UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☑ ***ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934***

For the Fiscal Year Ended December 31, 2025

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

Commission File Number: 001-36257

TRAVERE THERAPEUTICS, INC.

(Exact Name of Registrant as specified in its Charter)

Delaware	**27-4842691**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

3611 Valley Centre Drive, Suite 300

San Diego, CA 92130

(Address of Principal Executive Offices)

888-969-7879

(Registrant's telephone number, including area code)

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**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☑ Yes ☐ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ☐ Yes ☑ No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☑ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☑ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☑	Accelerated Filer	☐
Non-Accelerated Filer	☐	Smaller Reporting Company	☐
		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 7(a)(2)(B) of the Securities Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☑

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☑ No

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter. $1,309,524,306.

The number of shares of outstanding common stock, par value $0.0001 per share, of the registrant as of February 13, 2026 was 92,241,550.

DOCUMENTS INCORPORATED BY REFERENCE: Portions of the Proxy Statement for the registrant's 2026 Annual Meeting of Stockholders, to be filed within 120 days after the conclusion of the registrant's fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K.

FORM 10-K REPORT INDEX

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Certain information contained in this Annual Report on Form 10-K of Travere Therapeutics, Inc., a Delaware corporation (the “Company”) include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The statements herein which are not historical reflect our current expectations and projections about the Company’s future results, performance, liquidity, financial condition, prospects and opportunities and are based upon information currently available to the Company's management and is subject to its interpretation of what are believed to be significant factors affecting the Company's business, including many assumptions regarding future events. Such forward-looking statements include statements regarding, among other things:

- the estimated prevalence and/or addressable patient populations for FILSPARI® (sparsentan) in Immunoglobulin A nephropathy ("IgAN");
- the estimated prevalence and/or addressable patient populations related to our other products and products in development;
- expectations regarding our pivotal Phase 3 HARMONY Study to support the potential approval of pegtibatinase for the treatment of classical homocystinuria ("HCU"), including expectations regarding timing and the outcome thereof;
- expectations regarding the potential for sparsentan in focal segmental glomerulosclerosis ("FSGS") and related matters, including an anticipated new Prescription Drug User Fee Act ("PDUFA") target action date of April 13, 2026 for our supplemental new drug application ("sNDA") for FSGS;
- our ability to produce, sustain and expand sales of our products;
- our ability to develop, acquire and/or introduce new products including expectations with regard to clinical trials and preclinical studies;
- expectations regarding potential future milestone and royalty payments;
- our projected future sales, profitability, savings and other financial metrics;
- our future financing plans;
- our anticipated needs for working capital;
- the anticipated trends in our industry;
- acquisitions of other companies or assets that we might undertake in the future;
- our operations in the United States and abroad, and the domestic and foreign regulatory, economic and political conditions; and
- competition existing today or that will likely arise in the future.

Forward-looking statements, which involve assumptions and describe our future plans, strategies and expectations, are generally identifiable by use of the words “may,” “should,” “expect,” “anticipate,” “estimate,” “believe,” “intend,” “seek,” or “project” or the negative of these words or other variations on these words or comparable terminology. Actual results, performance, liquidity, financial condition and results of operations, prospects and opportunities could differ materially from those expressed in, or implied by, these forward-looking statements as a result of various risks, uncertainties and other factors, including the ability to raise sufficient capital to continue the Company’s operations. Actual events or results may differ materially from those discussed in forward-looking statements as a result of various factors, including, without limitation, the risks outlined under “Risk Factors” and matters described in this Annual Report generally. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information provides a reasonable basis for these statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

In light of these risks and uncertainties, there can be no assurance that the forward-looking statements contained in this Annual Report will in fact occur. Potential investors should not place undue reliance on any forward-looking statements. Except as expressly required by the federal securities laws, there is no undertaking to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changed circumstances or any other reason.

The specific discussions in this Annual Report about the Company include financial projections and future estimates and expectations about the Company's business. The projections, estimates and expectations are presented in this Annual Report only as a guide about future possibilities and do not represent actual amounts or assured events. All the projections and estimates are based exclusively on the Company management's own assessment of the business, the industry in which it works and the economy at large and other operational factors, including capital resources and liquidity, financial condition, fulfillment of contracts and opportunities. The actual results may differ significantly from the projections.

Potential investors should not make an investment decision based solely on the Company's projections, estimates or expectations.

Risk Factor Summary

Below is a summary of material factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found under the heading "Risk Factors" in Item 1A of Part I of this Annual Report on Form 10-K and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC before making investment decisions regarding our common stock.

- Our future prospects are highly dependent upon our ability to successfully develop and execute commercialization strategies for our products, including FILSPARI, and to attain market acceptance among physicians, patients and healthcare payers.
- In order to operate our business and increase adoption and sales of our products, we need to continue to develop our commercial organization, including maintaining a highly experienced and skilled workforce with qualified sales representatives.
- We face substantial generic and other competition, and our operating results will suffer if we fail to compete effectively.
- Healthcare reform initiatives, unfavorable pricing regulations and changes in reimbursement practices of third-party payers or patients' access to insurance coverage could affect the pricing of and demand for our products.
- We are dependent on third parties to manufacture and distribute our products.
- Our clinical trials are expensive and time-consuming and may fail to demonstrate the safety and efficacy of our product candidates.
- Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful.
- Communications and/or feedback from regulatory authorities related to our current or planned future clinical trials does not guarantee any particular outcome from or timeline for regulatory review, and expedited regulatory review pathways may not actually lead to faster development or approval.
- Interim, topline and preliminary data from our clinical trials that we announce or publish may change materially as more patient data become available and audit and verification procedures are complete.
- The market opportunities for our products and product candidates may be smaller than we believe they are.
- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or commercialization.
- We do not currently have patent protection for certain of our commercial products. If we are unable to obtain and maintain protection for the intellectual property relating to our technology and products, their value will be adversely affected.
- We expect to rely on orphan drug status to develop and commercialize certain of our products and product candidates, but our orphan drug designations may not confer marketing exclusivity or other expected commercial benefits.
- If we are unable to obtain and maintain coverage and adequate reimbursement from governments or third-party payers for any products that we may develop or if we are unable to obtain acceptable prices for those products, our prospects for generating revenue and achieving profitability will suffer.
- International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.
- We will likely experience fluctuations in operating results and could incur substantial losses.
- Negative publicity regarding any of our products could impair our ability to market any such product and may require us to spend time and money to address these issues.
- We may need substantial funding and may be unable to raise capital when needed.
- We may not receive some or all of the potential milestone and/or royalty payments from our corporate and licensing transactions.
- We may be unable to successfully integrate new products or businesses we may acquire.

- We may become involved in litigation matters, which could result in substantial costs, divert management's attention and otherwise have a material adverse effect on our business, operating results or financial condition.

- We are subject to significant ongoing regulatory obligations and oversight, which may result in significant additional expense and may limit our commercial success.

PART I

In this Annual Report on Form 10-K, unless the context requires otherwise, the terms “we”, “our”, “us”, “Travere” and the “Company” refer to Travere Therapeutics, Inc., a Delaware corporation, as well as our direct and indirect subsidiaries.

We own or have rights to various trademarks used in our business, including those referenced in the subsection of Item 1 below titled “Trademarks”. Our logos and trademarks are the property of Travere Therapeutics, Inc. All other brand names or trademarks appearing in this report are the property of their respective holders.

ITEM 1. BUSINESS

Those statements in the following discussion that are not historical in nature should be considered forward-looking statements that are inherently uncertain. Actual results and the timing of the events may differ materially from those contained in these forward-looking statements due to a number of factors, including those discussed in the “Cautionary Statement Regarding Forward-Looking Statements” and “Risk Factors” set forth elsewhere in this Annual Report.

Overview

We are a biopharmaceutical company headquartered in San Diego, California, focused on identifying, developing and delivering life-changing therapies to people living with rare kidney and metabolic diseases. Our approach centers on advancing our innovative pipeline with multiple late-stage clinical programs targeting rare diseases with significant unmet medical needs.

In September 2024, the U.S. Food and Drug Administration ("FDA") granted full approval to our lead development program, FILSPARI (sparsentan), which is indicated to slow kidney function decline in adults with primary Immunoglobulin A nephropathy ("IgAN") who are at risk of disease progression. IgAN is a rare progressive kidney disease and the most common type of primary glomerulonephritis worldwide. FILSPARI had previously been granted accelerated approval for IgAN in February 2023 based on the surrogate marker of proteinuria. Full approval was based on positive long-term confirmatory results from the PROTECT Study demonstrating that FILSPARI significantly slowed kidney function decline over two years compared to irbesartan.

Sparsentan is also in late-stage development for focal segmental glomerulosclerosis ("FSGS"). FSGS is a rare kidney disease and leading cause of kidney failure with no approved treatment options. In February 2025, we announced that we had completed a Type C meeting with the FDA and in March 2025, we announced that we had submitted an sNDA to the FDA seeking traditional approval of FILSPARI for the treatment of FSGS. In May 2025, we announced that the FDA accepted the sNDA, assigned a PDUFA target action date of January 13, 2026, and initially indicated that it planned to hold an advisory committee meeting to discuss the application. In September 2025, following further review of the sNDA, the FDA informed us that an advisory committee meeting was no longer needed. In January 2026, we announced that the FDA extended the review timeline for the sNDA, and the new PDUFA target action date is April 13, 2026. The extension followed the recent submission of responses requested by the FDA to further characterize the clinical benefit of FILSPARI. The FDA determined that the additional responses constituted a Major Amendment to the sNDA and extended the action date accordingly. The sNDA remains under review by the FDA with a PDUFA target action date of April 13, 2026.

We are also advancing pegtibatinase, a novel investigational enzyme replacement therapy for the treatment of HCU, a genetic disorder caused by a deficiency in a pivotal enzyme essential to the body. We are conducting a pivotal Phase 3 study to support the potential approval of pegtibatinase as the first disease modifying therapy for HCU. In September 2024, we announced a voluntary pause of enrollment in the Phase 3 HARMONY Study. The voluntary enrollment pause enabled us to address necessary process improvements in manufacturing scale-up to support initial commercial scale manufacturing as well as full enrollment in the HARMONY Study. Following further optimization of the manufacturing process in 2025, we restarted enrollment activities for the pivotal Phase 3 HARMONY Study in the first quarter of 2026.

In addition, we continue to evaluate potential opportunities to expand our pipeline and approved products through licenses and acquisitions of products in areas that will serve rare disease patients with serious unmet medical need and that we believe offer attractive growth characteristics. Our research and development efforts are at the forefront of our mission to address the unmet needs of patients and we support this innovation by reinvesting revenues from our commercialized products. We are committed to ensuring broad access and educational and diagnostic support for patients.

Our Strategy

Our vision is to become a leading biopharmaceutical company dedicated to the delivery of innovation and hope to patients in the global rare disease community. In order to achieve our vision, we intend to:

- **Focus on developing products to treat rare diseases characterized by severe unmet medical needs.** We believe that our research, development, and commercialization capabilities in rare disease represent distinct competitive advantages. We leverage our development

capabilities in rare disease to focus on advancing therapeutic candidates with life-changing potential. Given these capabilities, the well-established regulatory model and the ability to demonstrate clinical effects in small clinical studies, we believe that we can successfully bring new therapies to patients living with severe unmet medical needs.

- **Leverage our commercialization expertise to effectively deliver the therapies we develop.** Our strategy is to maximize the benefit and value of our commercial products through commercial execution and expertise needed to successfully support rare disease patients. Our approach may vary depending on the product and will be based on a number of factors including capital necessary to execute on each option, size of the market and terms of potential collaboration and/or licensing offers from other pharmaceutical and biotechnology companies with respect to jurisdictions outside the United States.

- **Develop a sustainable pipeline by employing disciplined decision criteria in the evaluation of potential in-licensing candidates.** We seek to build a sustainable product pipeline by employing multiple therapeutic approaches and by developing or acquiring orphan drug candidates. We seek to augment our internally developed pipeline projects by selectively and strategically acquiring pipeline assets that will add value to the portfolio. We continue to evaluate potential in-licensing, out-licensing and other potential relationships with other pharmaceutical or biotechnology companies. We intend to mitigate risk by employing rigorous decision criteria, favoring therapeutic candidates that have undergone at least some clinical study. Our decision to acquire rights to a therapeutic candidate also depends on the scientific merits of the available clinical data; the identifiable orphan patient population; the economic terms of any proposed acquisition of rights; the projected amount of capital required to develop the therapeutic candidate; and the economic potential of the therapeutic candidate, should it be commercialized. We believe this strategy minimizes our clinical development risk and allows us to accelerate the development and potential commercialization of current and future therapeutic candidates.

