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): FEBRUARY 10, 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 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

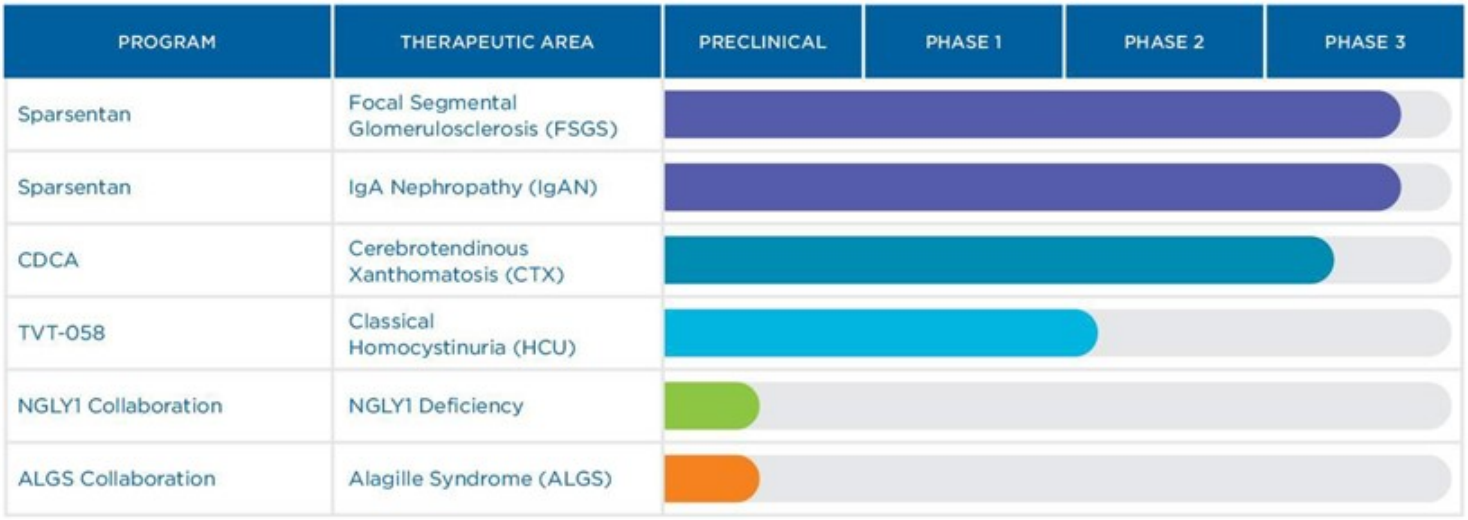
The information under the heading “Recent Developments—Certain Preliminary 2020 Financial Results” in Item 8.01 of this report is incorporated by reference under this Item 2.02.

ITEM 8.01 OTHER EVENTS.

We are filing the following information for the purpose of updating certain aspects of our publicly disclosed description of our business contained in our other filings with the Securities and Exchange Commission.

Our Product Candidates and Approved Products

The following table summarizes the status of our product candidates and products on the market, each of which is described in further detail below.



* CDCA is not indicated for CTX but has received a medical necessity determination in the US by the FDA for CTX. Travere Therapeutics is conducting a Phase 3 clinical trial to examine the safety and efficacy of CDCA (Chenodal®) for the treatment of CTX.

** TVT-058 is currently in a Phase 1/2 clinical study.

We currently have the following product candidates in clinical development:

Sparsentan (RE-021)

Sparsentan, also known as RE-021, is an investigational product candidate designed with a dual mechanism of action as a selective endothelin receptor antagonist that has shown in vitro selectivity toward endothelin receptor type A, and as a potent angiotensin receptor blocker. Sparsentan is currently being evaluated in two pivotal Phase 3 clinical studies intended to support submission of a New Drug Application (“NDA”) under the Subpart H accelerated approval pathway in the following indications:

- **Focal segmental glomerulosclerosis, or FSGS**, is a rare kidney disease characterized by proteinuria where the glomeruli become progressively scarred. FSGS is a leading cause of end-stage renal disease.
- **Immunoglobulin A nephropathy, or IgAN**, is an immune-complex-mediated glomerulonephritis characterized by hematuria, proteinuria, and variable rates of progressive renal failure. IgAN, while considered rare, is the most common primary glomerular disease.

