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 8, 2024

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 8, 2024, Travere Therapeutics, Inc. (the "Company") issued a press release announcing certain preliminary financial results for the fourth quarter and year ended December 31, 2023. 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 8, 2024.
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 8, 2024

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

Contact:

Investors:
888-969-7879
ir@travere.com

Media:
888-969-7879
mediarelations@travere.com

Travere Therapeutics Provides Corporate Update and 2024 Outlook

Received 459 new patient start forms for FILSPARI® (sparsentan) in the fourth quarter of 2023; preliminary net product sales of FILSPARI totaled $15 million for the fourth quarter

Company on track to submit sNDA to FDA in Q1 2024 for conversion of the existing U.S. accelerated approval of FILSPARI in IgAN to full approval

CHMP opinion on potential approval of sparsentan for the treatment of IgAN in Europe expected in Q1 2024

Pivotal Phase 3 study of pegtibatinase in classical homocystinuria (HCU) underway

SAN DIEGO, January 8, 2024 – Travere Therapeutics, Inc. (NASDAQ: TVTX) today announced that, based on preliminary and unaudited financial data, the Company expects net product sales from continuing operations for the fourth quarter of 2023 to be approximately $40 million. For the fiscal year 2023, the Company expects net product sales from continuing operations to be approximately $128 million. The Company ended 2023 with approximately $567 million in cash, cash equivalents, and marketable securities which is expected to support operations into 2028. The Company also provided an update on key corporate, clinical, and regulatory development initiatives, including anticipated milestones for 2024.

“Our strong fourth quarter results reflect the growing demand for FILSPARI in IgAN driven by our field teams’ education and outreach efforts to healthcare providers,” said Eric Dube, Ph.D., president and chief executive officer of Travere Therapeutics. “In 2024, we are well-positioned to drive sustained growth of FILSPARI as the only non-immunosuppressive therapy for IgAN through our continued strong commercial execution and the potential conversion from accelerated to full approval. Additionally, we are pleased to have recently initiated the pivotal HARMONY Study for pegtibatinase. We are focused on building momentum for enrollment of this important trial which is designed to support the potential approval of pegtibatinase as the first and only disease-modifying therapy for classical HCU. Looking forward, we believe our efforts will ultimately position FILSPARI and pegtibatinase as new treatment standards in IgAN and classical HCU, clearly helping to address the needs of patients living with these rare diseases.”

Program Updates and Anticipated 2024 Milestones

FILSPARI (sparsentan) is an endothelin and angiotensin II receptor antagonist indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a UPCR ≥1.5 g/g. In 2024, the Company anticipates conversion of FILSPARI from accelerated approval to full approval for IgAN as well as a potential approval for the treatment of IgAN in Europe. The Company is also generating additional data that is expected to support the clinical profile of FILSPARI and it anticipates updates to treatment guidelines for IgAN to include FILSPARI.

FILSPARI (sparsentan) – IgAN

- In the fourth quarter of 2023, the Company received 459 new patient start forms (PSFs), reflecting continued strength in physician demand.
- Preliminary net product sales of FILSPARI in the fourth quarter of 2023 were $15 million; $30 million since the beginning of commercial launch in February 2023.
- The Company is on track to submit a supplemental New Drug Application (sNDA) in the first quarter of 2024 for conversion of the existing U.S. accelerated approval of FILSPARI to full approval.
- Following submission of the two-year results from the PROTECT Study of FILSPARI in IgAN and a corresponding procedural review clock-stop, the Company and its collaborator CSL Vifor anticipate a review opinion by the Committee for Medicinal Products for Human Use (CHMP) on the potential approval of the Conditional Marketing Authorization (CMA) application for sparsentan for the treatment of IgAN in Europe in the first quarter of 2024. If approved, sparsentan would receive CMA in all member states of the European Union, as well as in Iceland, Liechtenstein, and Norway.
- In 2024, the Company expects additional data from its ongoing open-label studies evaluating the safety and efficacy of sparsentan in combination with sodium glucose cotransporter-2 inhibitors (SGLT2i) as well as from the ongoing SPARTAN Study evaluating the potential effect of FILSPARI as a first-line therapy in patients with newly diagnosed IgAN.
- In 2024, the Company anticipates inclusion of FILSPARI into the Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guideline for the Management of Glomerular Diseases.