- **Listen to patients.** Leadership in rare disease demands attention beyond innovative medicines. By listening to patients and leaders in the rare disease community, including those who have traditionally been underserved, we are focusing on barriers that prevent some patients from accessing the incredible innovation that our industry is delivering, including access to clinical trials and rare disease specialists.

- **Support earlier diagnosis.** We support efforts in furtherance of enabling earlier diagnosis. The growth of our commercial business reflects the strong capabilities of our commercial and medical teams to work across multiple medical specialties to help patients find a diagnosis.

Our Pipeline and Approved Products

We have a diversified pipeline designed to address areas of high unmet need in rare kidney and metabolic diseases. We invest revenues from our commercial portfolio into our pipeline with the goal of delivering new treatments for diseases with limited or no approved therapies.

The following table summarizes the status of our clinical programs, preclinical programs and approved products, each of which is described in further detail below.

1 On September 5, 2024, the FDA granted full approval of FILSPARI® (sparsentan) to slow kidney function decline in adults with primary IgAN who are at risk of disease progression. FILSPARI had previously been granted accelerated approval for IgAN in February 2023.

2 In May 2025, we announced that the FDA accepted our sNDA for traditional approval of FILSPARI for the treatment of FSGS and assigned a PDUFA target action date of January 13, 2026. In January 2026, we announced that the FDA extended the review timeline for the sNDA and the new PDUFA target action date is April 13, 2026.

3 Following a voluntary pause in enrollment, we restarted enrollment activities for the pivotal Phase 3 HARMONY Study in the first quarter of 2026.

FILSPARI® (sparsentan)

On September 5, 2024, the FDA granted full approval of FILSPARI® (sparsentan) to slow kidney function decline in adults with primary IgAN who are at risk of disease progression. FILSPARI had previously been granted accelerated approval in February 2023 based on the surrogate marker of proteinuria. Full approval was based on positive long-term confirmatory results from the PROTECT Study demonstrating that FILSPARI significantly slowed kidney function decline over two years compared to irbesartan.

FILSPARI is the only oral, once-daily, non-immunosuppressive medication that directly targets glomerular injury in the kidney by blocking two critical pathways of IgAN disease progression (endothelin-1 and angiotensin II).

The two-year efficacy data contained in the FDA-approved label is a modified intention to treat ("ITT") analysis and evaluates data from all patients regardless of treatment discontinuation. In the final analysis of the 404 randomized patients, FILSPARI significantly reduced the rate of decline in kidney function from baseline to Week 110 compared to irbesartan. In the ITT analysis included in the label, the mean eGFR slope from baseline to Week 110 was -3.0 mL/min/1.73 m^2/year for FILSPARI and -4.2 mL/min/1.73 m^2/year for irbesartan, corresponding to a statistically significant treatment effect of 1.2 mL/ min/1.73 m^2/year (p=0.0168). The positive treatment effects on proteinuria compared to the active control irbesartan that were observed at Week 36 were durable out to the two-year measurement period. Additional results from the PROTECT Study demonstrated the benefit of FILSPARI on absolute eGFR accrued over time and by Week 110 resulted in a 3.8 mL/min/1.73 m^2 difference in the mean change from baseline between FILSPARI and irbesartan.

Results from the PROTECT Study showed that FILSPARI was well tolerated with a clearly defined safety profile that has been consistent across all clinical trials conducted to date.

FILSPARI is a dual endothelin angiotensin receptor antagonist ("DEARA"). Pre-clinical data have shown that blockade of both endothelin type A and angiotensin II type 1 pathways in forms of rare chronic kidney disease, reduces proteinuria, protects podocytes and prevents glomerulosclerosis and mesangial cell proliferation. FILSPARI has been granted seven years of Orphan Drug Exclusivity in the U.S. (running from the date of accelerated approval) for the reduction of proteinuria in adults with primary IgAN at risk of rapid disease progression, and has been granted a separate seven years of Orphan Drug Exclusivity in the U.S. (running from the date of full approval) to slow kidney function decline in adults with primary IgAN who are at risk for disease progression, excluding the use provided for in the aforementioned Orphan Drug Exclusivity granted in connection with the accelerated approval.

IgAN is characterized by hematuria, proteinuria, and variable rates of progressive renal failure. With an estimated prevalence of up to 150,000 people in the United States and greater numbers in Europe and Asia, IgAN is the most common primary glomerular disease. Most patients are diagnosed between the ages of 16 and 35, with up to 40% progressing to kidney failure within 15 years. FILSPARI was the first non-immunosuppressive therapy approved for IgAN and is the only oral, once-daily, non-immunosuppressive therapy approved for this condition that directly targets glomerular injury in the kidney by blocking two critical pathways of IgAN disease progression (endothelin-1 and angiotensin II). We estimate more than 70,000 patients in the United States to be addressable under FILSPARI's full approval indication.

Data to support the approval of FILSPARI was generated from the Phase 3 PROTECT Study, the largest head-to-head interventional study to date in IgAN. It is a global, randomized, multicenter, double-blind, parallel-arm, active-controlled clinical trial that evaluated the safety and efficacy of 400mg of sparsentan, compared to 300mg of irbesartan, in 404 patients ages 18 years and up with IgAN and persistent proteinuria despite available angiotensin converting enzyme ("ACE") inhibitor or angiotensin receptor blockers ("ARB") therapy, and is currently ongoing in the open label extension phase of the study.

FILSPARI is available only through a risk evaluation and mitigation strategy ("REMS") approved by the FDA for liver monitoring regarding potential risk of hepatotoxicity, as has been required for certain other approved endothelin antagonists. Initially, as part of the liver monitoring REMS, monthly monitoring of each patient was required for the first year a patient was on treatment, and quarterly thereafter. In August 2025, the FDA approved updated REMS labeling, reducing the frequency of liver monitoring to every three months from the onset of treatment and also removing the embryo-fetal toxicity monitoring requirement from the REMS.

In April 2024, we and our partner CSL Vifor announced that the European Commission had granted conditional marketing authorization (“CMA”) for FILSPARI (sparsentan) for the treatment of adults with primary IgAN with a urine protein excretion ≥1.0 g/day (or urine protein-to-creatinine ratio ("UPCR") ≥0.75 g/g), and in April 2025, we and CSL Vifor announced that the European Commission had converted the CMA into a standard marketing authorization (“MA”) for FILSPARI for the treatment of adults with primary IgAN with a urine protein excretion ≥1.0 g/day (or UPCR ≥0.75 g/g). The MA was granted for all member states of the European Union, as well as in Iceland, Liechtenstein and Norway. As a result of the standard MA approval, we received a regulatory milestone payment of $17.5 million in May 2025 under the terms of the License Agreement. FILSPARI became commercially available in Europe under the CMA in August 2024, with an initial launch in Germany and Austria. In October 2024, we and CSL Vifor announced that Swissmedic has granted temporary marketing authorization for FILSPARI for the treatment of adults with primary IgAN with a urine protein excretion ≥1.0 g/day (or UPCR ≥0.75 g/g). In April 2025, the Medicines and Healthcare products Regulatory Agency ("MHRA") in the UK converted its conditional approval of FILSPARI in IgAN to standard approval. In the fourth quarter of 2025, we received a $40.0 million market access milestone payment from CSL Vifor.

In January 2024, we announced our entry into an exclusive licensing agreement with Renalys Pharma, Inc. ("Renalys"), to bring sparsentan for the treatment of IgAN to patients in Japan and other countries in Asia. In December 2024, Renalys announced that sparsentan received Orphan Drug Designation from the Japanese Ministry of Health, Labour and Welfare for the indication of primary IgA nephropathy as of November 27, 2024. In the fourth quarter of 2025, Renalys announced positive topline results from its Phase 3 study of sparsentan in Japanese patients with IgAN. Renalys has also announced that it has reached an agreement with the Pharmaceuticals and Medical Devices Agency ("PMDA") regarding development plans for two other Phase 3 clinical trials of sparsentan, one investigating the use of sparsentan in FSGS and the other in Alport syndrome, in Japan. In the fourth quarter of 2025, Renalys was acquired by and merged into Chugai Pharmaceutical Co., Ltd. (“Chugai”). Through the acquisition, Chugai gained exclusive rights to develop and commercialize sparsentan in Japan, South Korea, and Taiwan. As a minority shareholder in Renalys, we received $10.2 million at the closing of the transaction, and we are also eligible to receive multiple milestones according to the progress of sparsentan regulatory approval, and consideration linked to sparsentan's net sales in the applicable territory. Under the terms of the licensing agreement, Chugai is responsible for development, regulatory matters, and commercialization in the licensed territories. Chugai plans to file for the regulatory approval for sparsentan in Japan in 2026.

Clinical-Stage Programs:

Sparsentan for the treatment of FSGS

Sparsentan has been granted Orphan Drug Designation for the treatment of FSGS in the U.S. and the EEA.

FSGS is a leading cause of kidney failure and nephrotic syndrome. There are currently no FDA-approved pharmacologic treatments for FSGS and there remains a high unmet need for patients living with FSGS as off-label treatments such as ACE/ARBs, steroids, and immunosuppressant agents are effective in only a subset of patients and use of some of these off-label treatments may be further inhibited by their safety profiles. Every year approximately 5,400 patients are diagnosed with FSGS and we estimate that there are more than 40,000 FSGS patients in the United States and a similar number in Europe. We believe that there are up to 30,000 FSGS patients in the United States that are potentially addressable with FILSPARI, if approved.

In 2016, we generated positive data from our Phase 2 DUET study in FSGS. In 2018, we announced the initiation of the Phase 3 clinical trial designed to serve as the basis for an NDA and MAA filing for sparsentan for the treatment of FSGS (the "DUPLEX Study"). The DUPLEX Study is a global, randomized, multicenter, double-blind, parallel-arm, active-controlled clinical trial evaluating the safety and efficacy of sparsentan in 371 patients. The DUPLEX Study protocol provided for an unblinded analysis of at least 190 patients to be performed after 36 weeks of treatment to evaluate the interim efficacy endpoint - the proportion of patients achieving a FSGS partial remission of proteinuria endpoint ("FPRE"), which is defined as UPCR ≤1.5 g/g and a >40% reduction in UPCR from baseline, at week 36. In February 2021, we announced that the ongoing Phase 3 DUPLEX Study achieved its pre-specified interim FSGS partial remission of proteinuria endpoint following the 36-week interim period. 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). Following engagement with the FDA on the interim proteinuria analysis and a subsequent eGFR data-cut, we elected to forego the previously planned submission for accelerated approval and pursue a potential traditional approval upon completion of the DUPLEX Study.

In May 2023, we announced topline primary efficacy results from the pivotal Phase 3 DUPLEX Study of sparsentan in FSGS. The confirmatory primary endpoint of the DUPLEX Study designed to support traditional regulatory approval was the rate of change in eGFR over 108 weeks of treatment. At the end of the 108-week double-blind period, sparsentan was observed to have a 0.3 mL/min/1.73m^2 per year (95% CI: -1.74, 2.41) favorable difference on eGFR total slope and a 0.9 mL/min/1.73m^2 per year (95% CI: -1.27, 3.04) favorable difference on eGFR chronic slope compared to the active control irbesartan, which was not statistically significant. After 108 weeks of treatment, sparsentan achieved a mean reduction in proteinuria from baseline of 50%, compared to 32% for irbesartan. Although the DUPLEX Study did not achieve its two-year primary endpoint with statistical significance over the active control irbesartan, we are encouraged by the results, including the pre-specified secondary endpoints on proteinuria and exploratory endpoints, including renal outcomes, which trended favorably for sparsentan. In addition, a review of the safety results through 108 weeks of treatment indicate sparsentan was generally well-tolerated and the overall safety profile in the study to date was generally consistent between treatment groups.

