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 13, 2025

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 13, 2025, Travere Therapeutics, Inc. (the "Company") issued a press release announcing certain preliminary financial results for the fourth quarter and year ended December 31, 2024. 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 13, 2025.
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 13, 2025

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

EXHIBIT 99.1

Contact:

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

Travere Therapeutics Provides Corporate Update and 2025 Outlook

Received 693 new patient start forms for FILSPARI® (sparsentan) in the fourth quarter of 2024; approximately $50 million in preliminary net product sales of FILSPARI for the fourth quarter

sNDA requesting modification of liver monitoring for FILSPARI in IgAN accepted for review by FDA; PDUFA target action date of August 28, 2025

Company remains on track to provide regulatory update on sparsentan in FSGS by its fourth quarter 2024 earnings call

SAN DIEGO, January 13, 2025 – 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 2024 to be approximately $74 million. For the fiscal year 2024, the Company expects net product sales to be approximately $227 million. The Company ended 2024 with approximately $371 million in cash, cash equivalents, and marketable securities. The Company also provided an update on key corporate, clinical, and regulatory development initiatives, including anticipated 2025 milestones.

“The fourth quarter capped a tremendous year of execution for Travere. Following full approval of FILSPARI in September, the ongoing U.S. commercial launch resulted in nearly 700 new patient start forms in the fourth quarter as well as a 40% increase in FILSPARI net product sales compared to the third quarter,” said Eric Dube, Ph.D., president and chief executive officer of Travere Therapeutics. “As we look ahead to the new year, we expect to help even more patients with IgAN through continued strong commercial execution, the final publication of the updated KDIGO guidelines and potential approval of the recently accepted sNDA to modify liver monitoring for FILSPARI. Beyond IgAN, we believe that sparsentan has the potential to become an important new medicine for people with FSGS, and we remain on track to provide an update on our interactions with FDA to establish a potential regulatory pathway for this additional indication by our fourth quarter 2024 earnings call.”

Program Updates and Anticipated 2025 Milestones

FILSPARI® (sparsentan) – IgA Nephropathy (IgAN)

- In the fourth quarter of 2024, the Company received 693 new patient start forms (PSFs), driven by growth amongst new and repeat prescribers following full approval by the U.S. Food and Drug Administration (FDA) on September 5, 2024.
- Preliminary net product sales of FILSPARI in the fourth quarter of 2024 were approximately $50 million; $132 million for the full year 2024.
- The FDA recently accepted for review the Company’s supplemental New Drug Application (sNDA) requesting modification of liver monitoring for FILSPARI in IgAN and assigned a PDUFA target action date of August 28, 2025.
- In 2025, the Company anticipates final publication of the updated Kidney Disease Improving Global Outcomes (KDIGO) clinical guidelines for IgAN. The draft guidelines published in August 2024 recommended FILSPARI as a foundational kidney-targeted therapy and lowered the targeted proteinuria level for all IgAN patients to under 0.5 g/day or ideally complete remission (under 0.3 g/day).
- In 2025, the Company anticipates presenting additional data from its ongoing clinical studies to further support FILSPARI as foundational therapy in treating patients with IgAN.
- The Company’s collaborator CSL Vifor has launched FILSPARI for the treatment of IgAN in Germany, Austria, and Switzerland. FILSPARI also recently received approval in the UK.
- In 2025, the Company and CSL Vifor anticipate the current conditional marketing authorization (CMA) for FILSPARI for the treatment of IgAN in Europe will be converted to full approval. The Company expects to receive a $17.5 million milestone payment from CSL Vifor upon conversion of the CMA to full approval, and the Company remains eligible to receive additional milestone payments related to market access and sales-based achievements.

- In the second half of 2025, Travere's partner Renalys Pharma, Inc. expects topline results from its registrational Phase 3 clinical trial of sparsentan for the treatment of IgA nephropathy in Japan.

Sparsentan – Focal Segmental Glomerulosclerosis (FSGS)

- The Company remains on track to provide an update on interactions with the FDA regarding a potential regulatory pathway for a sparsentan FSGS indication by its fourth quarter 2024 earnings call.

Pegtibatinase – Classical Homocystinuria (HCU)

- The Company is making progress on necessary process improvements in manufacturing scale-up and is on track to restart enrollment in the Phase 3 HARMONY Study in 2026.

The Company expects to announce complete full year 2024 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, 2024, 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, 2024, 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.