Sparsentan – Focal Segmental Glomerulosclerosis (FSGS)

- In 2024, the Company is conducting additional analyses of FSGS data and will engage with regulators to evaluate potential regulatory pathways for a sparsentan FSGS indication.

Pegtibatinase – Classical HCU

The Company is advancing pegtibatinase, a novel investigational enzyme replacement therapy with the potential to become the first and only disease-modifying therapy for people living with classical homocystinuria (HCU).

- In December 2023, the Company initiated the pivotal Phase 3 HARMONY Study to support the potential approval of pegtibatinase for the treatment of classical HCU. The HARMONY Study is a global, randomized, multi-center, double-blind, placebo-controlled Phase 3 clinical trial designed to evaluate the efficacy and safety of pegtibatinase as a novel treatment to reduce total homocysteine (tHcy) levels. The trial is expected to enroll approximately 70 patients with a diagnosis of classical HCU and tHcy levels ≥50 μM while maintaining their standard-of-care treatment. Participants will be randomized 1:1 to receive 2.5 mg/kg of pegtibatinase or placebo, administered subcutaneously, for a 24-week blinded treatment duration. The primary endpoint is relative geometric mean change in plasma tHcy levels from baseline compared to weeks 6 through 12. Durability of treatment response through 24 weeks of treatment will also be measured as a secondary endpoint. Topline results from the HARMONY Study are expected in 2026.
- The Company will also be initiating the ENSEMBLE Study, a Phase 3b, open-label, long-term extension, that will evaluate the ongoing efficacy and long-term safety of pegtibatinase in participants with HCU following their completion of the COMPOSE Study or the HARMONY Study. ENSEMBLE will include an optional protein tolerance modification sub-study that will evaluate if patients can increase their natural dietary protein intake and maintain an acceptable level of metabolic control while receiving pegtibatinase.

The Company expects to announce complete full year 2023 financial results and provide a corporate update in February.

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, 2023, 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, 2023, 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.

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 FILSPARI (sparsentan)

FILSPARI (sparsentan) is a once-daily, oral medication designed to selectively target two critical pathways in the disease progression of IgAN (endothelin-1 and angiotensin II) and is the first and only non-immunosuppressive therapy approved for the treatment of this condition. FILSPARI is a prescription medicine indicated to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a UPCR ≥1.5 g/g.

FILSPARI (sparsentan) U.S. Indication

FILSPARI is an endothelin and angiotensin II receptor antagonist indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a UPCR ≥1.5 g/g.

This indication is granted under accelerated approval based on reduction in proteinuria. It has not been established whether FILSPARI slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

FILSPARI (sparsentan) Important Safety Information

BOXED WARNING: HEPATOTOXICITY AND EMBRYO-FETAL TOXICITY

Because of the risks of hepatotoxicity and birth defects, FILSPARI is available only through a restricted program called the FILSPARI REMS. Under the FILSPARI REMS, prescribers, patients and pharmacies must enroll in the program.

Hepatotoxicity

Some Endothelin Receptor Antagonists (ERAs) have caused elevations of aminotransferases, hepatotoxicity, and liver failure. In clinical studies, elevations in aminotransferases (ALT or AST) of at least 3-times the Upper Limit of Normal (ULN) have been observed in up to 2.5% of FILSPARI-treated patients, including cases confirmed with rechallenge.

Measure transaminases and bilirubin before initiating treatment and monthly for the first 12 months, and then every 3 months during treatment. Interrupt treatment and closely monitor patients who develop aminotransferase elevations more than 3x Upper Limit of Normal (ULN).

FILSPARI should generally be avoided in patients with elevated aminotransferases (>3x ULN) at baseline because monitoring for hepatotoxicity may be more difficult and these patients may be at increased risk for serious hepatotoxicity.