In December 2023, we announced that we had completed a planned Type C meeting with the FDA to discuss results from the Phase 3 DUPLEX Study of sparsentan in FSGS. The FDA acknowledged the high unmet need for approved therapies as well as the challenges in studying FSGS but indicated that the two-year results from the Phase 3 DUPLEX Study alone were not sufficient to support an sNDA submission. The FDA acknowledged the work being done by the larger nephrology community to better understand proteinuria and eGFR as endpoints in clinical trials of FSGS and indicated a willingness to continue to engage with us on a potential path forward for sparsentan in FSGS following our consideration of additional evidence. Subsequently, a collaborative international effort referred to as the PARASOL project was initiated with a goal to define the quantitative relationships between short-term changes in biomarkers (proteinuria and GFR) and long-term outcomes in order to support the use of alternative proteinuria-based endpoints as a basis for accelerated and traditional approval. The PARASOL project is led by several patient advocacy organizations focused on glomerular diseases, with participation from regulators and industry representatives. The principal finding from PARASOL was that in FSGS, reduction in proteinuria over 24 months is strongly associated with a reduction in the risk of kidney failure, and responder definitions based on thresholds of proteinuria are both biologically plausible and strongly supported by epidemiological data. Following the PARASOL public workshop in the fourth quarter of 2024, in which a multi-stakeholder group of rare kidney disease experts aligned around a potential proteinuria-based clinical trial endpoint for FSGS, we scheduled a Type C meeting with the FDA to discuss a potential regulatory pathway for a

sparsentan FSGS indication. In February 2025, we announced that we had completed a Type C meeting with the FDA and in March 2025, we announced that we had submitted an sNDA to the FDA seeking traditional approval of FILSPARI for the treatment of FSGS. In May 2025, we announced that the FDA accepted the sNDA, assigned a PDUFA target action date of January 13, 2026, and initially indicated that it planned to hold an advisory committee meeting to discuss the application. In September 2025, following further review of the sNDA, the FDA informed us that an advisory committee meeting was no longer needed. In January 2026, we announced that the FDA extended the review timeline of the sNDA, and that the new PDUFA target action date is April 13, 2026. The extension followed the recent submission of responses requested by the FDA to further characterize the clinical benefit of FILSPARI. The FDA determined that the additional responses constituted a Major Amendment to the sNDA and extended the action date accordingly. The sNDA remains under review by the FDA with a PDUFA target action date of April 13, 2026.

The sNDA is supported by two of the largest and most rigorous head-to-head interventional studies conducted to date in FSGS, the Phase 3 DUPLEX Study and the Phase 2 DUET Study. In these studies, FILSPARI demonstrated rapid, superior and sustained reductions in proteinuria when compared with maximum labeled dose irbesartan across adult and pediatric patients. As published in the New England Journal of Medicine, DUPLEX showed statistically significant and clinically meaningful proteinuria remission at 36 weeks that was durable through 2 years. The treatment effect of FILSPARI strengthened at more stringent thresholds down to complete remission. Patients who achieved partial or complete proteinuria remission in the DUPLEX Study, irrespective of the treatment arm, had a 67% to 77% lower risk of kidney failure, respectively. The results from these studies are in alignment with the findings of the independent PARASOL workgroup that support the importance of proteinuria in FSGS. If approved, FILSPARI could become the first and only FDA-approved medicine indicated for FSGS.

Together with CSL Vifor and Chugai, we continue to evaluate the potential for a regulatory pathway forward for sparsentan in FSGS in Europe and Japan.

Under the terms of our exclusive license to CSL Vifor, CSL Vifor is responsible for all commercialization activities in its licensed territories. We remain responsible for the clinical development of sparsentan in the applicable territories. If sparsentan receives marketing authorization in any of the territories covered by the exclusive license to Chugai, Chugai will be responsible for all development, regulatory matters, and commercialization activities in such licensed territories. We will retain all rights to sparsentan in the United States and rest of world outside of the territories licensed to CSL Vifor and Chugai, provided that CSL Vifor has a right of negotiation to expand the licensed territories into Canada and/or Mexico.

Pegtibatinase

Pegtibatinase is a novel investigational human enzyme replacement candidate being evaluated for the treatment of classical 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 complications. We estimate that there are approximately 7,000 to 10,000 addressable HCU patients globally. Pegtibatinase has been granted Rare Pediatric Disease, Fast Track and Breakthrough Therapy designations by the FDA, as well as orphan drug designation in the United States and European Union.

In December 2021, we announced positive topline results from the Phase 1/2 COMPOSE Study, a double blind, randomized, placebo-controlled dose escalation study to assess its safety, tolerability, pharmacokinetics, pharmacodynamics and clinical effects in patients with classical HCU. Pegtibatinase demonstrated dose-dependent reductions in total homocysteine ("tHcy") during the 12 weeks of treatment, and in the highest dose cohort to date evaluating 1.5 mg/kg of pegtibatinase twice weekly ("BIW"), treatment with pegtibatinase resulted in rapid and sustained reductions in tHcy through 12 weeks of treatment, including a 55.1% mean relative reduction in tHcy from baseline as well as maintenance of tHcy below a clinically meaningful threshold of 100 µmol. Additionally, in a dose-dependent manner in the study to date, methionine levels were substantially reduced and cystathionine levels were substantially elevated following treatment with pegtibatinase, suggesting that pegtibatinase acts in a manner similar to the native CBS enzyme.

In May 2023, we announced positive topline results from the sixth cohort of the Phase 1/2 COMPOSE Study, which was initiated to inform and refine formulation work for future development and commercial purposes and to further evaluate the dose response curve for pegtibatinase, and to further inform our pivotal development program to ultimately support potential approval of pegtibatinase for the treatment of HCU. In this cohort, five patients were randomized in a blinded fashion to receive 2.5 mg/kg of lyophilized pegtibatinase or placebo BIW, with four patients assigned to the treatment group. In this highest dose cohort to date, treatment with pegtibatinase resulted in rapid and sustained reductions in tHcy, with a 67.1% mean relative reduction in tHcy from baseline, as well as maintenance of mean tHcy below the clinically meaningful threshold of 100 µmol, over weeks 6 to 12. In the double-blind period, pegtibatinase was generally well-tolerated, with no discontinuations due to treatment-related adverse events.

In December 2023, we 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 tHcy levels. In the beginning of 2024, the first patients were dosed in the HARMONY Study.

In September 2024, we announced a voluntary pause of enrollment in the Phase 3 HARMONY Study. The voluntary enrollment pause was enacted following our determination that the desired drug substance profile was not achieved in the initial scale-up process, and it enabled us to address necessary process improvements in manufacturing scale-up to support initial commercial scale manufacturing as well as full enrollment in the HARMONY Study. Currently enrolled patients will be able to continue on study medication as scheduled for the duration of the trials in which they are

participating. Following further optimization of the manufacturing process in 2025, we restarted enrollment activities for the pivotal Phase 3 HARMONY Study in the first quarter of 2026.

We acquired pegtibatinase as part of the November 2020 acquisition of Orphan Technologies Limited.

Other Commercial Products:

Thiola and Thiola EC (tiopronin)

Thiola and Thiola EC are approved by the FDA for the treatment of cystinuria, a rare genetic cystine transport disorder that causes high cystine levels in the urine and the formation of recurring kidney stones. Due to the larger stone size, cystine stones may be more difficult to pass, often requiring surgical procedures to remove. More than 80 percent of people with cystinuria develop their first stone by the age of 20. More than 25 percent will develop cystine stones by the age of 10. Recurring stone formation can cause loss of kidney function in addition to substantial pain and loss of productivity associated with renal colic and stone passage. While a portion of people living with the disease are able to manage symptoms through diet and fluid intake, the prevalence of cystinuria in the U.S. is estimated to be 10,000 to 12,000, indicating that there may be as many as 4,000 to 5,000 affected individuals with cystinuria in the U.S. that would be candidates for Thiola or Thiola EC.

In June 2019 we announced that the FDA approved 100mg and 300mg tablets of Thiola EC, an 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.

In May 2021, a generic option for the 100mg version of the original formulation of Thiola (tiopronin tablets) became available and in June 2022, a second option for the 100mg version of the original formulation of Thiola (tiopronin tablets) was approved. These generic versions of the original formulation of Thiola have impacted our sales, and these or additional generic versions of either formulation could have a material adverse impact on sales. To date, several generic options for the 100mg and 300mg versions of Thiola EC have been approved by the FDA and become available. Accordingly, Thiola EC is subject to generic competition.

Sale of Bile Acid Product Portfolio

On July 16, 2023, we entered into an Asset Purchase Agreement (the “Purchase Agreement”) with Mirum Pharmaceuticals, Inc. ("Mirum Pharmaceuticals" or “Mirum”), pursuant to which Mirum agreed to purchase substantially all of the assets primarily related to our business of development, manufacture (including synthesis, formulation, finishing or packaging) and commercialization of Chenodal and Cholbam (also known as Kolbam, and together with Chenodal, the “Products”). This transaction was consummated on August 31, 2023. A portion of the consideration for the sale is in the form of potential milestone payments that only become payable upon the achievement of certain milestones based on specified amounts of annual net sales of the Products. Mirum achieved the first such milestone based on its annual net sales in 2025, we recognized a milestone of $25.0 million during 2025, and expect to receive payment in the second quarter of 2026, as a result of such achievement.

Competition

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. Many of our competitors are larger than our company and have substantially greater financial, marketing and technical resources than we have.

The development and commercialization of new products to treat rare diseases is highly competitive, and we expect considerable competition from major pharmaceutical, biotechnology and specialty pharmaceutical companies. As a result, there are, and will likely continue to be, extensive research and substantial financial resources invested in the discovery and development of new orphan drug products.

Our competition will be determined in part by the potential indications for which therapies are developed and ultimately approved by regulatory authorities. The speed with which we can develop products, complete preclinical testing, clinical trials, approval processes, and supply commercial quantities to market are expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price, reimbursement, patent position, and regulatory exclusivity.

FILSPARI/Sparsentan

IgAN

On September 5, 2024, the FDA granted full approval of FILSPARI to slow kidney function decline in adults with primary IgAN who are at risk of disease progression. FILSPARI is the only oral, once-daily, non-immunosuppressive medication that directly targets glomerular injury in the kidney by blocking two critical pathways of IgAN disease progression (endothelin-1 and angiotensin II). FILSPARI had previously been granted accelerated approval in February 2023 based on the surrogate marker of proteinuria. Full approval was based on positive long-term confirmatory results from the PROTECT Study demonstrating that FILSPARI significantly slowed kidney function decline over two years compared to irbesartan. In April 2024, the

European Commission granted CMA for FILSPARI and in April 2025, the European Commission converted the CMA into a standard MA for FILSPARI for the treatment of adults with primary IgAN with a urine protein excretion ≥1.0 g/day (or UPCR ≥0.75 g/g). The MA was granted for all member states of the European Union, as well as in Iceland, Liechtenstein and Norway. FILSPARI became commercially available in Europe under the CMA in August 2024, with an initial launch in Germany and Austria. In October 2024, the Company and CSL Vifor announced that Swissmedic has granted temporary marketing authorization for FILSPARI for the treatment of adults with primary IgAN with a urine protein excretion ≥1.0 g/day (or UPCR ≥0.75 g/g). In April 2025, the MHRA in the UK converted its conditional approval of FILSPARI in IgAN to standard approval.

The IgAN treatment landscape is evolving rapidly. Historically, traditional standard of care has been centered on renin-angiotensin system ("RAS") blockade, with immunosuppressive therapies used selectively in certain higher-risk patients.

In 2025, Kidney Disease Improving Global Outcomes (“KDIGO”) published updated guideline recommendations for the treatment of IgAN. The updated KDIGO guidelines suggest FILSPARI as a foundational kidney-targeted therapy for IgAN patients who are at risk of progressive kidney function loss and advocate for lowering targeted proteinuria levels for all IgAN patients to under 0.5 g/day, or ideally under 0.3 g/day, where achievable.

The updated guidelines provide a high-level treatment framework that recognizes immune-mediated disease activity and progressive kidney damage as key contributors to kidney function decline in IgAN. The guidelines emphasize that patients with IgAN who are at risk of progressive loss of kidney function, defined as patients with proteinuria of ≥0.5 g/day, should receive early, risk-appropriate treatment approaches that both target kidney injury already present and address immune-mediated disease drivers. Under the current framework, these two categories of treatment are viewed as complementary, with treatment sequencing and selection individualized based on patient risk, disease characteristics, and therapy availability.

On the kidney-targeted side, recent clinical guidance and emerging evidence support the use of foundational kidney-targeted therapies, such as optimized RAS inhibition or FILSPARI as a DEARA, as well as sodium-glucose cotransporter-2 (“SGLT2”) inhibitors which can be used in combination with the foregoing therapies, as appropriate. Recent clinical guidance and emerging evidence support the need for foundational kidney-targeted therapy to manage the consequences of IgAN-induced kidney damage, including glomerular hyperfiltration, persistent proteinuria, tubulointerstitial injury, and progressive decline in kidney function. Therapies in this category are positioned as long-term treatments. FILSPARI is the only therapy to date to demonstrate a statistically significant slowing of kidney function decline in a Phase 3 study compared to an active, maximally titrated RAS inhibitor.

