The Company faces 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; 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 the COVID-19 pandemic may have on its business, including, but not limited to (i) the Company's ability to continue its ongoing development activities and clinical trials, (ii) the timing of such clinical trials and the release of data from those trials, (iii) the Company's and its suppliers' ability to successfully manufacture its commercial products and product candidates, and (iv) 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.