Embryo-Fetal Toxicity

FILSPARI can cause major birth defects if used by pregnant patients based on animal data. Therefore, pregnancy testing is required before the initiation of treatment, during treatment and one month after discontinuation of treatment with FILSPARI. Patients who can become pregnant must use effective contraception before the initiation of treatment, during treatment, and for one month after discontinuation of treatment with FILSPARI.

Contraindications: FILSPARI is contraindicated in patients who are pregnant. Do not coadminister FILSPARI with angiotensin receptor blockers (ARBs), endothelin receptor antagonists (ERAs), or aliskiren.

Warnings and Precautions

- **Hepatotoxicity:**

  Hepatotoxicity: Elevations in ALT or AST of at least 3-fold ULN have been observed. To reduce the risk of potential serious hepatotoxicity, measure serum aminotransferase levels and total bilirubin prior to initiation of treatment, monthly for the first 12 months, then every 3 months during treatment.

  Advise patients with symptoms suggesting hepatotoxicity (nausea, vomiting, right upper quadrant pain, fatigue, anorexia, jaundice, dark urine, fever, or itching) to immediately stop treatment with FILSPARI and seek medical attention. If aminotransferase levels are abnormal at any time during treatment, interrupt FILSPARI and monitor as recommended.

  Consider re-initiation of FILSPARI only when hepatic enzyme levels and bilirubin return to pretreatment values and only in patients who have not experienced clinical symptoms of hepatotoxicity.

  Avoid initiation of FILSPARI in patients with elevated aminotransferases (>3x ULN) prior to drug initiation.

- **Embryo-Fetal Toxicity:** FILSPARI can cause fetal harm. Advise patients who can become pregnant of the potential risk to a fetus. Obtain a pregnancy test and advise patients who can become pregnant to use effective contraception prior to, during, and one month after discontinuation of FILSPARI treatment.
- **FILSPARI REMS:** FILSPARI is available only through a restricted program under a REMS called the FILSPARI REMS.

  Important requirements include:

  - Prescribers must be certified with the FILSPARI REMS by enrolling and completing training.
  - All patients must enroll in the FILSPARI REMS prior to initiating treatment and comply with monitoring requirements.
  - Pharmacies that dispense FILSPARI must be certified with the FILSPARI REMS and must dispense only to patients who are authorized to receive FILSPARI.

Further information is available at www.filsparirems.com or 1-833-513-1325.

Please see Full Prescribing Information for FILSPARI here

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 “on-track”, “positioned”, “look forward to”, “will,” “would,” “may”, “might”, “believes”, “anticipates”, “plans”, “expects”, “intends,” “potential” 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: continued progress with the FILSPARI launch and preliminary estimates of metrics related thereto; the planned submission of an sNDA for full approval of FILSPARI and the anticipated timing and outcome thereof; statements regarding the potential approval of sparsentan for the treatment of IgAN in Europe and the anticipated timing thereof; the potential for FILSPARI and pegtibatinase to become new treatment standards in IgAN and HCU; additional development and regulatory milestones, including expected data from additional studies; planned additional analyses of FSGS data and plans and timing for re-engaging with regulators; the advancement of the Company’s pipeline throughout the year; expectations regarding the Phase 3 HARMONY Study; the potential inclusion of FILSPARI in the KDIGO Clinical Practice Guideline for the Management of Glomerular Diseases; statements regarding financial metrics, preliminary estimates thereof, and expectations related thereto, including but not limited to statements regarding net product sales from continuing

operations, revenue, cash balances and cash runway. 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, as well as risks and uncertainties associated with the Company's business and finances in general and its recently announced strategic reorganization, the 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, as well as risks associated with the successful development and execution of commercial strategies for such products, including FILSPARI. 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 or anticipated future clinical trials will not proceed as planned. Specifically, the Company faces risks related to the timing and potential outcome of its Phase 3 HARMONY Study, the timing and potential outcome of its planned sNDA submission for full approval of sparsentan in IgAN, and the risk that the results from the Phase 3 DUPLEX Study of sparsentan in FSGS will not serve as a basis for a regulatory submission for approval of sparsentan for FSGS. There is no guarantee that regulators will grant full approval of sparsentan for IgAN or FSGS. The Company also faces the risk that its cash runway might not last as long as currently anticipated and 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 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, 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.