Other kidney-targeted agents under clinical development include Novartis’s atrasentan (Vanrafia), an endothelin receptor antagonist indicated to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally defined as a UPCR ≥1.5 g/g, which is currently approved under the FDA’s accelerated approval pathway. Based on publicly available information, confirmatory Phase 3 data for atrasentan are expected to begin reporting in 2026.

In addition to kidney-targeted therapies, there are several therapies that are approved or in development that target the upstream immunopathogenesis of IgAN. Approved immune-targeted therapies include targeted-release budesonide, such as Calliditas’s Tarpeyo, which has received full regulatory approval in the United States. Systemic corticosteroids remain used in clinical practice in selected patients, including under guideline-described regimens.

There is also a growing group of novel immune-targeted therapies that have received regulatory approval under accelerated approval pathways or are in late-stage clinical development. These include APRIL- and BAFF-pathway inhibitors designed to modulate pathogenic IgA production, such as Otsuka’s sibeprenlimab (Voyxact), which has received accelerated approval, as well as Vera Therapeutics’ atacicept, telitacicept (licensed to Vor Bio outside Greater China), Vertex’s povetacicept, and Novartis’s zigakibart, all of which are currently in late-stage clinical development.

Additional upstream immune-targeted approaches include complement pathway inhibitors, such as Novartis’s iptacopan (Fabhalta), which has received accelerated approval, and sefaxersen (Roche/Ionis), which is in late-stage clinical development. Terminal complement inhibitors, such as Alexion’s ravulizumab (Ultomiris), and plasma cell-directed therapies, such as Biogen’s felzartamab and Takeda’s mezagitamab, are also currently being evaluated in late-stage (Phase 3) IgAN studies, along with other B-cell- or plasma cell-directed therapies that remain under investigation.

From 2021 to 2024, there were global regulatory label expansions of two SGLT2 inhibitors—AstraZeneca’s Farxiga/Forxiga and Boehringer Ingelheim and Eli Lilly’s Jardiance—into chronic kidney disease ("CKD"), positioning this class as a potential background or complementary therapy to sparsentan in the treatment of IgAN and/or FSGS. Additionally, although patients diagnosed with IgAN are not included in the approved label and were not enrolled in the initial pivotal studies, Bayer’s non-steroidal mineralocorticoid receptor antagonist, Kerendia, could potentially be used in patients with diabetic kidney disease and concurrent IgAN and is currently being studied in patients with CKD without diabetes.

Finally, there are endothelin receptor antagonists ("ERAs") developed for CKD-related conditions that could potentially be used, if approved in CKD patients without a specific IgAN diagnosis. Idorsia Pharmaceuticals’ aprocitentan (branded as Tryvio in the United States and Jeraygo in Europe) was approved for the treatment of resistant hypertension by the FDA and the European Medicines Agency in March 2024 and June 2024, respectively; the pivotal study enrolled patients with resistant hypertension, including those with Stage 3 and Stage 4 CKD. In November 2023, AstraZeneca initiated a registrational fixed-dose combination study of zibotentan and Farxiga in CKD patients with high proteinuria. Patients with IgAN are not excluded from the study, and primary completion is anticipated in 2027.

FSGS

Currently, there are no products approved by the FDA or the European Commission that are indicated for the treatment of FSGS. The current standard of care for FSGS includes steroids, ACE/ARBs, calcineurin inhibitors, dialysis, and renal transplant. Moreover, as an adjuvant apheresis device which works to remove lipoproteins from blood, the Liposorber® LA-15 System (Kaneka Pharma America LLC) is FDA-approved for the treatment of adult and pediatric patients with Nephrotic Syndrome associated with primary FSGS when standard options are unsuccessful or post-transplant with FSGS recurrence. A post-approval study with this device is ongoing.

Dimerix is conducting a Phase 3 study of its CCR2 blocker DMX-200 in adult patients with FSGS, including primary, genetic, and undetermined causes, with an independent adolescent cohort also being evaluated. Boehringer Ingelheim has announced plans to conduct a Phase 3 study with BI 764198 (TRPC6 inhibitor) in adults and adolescent primary FSGS patients and FSGS patients with a TRPC6 gene mutation. Apellis Pharmaceuticals is conducting a dedicated sequential Phase 2/3 study in adults, followed by adolescents, with FSGS.

Additionally, Vertex Pharmaceuticals is conducting the Phase 3 portion of their Phase 2/3 study in adult and pediatric patients with APOL1-mediated kidney disease, which can include a subset of FSGS patients with known APOL1 mutations (G1/G1, G2/G2, or G1/G2). Based on publicly available information, interim data is expected in 2026. There are currently two other clinical stage APOL1 programs in development: Maze Therapeutics' MZE829 and AstraZeneca/Ionis' AZD2373 (an APOL1-targeting antisense oligonucleotide).

Based on public sources, several other companies have programs in clinical and/or pre-clinical development for the treatment of FSGS or related conditions, including, among others, the following Phase 2 and 3 programs: Vera Therapeutics (atacicept), Novartis (atrasentan), Sanofi (frexalimab, rilzabrutinib, brivekimig), Akebia (praliciguat). In addition to its FSGS program, Apellis Pharmaceuticals' pegcetacoplan is in a Phase 3 trial for other rare glomerular diseases (C3G/IC-MPGN).

Pegtibatinase

Current treatment options for homocystinuria ("HCU") are limited to protein-restricted diet and supplemental use of vitamin B6 and betaine.

According to public sources, Syntis Bio, Inc. has two pre-clinical development programs for a microbiome therapy for the management of HCU. Additionally, in July 2024, Innorna announced that they received FDA's Rare Pediatric Disease Designation for IN022 (pre-clinical) for the treatment of HCU.

Based on public sources, there are other pre-clinical development programs in HCU that may enter the clinic.

Thiola and Thiola EC (tiopronin)

In May 2021, a generic option for the 100mg version of the original formulation of Thiola (tiopronin tablets) became available and in June 2022, a second option for the 100mg version of the original formulation of Thiola (tiopronin tablets) was approved. These generic versions of the original formulation of Thiola have impacted our sales, and these or additional generic versions of either formulation could have a material adverse impact on sales. To date, several generic options for the 100mg and 300mg versions of Thiola EC have been approved by the FDA and become available. Accordingly, Thiola EC is subject to generic competition. Thiola also faces potential competition from compounded formulations and additional generic entrants.

In addition, certain penicillamine agents including but not limited to Cuprimine and Depen are FDA approved for the treatment of cystinuria. Additional generic versions of penicillamine have been approved by the FDA and some have entered the market. Captopril is not FDA approved for the treatment of cystinuria but has been prescribed for patients with cystinuria. Advicenne Pharma is developing a microtablet formulation containing potassium citrate monohydrate and potassium bicarbonate, for the potential oral treatment of cystinuria.

Based on public sources, there are other preclinical assets in development that may enter the clinic for the treatment of cystinuria.

Licenses and Royalties

Ligand License Agreement

In 2012, we entered into a license agreement with Ligand Pharmaceuticals, Inc. ("Ligand"), granting us a worldwide sublicense for the development, manufacture and commercialization of FILSPARI (sparsentan). Under the license agreement, Ligand granted us a sublicense under certain of its patents and other intellectual property in connection with the development and commercialization of sparsentan. Under the license agreement, Ligand is obligated to transfer to us certain information, records, regulatory filings, materials and inventory controlled by Ligand and relating to or useful for developing sparsentan. We must use commercially reasonable efforts to develop and commercialize sparsentan in specified major market countries and other countries in which we believe it is commercially reasonable to develop and commercialize such products.

As consideration for the license, we are required to make substantial payments upon the achievement of certain milestones, totaling up to $114.1 million. Through December 31, 2025, we have capitalized $47.2 million for contractual milestones achieved under the Ligand License Agreement. Pursuant to the Ligand License Agreement, we are obligated to pay Ligand (and Bristol-Myers Squibb Company ("BMS")) an escalating royalty between 15% and 17% of net sales of sparsentan, with payments due quarterly. We began incurring costs associated with such royalties following the February 2023 approval of FILSPARI (sparsentan). For the years ended December 31, 2025 and 2024, we capitalized $54.3 million and $20.3 million, respectively, to intangible assets for royalties owed on net sales of FILSPARI.

Under the terms of the license agreement, BMS has a right of first negotiation and Ligand has a right of second negotiation with respect to any license arrangement for a licensed compound, except to the extent such rights may be waived.

The license agreement will continue until neither party has any further payment obligations under the agreement and is expected to continue for approximately 10 to 20 years from the effective date. Ligand may terminate the license agreement due to (i) our insolvency, (ii) our material uncured breach of the agreement, (iii) our failure to use commercially reasonable efforts to develop and commercialize sparsentan as described above or (iv) certain other conditions. We may terminate the license agreement due to a material uncured breach of the agreement by Ligand.

Mission License Agreement

In 2014, we entered into a license agreement with Mission Pharmacal ("Mission"), pursuant to which we obtained an exclusive, royalty-bearing license to market, sell and commercialize Thiola (tiopronin) in the United States and Canada, and a non-exclusive license to use know-how relating to Thiola to the extent necessary to market Thiola ("Mission License Agreement"). Under the terms of the Mission License Agreement, as subsequently amended, which runs through May 2029, we are obligated to pay to Mission, the greater of $2.1 million, representing the guaranteed minimum royalty, or 20%, of our Thiola net sales generated globally during each calendar year.

Intellectual Property

The proprietary nature of, and protection for, our product candidates and our discovery programs, processes and know-how are important to our business. We have sought patent protection in the United States and certain other jurisdictions for sparsentan, where available and when appropriate. Our policy is to pursue, maintain and defend patent rights, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business.

Our commercial success will depend in part on obtaining and maintaining patent protection and for our current and future product candidates, their use in treating particular diseases, and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell, or importing our products depends on the extent to which we have rights under valid and enforceable patents that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes.

FILSPARI

As of December 31, 2025, our patent portfolio for FILSPARI (sparsentan) was comprised of six distinct patent families, one of which is exclusively licensed from Ligand (the “Ligand patent family”). The other five patent families are owned by Travere (the "Travere patent families"). We previously had one additional licensed patent family related to sparsentan that was owned by BMS, exclusively licensed to Ligand and sub-licensed to us by Ligand. However, the BMS patent family expired in 2019 and therefore is no longer in force.

The Ligand patent family is directed to methods of using sparsentan in the treatment of various diseases, including glomerulosclerosis and IgAN. As of December 31, 2025, this patent family included two U.S. patents (U.S. Patent No. 9,662,312, which we refer to herein as the ‘312 patent, and U.S. Patent No. 9,993,461, which we refer to herein as the ‘461 patent), a pending U.S. application, two European patents (European Patent No. EP2732818, which we refer to herein as the European ‘818 patent, and European Patent No. EP3222277, which we refer to herein as the European ‘277 patent), a pending European application, and two granted Hong Kong patents. The ‘312 patent and the European ‘818 patent claim the use of sparsentan for treating glomerulosclerosis. The ‘461 patent and the European '277 patent each claim both the use of sparsentan for treating glomerulosclerosis and the use of sparsentan for treating IgAN. The U.S. and foreign patents in this patent family have a stated expiration date in March 2030, which may potentially be extended in the United States via a pending patent term extension application. In November 2020, a third party filed an opposition to the European ‘277 patent in the European Patent Office ("EPO"). While we are vigorously defending the European '277 patent against the opposition, there is no guarantee that we will be successful in doing so. If we were to be unsuccessful in doing so, we would expect to rely on the data and/or marketing exclusivity that may be available in the EU, as described below under “Regulatory Exclusivity.”

The first Travere patent family is directed to methods of using sparsentan in the treatment of various kidney diseases, including FSGS and IgAN, e.g., by achieving a specified UPCR. As of December 31, 2025, this patent family was comprised of a granted U.S. patent (U.S. Patent No. 10,864,197, which we refer to herein as the ‘197 patent) and issued patents and pending patent applications in the U.S., and in certain jurisdictions outside the U.S., including Australia, Brazil, Canada, China, the EPO, Hong Kong, Japan, Korea, New Zealand and South Africa. The ‘197 patent

claims use of sparsentan for treating Alport syndrome and has a stated expiration date in October 2037. The pending patent claims in this patent family are directed at the use of sparsentan for treating FSGS and IgAN.