Chenodal

In January 2020, we randomized the first patients in a Phase 3 clinical trial to evaluate the effects of Chenodal in adult and pediatric patients with CTX. The pivotal study, known as the RESTORE study, is intended to support a NDA submission for marketing authorization of Chenodal for the treatment of CTX in the United States. Chenodal has also been the standard of care for CTX patients for more than three decades but is not currently approved for this indication.

TVT-058

TVT-058 (previously OT-58) is a novel investigational human enzyme replacement candidate being evaluated for the treatment of classical homocystinuria (HCU). Classical HCU is a rare metabolic disorder characterized by elevated levels of plasma homocysteine that can lead to vision, skeletal, circulatory and central nervous system issues. TVT-058 is currently being tested in a Phase 1/2 double blind, randomized, placebo-controlled dose escalation study to assess its safety, tolerability, pharmacokinetics,

pharmacodynamics and clinical effects in patients with classical HCU. At this time, topline data from the ongoing Phase 1/2 study are expected to become available in the third quarter of 2021. TVT-058 has been granted Rare Pediatric Disease designation for treatment of cystathionine B-synthase deficiency homocystinuria and Fast Track designation for treatment of cystathionine B-synthase deficiency homocystinuria by the FDA, as well as orphan drug designation in the United States for the treatment of homocystinuria and Europe for the treatment of homocystinuria. It is estimated that there are at least 3,500 people living with HCU in the US with similar numbers in Europe. We acquired TVT-058 as part of the November 2020 acquisition of Orphan Technologies Limited.

Cooperative Research and Development Agreements, or CRADAs

We are a participant in two CRADAs, which form a multi-stakeholder approach to pool resources with leading experts, and incorporate the patient perspective early in the identification and development process. We have partnered with the National Institutes of Health's National Center for Advancing Translational Sciences and leading patient advocacy organizations, NGLY1.org and Alagille Syndrome Alliance, aimed at the identification of potential small molecule therapeutics for NGLY1 deficiency and Alagille syndrome, respectively. There are no treatment options currently approved for these diseases.

We currently sell the following products:

- **Chenodal (chenodeoxycholic acid)** is approved in the United States for the treatment of patients suffering from gallstones in whom surgery poses an unacceptable health risk due to disease or advanced age. Chenodal has also been the standard of care for CTX patients for more than three decades and we are currently pursuing adding this indication to the label.
- **Cholbam (cholic acid)** is approved in the United States for the treatment of bile acid synthesis disorders due to single enzyme defects and is further indicated for adjunctive treatment of patients with certain peroxisomal disorders.
- **Thiola and Thiola EC (tiopronin)** are approved in the United States for the prevention of cystine (kidney) stone formation in patients with severe homozygous cystinuria. On June 28, 2019, we announced that the U.S. Food and Drug Administration approved 100 mg and 300 mg tablets of Thiola EC, a new enteric-coated formulation of Thiola, to be used for the treatment of cystinuria. Thiola EC offers the potential for administration with or without food, and the ability to reduce the number of tablets necessary to manage cystinuria. Thiola EC became available to patients in July 2019.

Recent Developments

Certain Unaudited Preliminary 2020 Financial Results

Although our financial results as of and for the fourth quarter and full year ended December 31, 2020 are not yet finalized, based on currently available information, we expect net product sales for the fourth quarter of 2020 to be approximately $51.0 million, net product sales for the full year ended December 31, 2020 to be approximately $198.3 million, operating expenses for the full year ended December 31, 2020 to be approximately $374.5 million (of which approximately $97.1 million is related to in process research and development expense associated with our acquisition of Orphan Technologies Limited in November 2020), and our cash, cash equivalents and available-for-sale debt securities as of December 31, 2020 to be approximately $361.6 million.