FILSPARI® (sparsentan) U.S. Indication

FILSPARI (sparsentan) is indicated to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.

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 3.5% 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 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), ERAs, or aliskiren.

Warnings and Precautions

- **Hepatotoxicity:** Elevations in ALT or AST of at least 3-fold ULN have been observed in up to 3.5% of FILSPARI-treated patients, including cases confirmed with rechallenge. While no concurrent elevations in bilirubin >2-times ULN or cases of liver failure were

observed in FILSPARI-treated patients, some ERAs have caused elevations of aminotransferases, hepatotoxicity, and liver failure. To reduce the risk of potential serious hepatotoxicity, measure serum aminotransferase levels and total bilirubin prior to initiation of treatment and 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 because monitoring hepatotoxicity in these patients may be more difficult and these patients may be at increased risk for serious hepatotoxicity.

- **Embryo-Fetal Toxicity:** FILSPARI can cause fetal harm when administered to a pregnant patient and is contraindicated during pregnancy. Advise patients who can become pregnant of the potential risk to a fetus. Obtain a pregnancy test prior to initiation of treatment with FILSPARI, monthly during treatment, and one month after discontinuation of treatment. Advise patients who can become pregnant to use effective contraception prior to initiation of treatment, during treatment, and for one month after discontinuation of treatment with FILSPARI.
- **FILSPARI REMS:** Due to the risk of hepatotoxicity and embryo-fetal toxicity, FILSPARI is available only through a restricted program called the FILSPARI REMS. Prescribers, patients, and pharmacies must be enrolled in the REMS program and comply with all requirements (www.filsparirems.com).
- **Hypotension:** Hypotension has been observed in patients treated with ARBs and ERAs. There was a greater incidence of hypotension-associated adverse events, some serious, including dizziness, in patients treated with FILSPARI compared to irbesartan. In patients at risk for hypotension, consider eliminating or adjusting other antihypertensive medications and maintaining appropriate volume status. If hypotension develops, despite elimination or reduction of other antihypertensive medications, consider a dose reduction or dose interruption of FILSPARI. A transient hypotensive response is not a contraindication to further dosing of FILSPARI, which can be given once blood pressure has stabilized.
- **Acute Kidney Injury:** Monitor kidney function periodically. Drugs that inhibit the renin-angiotensin system (RAS) can cause kidney injury. Patients whose kidney function may depend in part on the activity of the RAS (e.g., patients with renal artery stenosis, chronic kidney disease, severe congestive heart failure, or volume depletion) may be at particular risk of developing acute kidney injury on FILSPARI. Consider withholding or discontinuing therapy in patients who develop a clinically significant decrease in kidney function while on FILSPARI.
- **Hyperkalemia:** Monitor serum potassium periodically and treat appropriately. Patients with advanced kidney disease, taking concomitant potassium-increasing drugs (e.g., potassium supplements, potassium-sparing diuretics), or using potassium-containing salt substitutes are at increased risk for developing hyperkalemia. Dosage reduction or discontinuation of FILSPARI may be required.
- **Fluid Retention:** Fluid retention may occur with ERAs, and has been observed in clinical studies with FILSPARI. FILSPARI has not been evaluated in patients with heart failure. If clinically significant fluid retention develops, evaluate the patient to determine the cause and the potential need to initiate or modify the dose of diuretic treatment then consider modifying the dose of FILSPARI.

Most common adverse reactions

The most common adverse reactions (≥5%) are hyperkalemia, hypotension (including orthostatic hypotension), peripheral edema, dizziness, anemia, and acute kidney injury.