The second Travere patent family is directed to methods of using sparsentan for treating hearing loss associated with Alport syndrome. As of December 31, 2025, this patent family was comprised of a granted U.S. patent (U.S. Patent No. 11,207,299) and issued patents and pending patent applications in the U.S., and in certain jurisdictions outside the U.S., including Australia, Brazil, Canada, China, the EPO, Hong Kong, Israel, Japan, Korea, Mexico, New Zealand and South Africa.

The third Travere patent family is comprised of a pending international patent application, related to methods of treating a kidney disease or disorder comprising sparsentan, and a SGLT2 inhibitor.

The fourth Travere patent family is comprised of a pending international patent application, related to methods of treating IgA mediated diseases or disorders comprising sparsentan as well as corresponding pending patent applications in the U.S. and in certain foreign jurisdictions.

The fifth Travere patent family is comprised of a pending international patent application, related to methods of treating IgA mediated kidney diseases or disorders comprising sparsentan.

In addition, we have filed pending U.S. provisional patent applications directed to additional methods of use of sparsentan. U.S. provisional patent applications are not published and may not result in issued patents unless we timely file corresponding non-provisional applications; accordingly, we do not include such provisional filings in the patent family count described above.

The U.S. and some countries outside the U.S. similarly offer forms of patent term extension or restoration. For example, Supplementary Protection Certificates are available to extend the life of a European patent up to an additional five years (subject to a 15-year cap from European Medicines Agency ("EMA") approval) and in Japan patent terms can be extended up to five years.

We have filed an application for patent term extension of the ‘461 patent, and subsequently filed a supplement to this application to reflect the FDA-determined regulatory review period for sparsentan, which, if granted, could extend the term of the ‘461 patent to January 2033. There is no guarantee that such patent term extension will be granted to such date, or at all. Patent term extensions or Supplemental Protection Certificates ("SPCs") also may be available in certain foreign jurisdictions upon regulatory approval.

In the EU, a CMA for FILSPARI was issued by the European Commission in April 2024 (the ”FILSPARI CMA”) and was converted into a standard MA by the European Commission in April 2025. Because there has been no prior European approval for FILSPARI, we and Vifor have obtained certain SPCs and are pursuing additional SPCs throughout the European Economic Area ("EEA") based on this FILSPARI CMA.

Likewise, it is possible, if sparsentan achieves regulatory approval elsewhere in the world, depending upon local law and regulation, patent term extensions or SPCs may be pursued in additional jurisdictions.

Pegtibatinase

As of December 31, 2025, our patent portfolio for pegtibatinase was comprised of six distinct patent families, which we obtained upon our acquisition of Orphan Technologies Limited (now Travere Therapeutics Switzerland GmbH). Orphan Technologies obtained the rights to the first five patent families under an exclusive license agreement with the University of Colorado, while the sixth patent family was owned by Orphan Technologies. The first three patent families are owned by the University of Colorado and exclusively licensed to Travere Therapeutics Switzerland GmbH (the “CU patent families”). The first CU patent family is directed to human cystathionine β-synthase variants and methods for their production, the second CU patent family is directed to methods of purifying human cystathionine β-synthase variants, and the third CU patent family is directed to compositions comprising human cystathionine β-synthase variants and methods of treating homocystinuria. The next two families are co-owned by the University of Colorado and Travere Therapeutics Switzerland GmbH, with the University of Colorado’s interest exclusively licensed to Travere Therapeutics Switzerland GmbH (the “co-owned patent families”). The first co-owned patent family is directed to methods of pegylating human cystathionine β-synthase variants, while the second co-owned patent family is directed to pharmaceutical formulations comprising pegylated human cystathionine β-synthase variants and their use in treating homocystinuria. Lastly, the sixth patent family is owned by Travere Therapeutics Switzerland GmbH (the “Travere patent family”). The Travere patent family is directed to methods for treating human cystathionine β-synthase deficiency in patients with elevated homocysteine levels.

Thiola

Our patent portfolio for Thiola is comprised of a patent family which is exclusively licensed from Mission Pharmacal (the “Mission patent family”). The Mission patent family is directed to a formulation of Thiola, known as Thiola EC. As of December 31, 2025, this patent family included a granted U.S. patent (U.S. Patent No. 11,458,104, which we refer to herein as the ‘104 patent). The '104 patent claims a method for treating cystinuria by administering a formulation of tiopronin with food.

Regulatory Exclusivity

If we obtain marketing approval for sparsentan for the treatment of FSGS in the United States or in certain jurisdictions outside of the United States, we may be eligible for regulatory exclusivity for the approved therapy. In the United States, an FDA-approved therapy may be eligible to receive five years of new chemical entity ("NCE") exclusivity for the first FDA approval of a new chemical entity or, for drugs granted an orphan designation by the FDA, seven years of orphan drug exclusivity ("Orphan Drug Exclusivity" or "ODE"). In addition, both the five-year NCE period and the seven-year ODE period may be extended by six months if the FDA grants pediatric exclusivity, which generally requires that the FDA issue a written request for pediatric studies and that the sponsor submit satisfactory written reports of such studies. There can be no assurance that we will qualify for any such pediatric exclusivity.

Likewise, if we obtain marketing approval for pegtibatinase in the United States or in certain jurisdictions outside of the United States, we may be eligible for regulatory exclusivity for the approved product. Pegtibatinase is a biologic product and therefore its application for approval would be via a biologic license application (“BLA”). In the United States, an FDA-approved biologic product may be eligible to receive twelve years of regulatory exclusivity. In addition, the twelve-year BLA exclusivity period may be extended by six months if the FDA grants pediatric exclusivity, which generally requires that the FDA issue a written request for pediatric studies and that we submit satisfactory written reports. There can be no assurance that we will qualify for any such pediatric exclusivity.

In the European Union and European Free Trade Association ("EFTA") countries, innovative medicinal products approved by the European Commission may receive eight years of data exclusivity and an additional two years of market exclusivity. The 10-year period of data and market exclusivity may extend to 11 years if, during the eight-year period of data exclusivity, the product receives marketing authorization for a second therapeutic that provides a significant clinical benefit in comparison to existing therapies. Additionally, upon approval by the European Commission, orphan drugs may receive 10 years of market exclusivity or, in the case of orphan drugs for which a pediatric investigational plan ("PIP") has been completed, 12 years of market exclusivity. This period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. The regulatory exclusivity periods run from the date of European Commission approval. There can be no assurance that we will qualify for any such regulatory exclusivity, or that any such exclusivity will prevent competitors from seeking approval solely on the basis of their own studies. In addition, future changes to EU legislation may affect the availability, scope, or duration of rights granted after such changes take effect. See “Government Regulation” below.

FILSPARI

FILSPARI (sparsentan) received orphan drug designation in the United States and in the European Union for the treatment of IgAN in 2021 and FSGS in 2015. FILSPARI has been granted seven years of Orphan Drug Exclusivity in the U.S. (running from the date of accelerated approval) for the reduction of proteinuria in adults with primary IgAN at risk of rapid disease progression, and has been granted a separate seven years of Orphan Drug Exclusivity in the U.S. (running from the date of full approval) to slow kidney function decline in adults with primary IgAN who are at risk for disease progression, excluding the use provided for in the aforementioned Orphan Drug Exclusivity granted in connection with the accelerated approval.

Thiola

Thiola does not have regulatory exclusivity in the United States.

Trademarks

Our trademark portfolio includes both Travere-owned and Travere-licensed trademarks and is comprised of various U.S. and foreign registered trademarks and pending trademark applications relating to our company name and our commercial products (FILSPARI, Thiola, and Thiola EC).

More specifically, as of December 31, 2025, our trademark portfolio included registered U.S. and foreign trademarks for the wordmark “Travere Therapeutics” and its logo, registered U.S. and foreign trademarks relating to FILSPARI (sparsentan), registered U.S. trademarks for both the wordmark “TRAVERE TOTAL CARE”, and its logo, a registered trademark for both the wordmark “TOTAL CARE HUB” and its logo, and a registered trademark for “In Rare for Life”. In addition, under our license agreement with Mission we have an exclusive license to use Mission’s trademarks related to Thiola and Thiola EC, including three registered U.S. trademarks and one registered Canadian trademark for the mark “THIOLA”, and one registered U.S. trademark for the mark "Thiola EC", in the United States and Canada.

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. We seek to protect our proprietary data and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors, and partners. These agreements are designed to protect our proprietary information. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of

our information technology systems. Trade secrets and know-how can be difficult to protect. Consequently, we anticipate that trade secrets and know-how will, over time, be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from academic to industry scientific positions.

Manufacturing

STA Pharmaceutical Hong Kong Limited manufactures the active pharmaceutical ingredient for FILSPARI. Catalent Pharma Solutions manufactures FILSPARI and performs primary packaging. PCI Pharma Services performs secondary packaging and serialization for FILSPARI. Mission Pharmacal manufactures Thiola and Thiola EC.

We intend to continue to use our financial resources to accelerate development of our therapeutic candidates rather than establishing our own manufacturing facilities. We intend to meet our preclinical and clinical trial manufacturing requirements by establishing relationships with third-party manufacturers and other service providers to perform these services for us. Because we rely on these third parties, we have personnel with pharmaceutical development and manufacturing experience who are responsible for maintaining our third-party manufacturing relationships.

Should any of our therapeutic candidates obtain marketing approval, we anticipate establishing relationships with third-party manufacturers and other service providers in connection with the commercial production of our products. We have some flexibility in securing other manufacturers to produce our therapeutic candidates; however, our alternatives may be limited due to proprietary technologies or methods used in the manufacture of some of our therapeutic candidates.

Sales, Marketing and Distribution

In 2025, we continued to utilize our specialty sales force to market our FDA-approved products in the U.S. Through our deep understanding of patient and healthcare provider needs, we believe we are able to:

- serve patients living with rare disease that have limited treatment options;
- drive optimum performance of our marketed products;
- educate and train healthcare providers about our products and the diseases for which they are approved to treat;
- support access to and reimbursement coverage for our products without significant restrictions;
- support compliant use by providing patients with support services and disease education, to the extent and in the manner permitted under applicable laws, to help them utilize our products in a manner consistent with the label and maximize the benefits of treatment; and
- successfully launch new treatment options once approved.

Our U.S. commercial initiatives are designed to support patients living with rare diseases and clinicians treating these patients. We commercialize our products in the United States with a dedicated specialty sales force. Nephrologists are the primary call point for FILSPARI. The primary call points for Thiola and Thiola EC include urologists and nephrologists.

Our sales force is differentiated by its deep pharmaceutical experience and significant expertise in rare disease. Our commercial management and operations team similarly has extensive experience in pharmaceutical commercialization, particularly in specialty and rare disease markets.

Our marketing and patient access teams, supported by third-party agencies with rare disease experience, drive our commercialization and disease awareness efforts in the United States. Specifically, we implement a variety of industry accepted programs to educate physicians, including direct-to-physician contact by sales representatives, peer-to-peer educational programs, and participation in targeted medical convention programs.

We distribute FILSPARI in the United States through direct-to-patient pharmacies, and operate Travere TotalCare, pursuant to which we provide our comprehensive patient support services. This patient support program for FILSPARI in the United States provides services, assistance and resources that help patients understand IgAN, manage the insurance process, fill their prescriptions and initiate treatment.

We distribute our other products, Thiola and Thiola EC, through a direct-to-patient pharmacy that also provides our comprehensive patient support services in the United States. This patient support program includes a case-managed approach to patient education, insurance verification and reimbursement support, co-pay and other financial assistance for eligible patients, monitoring and support of adherence, and 24/7 access to pharmacist counseling.

In April 2024, we and CSL Vifor, with whom we entered into a license and collaboration agreement ("License Agreement") in September 2021, announced that the European Commission granted CMA for FILSPARI (sparsentan) for the treatment of adults with primary IgAN with a urine protein excretion ≥1.0 g/day (or UPCR ≥0.75 g/g), and in April 2025, we and CSL Vifor announced that the European Commission had converted the CMA

into a standard MA for FILSPARI for the treatment of adults with primary IgAN with a urine protein excretion ≥1.0 g/day (or UPCR ≥0.75 g/g). The MA was granted for all member states of the European Union, as well as in Iceland, Liechtenstein and Norway. As a result of the standard MA approval, we received a regulatory milestone payment of $17.5 million in May 2025 under the terms of the License Agreement. FILSPARI became commercially available in Europe under the CMA in August 2024, with an initial launch in Germany and Austria. In October 2024, we and CSL Vifor announced that Swissmedic has granted temporary marketing authorization for FILSPARI for the treatment of adults with primary IgAN with a urine protein excretion ≥1.0 g/day (or UPCR ≥0.75 g/g). In April 2025, the MHRA in the UK converted its conditional approval of FILSPARI in IgAN to standard approval. In the fourth quarter of 2025, we received a $40.0 million market access milestone payment from CSL Vifor.