The preliminary results set forth above are based on management's initial review of our operations for the quarter and full year ended December 31, 2020 and are subject to revision based upon our year-end closing procedures and the completion and external audit of the our year-end financial statements. Our independent registered public accounting firm has not audited these preliminary financial results. Actual results may differ materially from these preliminary results as a result of the completion of year-end closing procedures, final adjustments, and other developments arising between now and the time that our financial results are finalized. In addition, these preliminary results are not a comprehensive statement of our financial results for the fourth quarter or full year ended December 31, 2020, 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 our results for any future period.

Interim Results from Phase 3 DUPLEX Study

In February 2021, we announced that our ongoing pivotal Phase 3 DUPLEX Study of sparsentan in focal segmental glomerulosclerosis ("FSGS") achieved its pre-specified interim FSGS partial remission of proteinuria endpoint ("FPRE") after 36 weeks of treatment. Consistent with prior guidance, we are providing limited data from the interim analyses to maintain trial integrity in the ongoing study.

In the DUPLEX Study, a total of 371 patients were randomized 1:1 to receive either sparsentan or irbesartan, the active control. The study protocol provided for an unblinded analysis to evaluate the interim efficacy endpoint – the proportion of patients achieving FPRE, which is a clinically meaningful endpoint defined as urine protein-to-creatinine ratio (UP/C) £1.5 g/g and a >40 percent reduction in UP/C from Baseline, at Week 36 – following the first approximately 190 patients reaching 36 weeks of treatment. After 36 weeks of treatment, 42.0 percent of patients receiving sparsentan achieved FPRE, compared to 26.0 percent of irbesartan-treated patients (p=0.0094). A preliminary review of the interim safety results indicates that to date in the study, sparsentan has been generally well-tolerated and the overall safety results in the study to date have been generally comparable between treatment groups.

The confirmatory primary endpoint of the DUPLEX Study to support full regulatory approval is the rate of change in eGFR over 108 weeks of treatment. As of the time of the interim analyses, available long-term eGFR data for the confirmatory endpoint were limited. Consistent with the DUPLEX Study protocol, patients will continue in a blinded manner to assess the treatment effect on eGFR slope over 108 weeks in the confirmatory endpoint analysis. The DUPLEX Study is fully enrolled and topline results from the confirmatory endpoint are expected in the first half of 2023.

Based on the data from the interim analysis, we intend to pursue submissions for accelerated approval of sparsentan for FSGS under the Subpart H regulatory pathway in the United States and pursuant to Conditional Marketing Authorization (“CMA”) in Europe. During the first half of 2021, we plan to have a pre-NDA meeting with the U.S. Food and Drug Administration (“FDA”), and to initiate corresponding interactions with the European Medicines Agency (“EMA”), to discuss the ongoing study and to establish next steps for filing with the available data set.

It is possible that FDA or EMA could disagree with our planned submission of an NDA under Subpart H for accelerated approval, or a Marketing Approval Application (“MAA”) under the CMA pathway, based on the existing data. In that case, there would be a delay in our submission timeline, including the possibility of foregoing submissions for accelerated approval and instead awaiting results from the confirmatory endpoint before determining whether to submit applications for regulatory approval. Also, there is no guarantee that the FDA will accept for filing the NDA under the Subpart H pathway. If the FDA or EMA agree to review our regulatory submissions for accelerated approval, we expect that their determination as to whether the sufficiency of the interim data from the DUPLEX Study supports an accelerated approval in either jurisdiction will be made based on the totality of the data, including eGFR data available at the time of the regulatory submissions. The FDA or EMA may deem our achievement of statistical significance on the interim FPRE endpoint to be insufficient to grant accelerated approval or Conditional Marketing Authorization. In addition, interim data may not be predictive of final data, and even if sparsentan is granted accelerated approval for FSGS, the results from the confirmatory primary endpoint of the DUPLEX trial may not support full approval of sparsentan as a treatment for FSGS.

ITEM 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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: February 10, 2021

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