Drug interactions

- **Renin-Angiotensin System (RAS) Inhibitors and ERAs:** Do not coadminister FILSPARI with ARBs, ERAs, or aliskiren due to increased risks of hypotension, syncope, hyperkalemia, and changes in renal function (including acute renal failure).
- **Strong and Moderate CYP3A Inhibitors:** Avoid concomitant use of FILSPARI with strong CYP3A inhibitors. If a strong CYP3A inhibitor cannot be avoided, interrupt FILSPARI treatment. When resuming treatment with FILSPARI, consider dose titration. Monitor blood pressure, serum potassium, edema, and kidney function regularly when used concomitantly with moderate CYP3A inhibitors. Concomitant use with a strong CYP3A inhibitor increases sparsentan exposure which may increase the risk of FILSPARI adverse reactions.
- **Strong CYP3A Inducers:** Avoid concomitant use with a strong CYP3A inducer. Concomitant use with a strong CYP3A inducer decreases sparsentan exposure which may reduce FILSPARI efficacy.
- **Antacids and Acid Reducing Agents:** Administer FILSPARI 2 hours before or after administration of antacids. Avoid concomitant use of acid reducing agents (histamine H2 receptor antagonist and PPI proton pump inhibitor) with FILSPARI. Sparsentan exhibits pH-dependent solubility. Antacids or acid reducing agents may decrease sparsentan exposure which may reduce FILSPARI efficacy.
- **Non-Steroidal Anti-Inflammatory Agents (NSAIDs), Including Selective Cyclooxygenase-2 (COX-2) Inhibitors:** Monitor for signs of worsening renal function with concomitant use with NSAIDs (including selective COX-2 inhibitors). In patients with volume depletion

(including those on diuretic therapy) or with impaired kidney function, concomitant use of NSAIDs (including selective COX-2 inhibitors) with drugs that antagonize the angiotensin II receptor may result in deterioration of kidney function, including possible kidney failure.

- **CYP2B6, 2C9, and 2C19 Substrates:** Monitor for efficacy of concurrently administered CYP2B6, 2C9, and 2C19 substrates and consider dosage adjustment in accordance with the Prescribing Information. Sparsentan decreases exposure of these substrates, which may reduce efficacy related to these substrates.
- **P-gp and BCRP Substrates:** Avoid concomitant use of sensitive substrates of P-gp and BCRP with FILSPARI. Sparsentan may increase exposure of these transporter substrates, which may increase the risk of adverse reactions related to these substrates.
- **Agents Increasing Serum Potassium:** Monitor serum potassium frequently in patients treated with FILSPARI and other agents that increase serum potassium. Concomitant use of FILSPARI with potassium-sparing diuretics, potassium supplements, potassium-containing salt substitutes, or other drugs that raise serum potassium levels may result in hyperkalemia.

Please see the full Prescribing Information, including BOXED WARNING, for additional Important Safety Information.

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 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 trends and preliminary estimates of metrics related thereto; statements regarding the FDA’s review of the sNDA requesting modification of liver monitoring for FILSPARI in IgAN and the anticipated timing and outcome thereof; expectations for the presentation of additional data to further support FILSPARI as foundational therapy in treating patients with IgAN; statements regarding the potential full approval of sparsentan for the treatment of IgAN in Europe, the anticipated timing thereof, and potential milestone payments related to full approval, market access and sales-based achievements in Europe; additional development and regulatory milestones, including expected data from the studies described herein and the potential outcome and timing thereof; statements regarding the potential for sparsentan to become an important new medicine for people with FSGS, and the Company’s plans to provide an update on interactions with the FDA regarding establishing a potential regulatory pathway for sparsentan in FSGS and the anticipated timing and outcome thereof; statements regarding the Phase 3 HARMONY Study, including expectations regarding process improvements and the potential timeline to restart enrollment; statements and expectations regarding the KDIGO guidelines; statements regarding financial metrics, preliminary estimates thereof, and expectations related thereto, including but not limited to statements regarding net product sales from continuing operations and cash balances. 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 related to the timing and outcome of the studies described herein and uncertainties associated with the regulatory review and approval process, as well as risks and uncertainties associated with enrollment of clinical trials for rare diseases, and risks that ongoing or planned clinical trials may not succeed or may be delayed for safety, regulatory or other reasons. The Company also faces risks related to its business and finances in general, the success of its commercial products and risks and uncertainties associated with its preclinical and clinical stage pipeline. Specifically, the Company faces risks associated with the ongoing commercial launch of FILSPARI, the timing and potential outcome of its and its partners’ clinical studies, the timing and potential outcome of the FDA’s review of the sNDA requesting modification of liver monitoring for FILSPARI in IgAN, the regulatory approval process in Europe and the ability to receive certain milestone payments under the license agreement with CSL Vifor, market acceptance of its commercial products including efficacy, safety, price, reimbursement, and benefit over competing therapies, risks related to the challenges of manufacturing scale-up, risks associated with the successful development and execution of commercial strategies for such products, including FILSPARI, and risks related to the outcome of the Company’s interactions with FDA regarding establishing a potential regulatory pathway for sparsentan in FSGS. There is no guarantee that regulators will grant approval of sparsentan for FSGS. 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. The Company also faces 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.