In June 2025, the CSL Vifor License Agreement was amended in order to, among other things, expand the license to cover the following additional countries: Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates (collectively, the "Gulf Cooperation Council Countries"), and Brazil, Chile and Israel (together with Europe, Australia and New Zealand, the "CSL Vifor Licensed Territories") and to provide that the license rights to each additional country will revert to the Company if CSL Vifor does not take certain specified actions within specified timelines with respect to such country. CSL Vifor is responsible for all commercialization activities in the CSL Vifor Licensed Territories. CSL Vifor also has first right of negotiation to expand the licensed territories into Canada and/or Mexico.

In January 2024, we announced our entry into an exclusive licensing agreement with Renalys Pharma, Inc. to bring sparsentan for the treatment of IgAN to patients in Japan and other countries in Asia. In December 2024, Renalys announced that sparsentan received Orphan Drug Designation from the Japanese Ministry of Health, Labour and Welfare for the indication of primary IgA nephropathy as of November 27, 2024. In the fourth quarter of 2025, Renalys announced positive topline results from its Phase 3 study of sparsentan in Japanese patients with IgAN. Renalys has also announced that it has reached an agreement with the PMDA regarding development plans for two other Phase 3 clinical trials of sparsentan, one investigating the use of sparsentan in FSGS and the other in Alport syndrome, in Japan. In the fourth quarter of 2025, Renalys was acquired by and merged into Chugai. Through the acquisition, Chugai gained exclusive rights to develop and commercialize sparsentan in Japan, South Korea, and Taiwan. As a minority shareholder in Renalys, we received a portion of the upfront payment at the closing of the transaction, and we are also eligible to receive multiple milestones according to the progress of sparsentan regulatory approval, and consideration linked to sparsentan's net sales in the applicable territory. Under the terms of the licensing agreement, Chugai is responsible for development, regulatory matters, and commercialization in the licensed territories. Chugai plans to file for the regulatory approval for sparsentan in Japan in 2026.

Medical Affairs

We have a global Medical Affairs organization with teams located in the United States and Europe that supports scientific exchange, data dissemination, education, and evidence generation across therapeutic areas relevant to our pipeline and commercial products. Our Medical Affairs activities are designed to advance scientific understanding, support the appropriate use of our therapies, and engage external stakeholders. The responsibilities of our Medical Affairs personnel include execution and support of real-world evidence studies, scientific exchange with external stakeholders, medical communications through peer-reviewed publications and presentations at medical congresses, and providing medical information support to HCPs regarding our pipeline products and approved therapies. Medical Affairs also conducts scientific advisory boards to obtain insights from experts and practitioners and reviews and supports independent medical education grants and research on topics relevant to our products and associated disease states.

Government Regulation

Regulation by government authorities in the United States and foreign countries is a significant factor in the development, manufacture and marketing of proposed products and in ongoing research and product development activities. All pipeline products will require regulatory approval by competent regulatory authorities prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical studies and clinical trials and other approval procedures of the FDA and similar regulatory authorities in foreign countries. Various federal and state statutes and regulations also govern or influence analytical testing, manufacturing, safety evaluation, labeling, storage, inspection and record-keeping related to such products and their marketing. The process of obtaining these approvals and the subsequent compliance with appropriate federal and state statutes and regulations require the expenditure of substantial time and financial and human resources.

FDA Drug Approval Process

In the United States, pharmaceutical products (drugs and biologics) are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug or new biologic license applications, or NDAs and BLAs, respectively, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution. Firms are also subject to potential inspection by FDA.

We cannot market a drug product candidate in the United States until the drug has received FDA approval. The key steps required before a drug may be marketed in the United States generally include the following:

- completion of extensive preclinical laboratory tests, animal studies, toxicology, pharmacology, and formulation studies in accordance with the FDA's GLP regulations;
- submission to the FDA of an IND, and oversight by an Institutional Review Board, for human clinical testing, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials (phase 1-3) in accordance with Good Clinical Practices ("GCP") requirements to establish the safety and efficacy of the drug for each proposed indication;
- submission to the FDA of an NDA or BLA after completion of the required pivotal clinical trials;
- satisfactory completion of any FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess compliance with current Good Manufacturing Practices ("cGMPs"); and
- FDA review and approval of the NDA or BLA.

Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. If the FDA raises concerns or questions about the conduct of the trial, such as whether human research subjects will be exposed to an unreasonable health risk, the IND sponsor must resolve any outstanding FDA concerns or questions before clinical trials can proceed.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations, including GCP requirements, as well as under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol and subsequent protocol amendments must be submitted to the FDA as part of the IND. Certain studies must also be posted on clinicaltrials.gov.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials also must be submitted for approval to an institutional review board, or IRB, for approval at each site at which the clinical trial will be conducted. An IRB also may require the clinical trial at its site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial administration of the drug to healthy human subjects or patients, the drug is tested to assess pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine metabolism, pharmacokinetics, the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials, also called pivotal trials, are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 clinical trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and where confirmation of the result in a second Phase 3 trial would be impractical or unethical.

After completion of the required clinical testing, an NDA or BLA submission is prepared and submitted to the FDA. FDA approval of the submission is required before marketing of the product in the United States may begin. The submission must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting a submission is substantial. The submission of most NDAs and BLAs is additionally subject to a substantial application user fee, and the sponsor of an approved NDA or BLA is also subject to an annual program user fee. These fees typically are increased annually.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs and BLAs. Most such applications for standard review drug products are reviewed within 10 months of filing; most applications for priority review drugs are reviewed within six months of filing. Priority review can be applied to drugs to treat serious conditions that the FDA determines offer significant improvement in safety or effectiveness. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA also may refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA or BLA, the FDA typically will inspect one or more clinical sites to assure compliance with GCPs. Additionally, the FDA may inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMPs is satisfactory and the submission contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA or BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of approval, the FDA may require a REMS to ensure that the benefits of the drug outweigh the potential risks. REMS can include a medication guide, a communication plan for healthcare professionals and elements to assure safe use, such as special training and certification requirements for individuals who prescribe or dispense the drug, requirements that patients enroll in a registry and other measures that the FDA deems necessary to assure the safe use of the drug. The requirement for REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs. Such supplements typically are reviewed within 10 months of receipt.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting an NDA. After the FDA confers orphan drug status, the generic identity of the drug and its potential orphan indication are disclosed publicly by the FDA. Orphan drug designation in and of itself does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular indication with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Prior to FDA approval, orphan designation provides incentives for sponsors including tax credits for clinical research expenses, the opportunity to obtain government grant funding to support clinical research, and an exemption from FDA user fees.

Expedited Development and Review Programs

A sponsor may seek to develop and obtain approval of its products under programs designed to accelerate the development, FDA review and approval of new products that meet certain criteria.

Fast track is a process designed by the FDA to facilitate the development of drugs to treat serious conditions through expediting their review. The purpose is to get important new drugs to patients earlier. Fast Track addresses a broad range of serious conditions. Determining whether a condition is serious is a matter of judgment, but generally is based on whether the drug will have an impact on such factors as survival, day-to-day functioning, or the likelihood that the condition, if left untreated, will progress from a less severe condition to a more serious one.

A drug that receives Fast Track designation is eligible for some or all of the following:

- more frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
- more frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers;
- eligibility for Accelerated Approval and Priority Review, if relevant criteria are met; and
- Rolling Review, which means that a drug company can submit completed sections of its NDA or BLA for review by FDA, rather than waiting until every section is completed before the entire application can be reviewed. NDA or BLA review usually does not begin until the drug company has submitted the entire application to the FDA.

Once a drug receives Fast Track designation, early and frequent communication between the FDA and a drug company is encouraged throughout the entire drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.

Breakthrough therapy designation is available if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the product candidate to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross- disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. Breakthrough therapy designation comes with the benefits of Fast Track designation, which means that the sponsor may submit sections of the NDA or BLA for review on a rolling basis.

Accelerated Approval

Under the FDA's accelerated approval regulations, FDA may approve a drug or biologic for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint with regular reporting to FDA on the status of such trials. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by FDA.

The Hatch-Waxman Amendments: Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product or its use for the relevant application. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning all patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or

carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. Unless the submission of the ANDA pre-dates the listing of the patent in the Orange Book, the filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet and social media. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, surveillance to monitor the effects of an approved product, or restrictions on the distribution or use of the product. In addition, quality-control, drug manufacturing, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market and/or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

Pricing and Reimbursement

A portion of our product demand for our approved therapies comes from patients covered under Medicaid, Medicare and other federal and state government-related programs such as TRICARE and the Department of Veterans Affairs, or the VA. As required by Federal regulations, we provide rebates and discounts in connection with these programs.

Our commercial success depends in significant part on the extent to which coverage and adequate reimbursement for these products will be available from third-party payers, including government health administration authorities, private health insurers and other organizations. Third-party payers determine which medications they will cover and establish reimbursement levels. Even if a third-party payer covers a particular product, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payers to reimburse all or part of the costs associated with prescription therapies. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to product acceptance. Further, coverage policies and third-party payer reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

Government authorities and other third-party payers have and are developing methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. For example, the U.S. Department of Health and Human Services ("HHS") imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. In addition, HHS has been empowered to negotiate the price of certain single-source biologics that have been on the market for at least 11 years covered under

Medicare as part of the Medicare Drug Price Negotiation Program. Each year up 20 products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. Increasingly, third-party payers are requiring that therapeutic companies provide them with predetermined discounts/rebates from list prices as a condition of coverage, are using restrictive formularies and preferred therapy lists to leverage greater discounts in competitive classes, and are challenging the prices charged for medical products. Third party payers also are carefully evaluating the medical necessity and cost-effectiveness of medical products and services, in addition to a product's safety and efficacy, which may require us to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products. Further, no uniform policy requirement for coverage and reimbursement for therapies exists among third-party payers in the United States. Therefore, coverage and reimbursement for therapies can differ significantly from payer to payer. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

In addition, it is possible that future legislation in the U.S. and other jurisdictions could be enacted which could potentially influence the coverage and reimbursement rates for our products and also could further impact the levels of discounts and rebates paid to federal and state government entities, as well as commercial payers. Any legislation that influences these areas could impact, in a significant way, our ability to generate revenues from sales of products that, if successfully developed, we bring to market.

There have been a number of enacted or proposed legislative and regulatory changes affecting the healthcare system and pharmaceutical industry that could affect our commercial success. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, (collectively, the “PPACA”) was signed into law, which intended to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes, rebates and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. There have been executive, judicial and Congressional challenges and amendments to certain aspects of the PPACA. For example, on July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law, which narrowed access to PPACA marketplace exchange enrollment and declined to extend the PPACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired PPACA subsidies.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and, due to subsequent legislative amendments, will stay in effect until 2032, unless additional Congressional action is taken.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission’s Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact “The Great Healthcare Plan,” to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers’ global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court’s Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and,

in some cases, designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program ("SIP") proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs.

We expect that the PPACA and other federal and state healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any of our products, and could seriously affect our future revenues. In addition, it is possible that future legislation in the United States and other jurisdictions could be enacted which could potentially impact the reimbursement rates for the products we are developing and may develop in the future and also could further impact the levels of discounts and rebates paid to federal and state government entities. Any legislation that impacts these areas could impact, in a significant way, our ability to generate revenues from sales of products that, if successfully developed, we bring to market.

Health Care Regulatory Laws

In addition to FDA marketing restrictions and regulation of pharmaceutical products, several other types of state and federal laws have been applied to restrict and regulate certain business practices in the pharmaceutical industry in recent years. These laws include, without limitation, anti-kickback statutes and false claims laws, data privacy and security laws, and transparency laws regarding payments or other items of value provided to healthcare providers.

The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce; or in return for; purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers, among others, on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that may induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the anti-kickback statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal anti-kickback statute has been violated. Additionally, the PPACA amended the federal anti-kickback statute to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the PPACA codified case law that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Federal false claims laws, including the civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. The False Claims Act contains qui tam provisions, which allow a private individual, or relator, to bring a civil action on behalf of the federal government alleging that the defendant submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. For example, pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate federal false claims laws.

Also, many states have similar fraud and abuse statutes or regulations, including state anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

The U.S. Foreign Corrupt Practices Act, and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to government officials for the purpose of obtaining or retaining business. Our policies mandate compliance with these anti-bribery laws. We operate in parts of the world that have experienced governmental corruption to some degree and in certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices or may require us to interact with doctors and hospitals, some of which may be state controlled, in a manner that is different than in the United States. We cannot assure you that our internal control policies and procedures will protect us from reckless or criminal acts committed by our employees or agents. Violations of these laws, or allegations of such violations, could disrupt our business and result in criminal or civil penalties or remedial measures, any of which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common stock to decline.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), created new federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party

payers, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal anti-kickback statute, the PPACA amended the intent standard for certain healthcare fraud provisions under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

In addition, we are subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH, through its implementing regulations, makes certain of HIPAA's privacy and security standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains or transmits protected health information for or on behalf of a covered entity for a function or activity regulated by HIPAA and their covered subcontractors.

Additionally, the federal Physician Payments Sunshine Act within the PPACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to annually report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians (defined to include to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

Further, certain states require implementation of commercial compliance programs and marketing codes, compliance with the pharmaceutical industry's voluntary compliance guidelines, and compliance with the applicable compliance guidance promulgated by the federal government. Other various state level requirements include restricting payments or the provision of other items of value that may be made to healthcare providers and other potential referral sources; restricting various marketing practices; requiring prescription drug companies to report expenses relating to the marketing and promotion of drug products; requiring the posting of information relating to clinical studies and their outcomes; requiring the registration of sales representatives; requiring the reporting of certain information related to drug pricing; and requiring drug manufacturers to track and report information related to payments, gifts, compensation, and other items of value to physicians and other healthcare providers. Additionally, states that have not implemented these types of regulations are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to significant penalties, including imprisonment, criminal fines, civil monetary penalties, administrative penalties, disgorgement, exclusion from participation in federal healthcare programs, contractual damages, injunctions, recall or seizure of products, total or partial suspension of production, reputational harm, administrative burdens, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar agreement to resolve allegation of non-compliance with these laws, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Foreign Regulation

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials and approval of foreign countries or economic areas, such as the European Union, before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Clinical Trials and Marketing Authorization in the European Union

In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014, or CTR, which entered into application on January 31, 2022 repealing and replacing the former Clinical Trials Directive 2001/20, or CTD. The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal", the Clinical Trials Information System, or CTIS; a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

In all cases, clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Medicines used in clinical trials must be manufactured in accordance with the guidelines on cGMP and in a GMP licensed facility, which can be subject to GMP inspections.

Under European Union regulatory systems, a company may not market a medicinal product without a marketing authorization.

In the EU, medicinal products can only be commercialized after a related MA, has been granted. To obtain an MA for a product in the EU, an applicant must submit a Marketing Authorization Application ("MAA"), either under a centralized procedure administered by the EMA or one of the procedures administered by the competent national authorities of EU Member States: (i) the national procedure, (ii) the mutual recognition procedure; or (iii) the decentralized procedure. The submission strategy for a given product will depend on the nature of the product, the target indication(s), the history of the product and the marketing plan. The centralized procedure provides for the grant of a single MA by the European Commission that is valid throughout the European Economic Area (which is comprised of the 27 EU Member States plus Norway, Iceland and Liechtenstein). The centralized procedure is compulsory for certain medicinal products which are produced by biotechnology processes, advanced therapy medicinal products, products which are designated as orphan medicinal products and products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

Under the centralized procedure, the EMA's Committee for Human Medicinal Products ("CHMP") conducts the initial assessment of a product. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA by the EMA is 210 days. This excludes so-called clock stops, during which additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. At the end of the review period, the CHMP provides an opinion to the European Commission. If this opinion is favorable, the Commission may then adopt a decision to grant a marketing authorization. In exceptional cases, the CHMP might perform an accelerated review of an MAA in no more than 150 days, excluding clock stops. This is usually when the product targets an unmet medical need and is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures – Human ("CMDh) for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five-year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

Pediatric Development in the European Union

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, or SPC, if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

An innovator company enjoys a period of "data exclusivity" during which their pre-clinical and clinical trials data may not be referenced in the regulatory filings of another company (typically a generic company) for the same drug substance.

Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

Orphan Designation in the European Union

In the EU, Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than five in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product. An application for the designation of a medicinal product as an orphan medicinal product must be submitted at any stage of development of the medicinal product but before filing of an MAA. An MA for an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate marketing authorization has to be sought.

Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Post-authorization Requirements

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk- minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

Other Laws and Regulatory Processes

We are subject to a variety of financial disclosure and securities trading regulations as a public company in the United States, including laws relating to the oversight activities of the Securities and Exchange Commission ("SEC"), and Nasdaq rules under which our stock is listed. In addition, the Financial Accounting Standards Board ("FASB"), the SEC, and other bodies that have jurisdiction over the form and content of our accounts, our financial statements and other public disclosures are constantly considering and interpreting proposals and existing pronouncements designed to ensure that companies best display relevant and transparent information relating to their respective businesses.

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import and export and use and disposal of hazardous or potentially hazardous substances used in connection with our research work are or may be applicable to our activities. Certain agreements entered into by us involving exclusive license rights or acquisitions may be subject to national antitrust regulatory control, the effect of which cannot be predicted. The extent of government regulation which might result from future legislation or administrative action also cannot be predicted with accuracy.

Employees and Human Capital Management

As of January 31, 2026, we had 497 full-time employees, with most of those based in the United States and a small number outside of the United States. We consider the intellectual capital and well-being of our employees to be an important driver of our business and key to our future success. The biopharmaceutical industry is very competitive and we believe that our future success largely depends upon our continued ability to attract, develop and retain highly skilled employees as our operations expand, as well as our continued focus on our culture and patient centricity. Our workforce primarily consists of college-educated workers with experience in the biopharmaceutical industry, many of whom have advanced degrees. Our employees primarily focus on our drug development and commercialization efforts, including sales and general and administrative operational support of those functions. Currently, we rely on third-party contract manufacturers and conduct our discovery research efforts via collaborations and/or contracted third-party engagements. None of our employees in the United States are represented by a labor union or covered by collective bargaining agreements. We consider our current employee relations to be good.

We are committed to cultivating a workplace where every individual feels seen and appreciated, understanding that our strength lies in embracing the rich diversity of our employees' lives and experiences. We know from our experience over more than a decade that rare diseases affect

individuals across all demographics, and there are clear disparities in diagnosis, access to care, and support that remain significant barriers for many. By fostering inclusivity and a strong sense of belonging within our workforce, we are better able to incorporate diverse viewpoints, which we believe positively influences our ability to achieve our objectives and ultimately impact patient outcomes – this is key to operating within our mission, and successfully helping the patients we aim to serve. In line with embracing this inclusivity, we support a number of initiatives that directly impact our human capital, workforce and community, such as efforts focused on professional development, cultural awareness, and engagement. Additionally, we provide information about these efforts on our website, though the information on our website is not incorporated in this annual report on Form 10-K.

We strive to provide compensation, benefits and support services that help meet the varying needs of our employees. In the United States, our total compensation package includes competitive pay, including opportunities for performance-based bonuses; comprehensive healthcare benefits; paid time off and paid holidays, and the opportunity for equity ownership through our equity incentive plan and our employee stock purchase plan, as well as a suite of wellness focused offerings. We also sponsor a 401(k) plan that includes a discretionary matching contribution. A similar package of benefits is provided to our employees outside of the United States, subject to regional differences.

By focusing on employee retention, engagement and development opportunities, we believe we also improve our ability to support our clinical trials, our pipeline, our business and our operations. We value the growth and professional development of our employees. We do this through clear organizational, team, and individual goal setting, performance measurement, customized professional development, and employee training and development sessions on various topics. Our success also depends on our ability to respond to the needs of employees. We do this by listening to our employees through many avenues, including formal engagement initiatives, such as surveys, as well as informal listening sessions hosted by senior leaders, including our CEO and our human resources department. The response rate for our latest employee engagement survey, which was conducted in September 2025, was 86%. During 2025 we continued to focus on ways to maximize a people-centered, inclusive, and recognition-based company culture, building on initiatives that have been implemented over the last several years. Also during 2025, we continued to enhance our hybrid workforce program that provides a variety of virtual and in-person collaboration opportunities. In 2024, we solicited feedback on ways to enhance employees' experience, with a focus on engagement and collaboration, and we implemented several of the suggestions over the last year. As we continue to navigate through new ways of working, we take pride in the role we play in helping to ensure our employees are as productive and engaged as possible and their physical and emotional health, well-being and safety remains a key priority. We are committed to providing a safe and healthy working environment for our employees.

Available Information

We were incorporated in the state of Delaware in February 2011. Our website address is travere.com. We post links on our website to the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the SEC: annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, and any amendments to those reports filed or furnished pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended. All such filings are available through our website free of charge. The SEC also maintains an internet site at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

ITEM 1A. RISK FACTORS

Our business, as well as an investment in our common stock, is highly speculative in nature and involves a high degree of risk. Our securities should be purchased only by persons who can afford to lose their entire investment. Carefully consider the risks and uncertainties described below together with all of the other information included herein, including the financial statements and related notes, before deciding to invest in our common stock. If any of the following risks actually occur, they could adversely affect our business, prospects, financial condition and results of operations. In such event(s), the market price of our common stock could decline and result in a loss of part or all of your investment. Accordingly, prospective investors should carefully consider, along with other matters referred to herein, the following risk factors in evaluating our business before purchasing any shares of our common stock.

Risks Related to the Commercialization of Our Products

Our future prospects are highly dependent upon our ability to successfully develop and execute commercialization strategies for our products, including FILSPARI, and to attain market acceptance among physicians, patients and healthcare payers.

Our ability to generate significant product revenues and to achieve commercial success in the near-term will depend almost entirely on our ability to successfully commercialize our products in the United States, including FILSPARI (sparsentan) to slow kidney function decline in adults with primary IgAN who are at risk of disease progression, which was granted full approval by the FDA in September 2024. FILSPARI had previously been granted accelerated approval for IgAN in February 2023 based on the surrogate marker of proteinuria. As a product for a rare disease that had no previously-approved non-immunosuppressive treatment, the successful launch and commercialization of FILSPARI is subject to many risks. There are numerous examples of unsuccessful product launches and failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than we have. While we have established our commercial team and U.S. sales force, we will need to continue to train and further develop the team in order to successfully coordinate the ongoing launch and commercialization of FILSPARI in the United States. There are many factors that could cause the launch and commercialization of FILSPARI to be unsuccessful, including a number of factors that are outside our control. Because no non-immunosuppressive product had previously been approved by the FDA for the treatment of IgAN, it is difficult to estimate FILSPARI's market potential or the time it will take to increase patient and physician awareness of FILSPARI and change current treatment paradigms.

The commercial success of FILSPARI depends on the extent to which patients and physicians accept and adopt FILSPARI for IgAN patients. For example, if the addressable patient population suffering from primary IgAN is smaller than we estimate, if it proves difficult to educate physicians as to the availability and potential benefits of FILSPARI, or if physicians are unwilling to prescribe or patients are unwilling to take FILSPARI, the commercial potential of FILSPARI will be limited. We also do not know how physicians, patients and payers will respond to the pricing of FILSPARI, the updated, full approval label, clinical practice guidelines and any future changes thereto, developments related to competitive products, and any future publications in an evolving treatment landscape. Physicians may not prescribe FILSPARI and patients may be unwilling to use FILSPARI if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Thus, significant uncertainty remains regarding the commercial potential of FILSPARI. If the launch or commercialization of FILSPARI is unsuccessful or perceived as disappointing, the price of our common stock could decline significantly and long-term success of the product and our company could be harmed.

In order to operate our business and increase adoption and sales of our products, we need to continue to develop our commercial organization, including maintaining a highly experienced and skilled workforce with qualified sales representatives.

In order to successfully commercialize our products in the United States, we have built a specialized sales force. In order to successfully commercialize any approved products, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. Factors that may hinder our ability to successfully market and commercially distribute our products include:

- inability of sales personnel to obtain access to or educate adequate numbers of physicians on the benefits and safety of prescribing our products;
- inability to recruit, retain and effectively manage adequate numbers of effective sales personnel;
- lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies that have more extensive product lines; and
- unforeseen delays, costs and expenses associated with maintaining our sales organization.

If we are unable to maintain an effective sales force for our products, including the recently expanded sales force for FILSPARI or any other potential future approved products, we may not be able to generate sufficient product revenue in the United States. In addition, until the commencement of our commercial launch in February 2023, no one in our sales force had promoted FILSPARI or any other medicine for the treatment of IgAN patients. We are required to expend significant time and resources to train our sales force to be credible in educating physicians and pharmacists on the benefits of our products. In addition, we must continually train our sales force to ensure that a consistent and appropriate message about our products is

being delivered to our potential customers. We currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market our products and any additional products we may develop or acquire will be expensive and time-consuming. We also cannot be certain that we will be able to continue to successfully develop this capability.

We have granted exclusive licenses to third parties for the commercialization of sparsentan in certain territories outside of the United States, including Europe, Australia, New Zealand, Japan, South Korea, Taiwan, Brazil, Chile, Israel and the Gulf Cooperation Council Countries. If these third parties do not effectively engage or maintain their sales force for sparsentan if approved in the applicable territories, our ability to recognize milestone payments and royalties from the sales in such territories will be adversely affected.

We will need to continue to expend significant time and resources to train our sales forces to be credible in discussing our products with the specialists treating the patients indicated under the product's label. In addition, if we are unable to effectively train our sales force and equip them with effective marketing materials our ability to successfully commercialize our products could be diminished, which would have a material adverse effect on our business, results of operations and financial condition.

We are dependent on third parties for the successful commercialization of sparsentan in certain key territories outside of the United States, if approved, and such third parties' commercialization efforts may fail to meet our expectations. We may not be able to establish additional collaborations or other arrangements for sparsentan in other territories, which may adversely impact our ability to generate product revenue in additional jurisdictions.

We have granted exclusive licenses to third parties for the commercialization of sparsentan in certain territories outside of the United States, including Europe, Australia, New Zealand, Japan, South Korea, Taiwan, Brazil, Chile, Israel and the Gulf Cooperation Council Countries. Consequently, the commercial success of sparsentan in these territories will depend in significant part on the efforts of such third parties, over which we will have limited control. In August 2022, Vifor Pharma Group was acquired by CSL Limited, parent company to CSL Behring and is now operating under the brand CSL Vifor. Similarly, in the fourth quarter of 2025, Renalys was acquired by and merged into Chugai. While our agreements with these partners remain in place following the acquisitions, there is no guarantee that our collaboration with these partners will not be affected, adversely or otherwise, by the changes in ownership. Moreover, in connection with the acquisitions and related restructurings, substantially less resources could be devoted to the commercialization of sparsentan in the territories licensed to such parties, or such efforts could be discontinued entirely. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell sparsentan in territories outside of the United States, if approved, our ability to generate product revenue outside of the United States may be limited.

The commercial success of our products depends on them being considered to be effective drugs with advantages over other therapies.

The commercial success of our products depends on them being considered to be effective drugs with advantages over other therapies. A number of factors, as discussed in greater detail below, may adversely impact the degree of acceptance of these products, including their efficacy, safety, price and benefits over competing therapies, as well as the coverage and reimbursement policies of third-party payers, such as government and private insurance plans.

Pegtibatinase, if approved, is expected to be administered by patients or caregivers through self-administration using a delivery device. While we have not observed material issues related to self-administration in clinical studies to date, patient acceptance, proper use of the device, and adherence in broader or longer-term real-world use may differ from clinical trial experience, which could adversely affect utilization, outcomes, or commercial success.

If unexpected adverse events are reported in connection with the use of any of these products, physician and patient acceptance of the product could deteriorate and the commercial success of such product could be adversely affected. We are required to report to the FDA events associated with our products relating to death or injury. Adverse events could result in additional regulatory controls, such as a requirement for costly post-approval clinical studies or revisions to our approved labeling which could limit the indications or patient population for a product or could even lead to the withdrawal of a product from the market.

We face substantial generic and other competition, and our operating results will suffer if we fail to compete effectively.

Under the Hatch-Waxman Amendments of the Federal Food, Drug, and Cosmetic Act, a pharmaceutical manufacturer may file an ANDA seeking approval of a generic copy of an approved innovator product or an NDA under Section 505(b)(2) that relies on the FDA's prior findings of safety and effectiveness in approving the innovator product. A Section 505(b)(2) NDA may be for a new or improved version of the original innovator product. Our product Thiola, and products from which we may receive milestone payments such as Cholbam, are subject to immediate competition from compounded and generic entrants, as the ANDA and/or NDA for these drug products have no remaining or current patent or non-patent exclusivity. In April 2021, a generic option for the 100mg version of the original formulation of Thiola (tiopronin tablets) was approved by the FDA and an additional generic option of the original formulation of Thiola (tiopronin tablets) was approved in June 2022 and during the year ended December 31, 2022, we experienced a decrease in total net product revenues compared to the year ended December 31, 2021, which was due in part to competition from generic tiopronin tablets (100mg version of the original formulation). Additional generic versions of Thiola may be approved in the

future. Several generic options for the 100mg and 300mg versions of Thiola EC have been approved by the FDA and become available. Our future net product revenues from Thiola and/or Thiola EC may be materially impacted by competition from existing or additional generic versions of Thiola or Thiola EC.

In addition, there have been a number of recent regulatory and legislative initiatives designed to encourage generic competition for pharmaceutical products, including expedited review procedures for generic manufacturers, proposed "skinny label" legislation, and incentives designed to spur generic competition of branded drugs. In particular, the FDA and the U.S. Federal Trade Commission (“FTC”) have been focused on brand companies’ denial of drug supply to potential generic competitors for testing. In December 2019, the CREATES Act was enacted, which provides a legislatively defined private right of action under which generic companies can bring suit against companies who refuse access to product for the bioequivalence testing needed to support approval of a generic product.

In 2020, we completed our response to a civil investigative demand from the FTC related to the marketing, sale, distribution and pricing of our products, including Thiola. While the investigation remains open, at this time the FTC has not indicated that it has additional questions for us and has not initiated any claim or proceeding against us relating to these matters.

We cannot currently predict the specific outcome or impact on our business of such regulatory and legislative initiatives, litigation or investigation. However, it is our policy, which is in compliance with the CREATES Act, to evaluate requests for samples of our branded products, and to provide samples in response to bona fide requests from qualified third parties, including generic manufacturers, subject to specified conditions. We have provided samples to certain generic manufacturers.

If additional generic versions of Thiola or Thiola EC, any generic versions of FILSPARI following the expiration of patent or regulatory exclusivity for the product, or generic versions of any other current or future products are approved, sales of that product likely would be negatively impacted, which could have a material adverse impact on our revenue and profitability. If generic versions of products from which we may receive milestone payments, such as Cholbam, are approved, our potential to receive milestone payments may be negatively impacted. In addition, the defense of litigation and response to investigation requests could result in substantial costs, reputational impact, and the diversion of management attention and resources.

The Drug Price Competition and Patent Term Restoration Act (commonly referred to as the "Hatch-Waxman Act") requires an ANDA applicant seeking FDA approval of its proposed generic product prior to the expiration of an Orange Book-listed patent (as defined below) to certify that the applicant believes that the patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the drug for which the application has been submitted (a paragraph IV certification) and notify the NDA and patent holder of such certification (a paragraph IV notice). Upon receipt of a paragraph IV notice, the Hatch-Waxman Act allows the patent holder, with proper basis, to bring an action for patent infringement against the ANDA filer, asking that the proposed generic product not be approved until after the patent expires. For ANDAs that are filed (“received”) after the listing of the patent in the Orange Book, if the patent holder commences a lawsuit within 45 days from receipt of the paragraph IV notice, the Hatch-Waxman Act provides a 30-month stay during which time the FDA cannot finally approve the generic’s application. If the litigation is resolved in favor of the ANDA applicant during the 30-month stay period, the stay is lifted and the FDA may finally approve the ANDA if it is otherwise ready for approval. For ANDAs that are filed (“received”) before the listing of the patent in the Orange Book, the 30-month stay provision of the Hatch-Waxman Act does not apply. It also may be possible, depending on the approved label, for an ANDA applicant to elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

Healthcare reform initiatives, unfavorable pricing regulations and changes in reimbursement practices of third-party payers or patients' access to insurance coverage could affect the pricing of and demand for our products.

The business and financial condition of healthcare-related businesses will continue to be affected by efforts of governments and third-party payers to contain or reduce the cost of healthcare through various means. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our current product candidates or any future product candidate that we develop, restrict or regulate post-approval activities and affect our ability to profitably sell sparsentan, pegtibatinase, or any other product candidate for which we obtain marketing approval.

Our products are sold to patients whose healthcare costs are met by third-party payers, such as government programs, private insurance plans and managed-care programs. These third-party payers are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for medical products and services. Levels of reimbursement, if any, may be decreased in the future, and future healthcare reform legislation, regulations or changes to reimbursement policies of third-party payers may otherwise adversely affect the demand for and price levels of our products, which could have a material adverse effect on our sales and profitability.

The current administration has indicated that it plans to pursue additional policies aimed at lowering prescription drug costs. For example, in May 2025, the administration published an executive order regarding most favored nation (“MFN”) drug pricing, which is sometimes referred to as international reference pricing. This executive order directed the Secretary of Health and Human Services to communicate MFN price targets to pharmaceutical manufacturers, and if significant progress towards MFN pricing is not delivered, to propose a rulemaking plan to impose MFN pricing. The scope, timing, and potential impact of current and future policy initiatives remain uncertain, and accordingly, we cannot predict how such legal

and regulatory changes may affect our business, operations, or financial condition. If MFN pricing or other legal or regulatory changes are implemented in a way that is broadly applicable to our products, there could be a material negative impact.

Economic, social, and congressional pressure may result in individuals and government entities increasingly seeking to achieve cost savings through mechanisms that limit coverage or payment for our products. For example, state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and are requiring prior authorization for use of drugs. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products.

In addition, patients' access to employer sponsored insurance coverage may be negatively impacted by economic factors that result in increased rates of unemployment. To the extent patients taking our approved therapies become unemployed and experience a reduction to, or increased costs associated with, their insurance coverage, demand for our products could decline, which could have a material adverse effect on our sales and profitability, either as a result of decreased sales of our products and/or increased provision by us of free product to uninsured or commercially insured patients. The extent and duration of this potential impact on our business is currently unknown.

We are dependent on third parties to manufacture and distribute our products.

We have no manufacturing capabilities and rely on third-party manufacturers who are currently sole source suppliers for manufacturing of FILSPARI and Thiola. The facilities used by our third-party manufacturers must be approved by the FDA and comparable foreign regulatory authorities. Our dependence on third parties for the manufacture of our products may harm our profit margin on the sale of products and our ability to deliver products on a timely and competitive basis. Because we are ultimately responsible for ensuring that our API and finished products are manufactured in accordance with cGMP regulations and similar regulatory requirements outside the United States, it is critical that we maintain effective management practices and oversight with respect to our third-party manufacturers, including routine auditing. If our third-party manufacturers are unable to manufacture to specifications or in compliance with applicable regulatory requirements, our ability to commercialize our products will be adversely impacted and could affect our ability to gain market acceptance for our products and negatively impact our revenues.

Based on the complex relationships between the United States and certain foreign countries, there is inherent risk that political, diplomatic and national security influences might lead to trade disputes and impacts and/or disruptions to our third-party manufacturers and product supply. There is currently significant uncertainty about the future relationship between the United States and Mexico, Canada, China and certain other countries, including potential changes with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. We currently source products and various materials that are necessary for the manufacturing of our products from countries that are subject to tariffs, and any changes in tariffs, trade barriers, and other regulatory requirements could lead to higher cost of goods, which would have an adverse effect on our business, financial condition and operating results, the extent of which cannot be predicted with certainty at this time.

We currently have no in-house distribution channels for FILSPARI or Thiola and we are dependent on third-party distributors to distribute such products. The outsourcing of our distribution function is complex, and we may experience difficulties that could reduce, delay or stop shipments of such products. If we encounter such distribution problems, and we are unable to quickly enter into a similar agreement with another distributor on substantially similar terms, distribution of FILSPARI and/or Thiola could become disrupted, resulting in lost revenues, provider dissatisfaction, and/or patient dissatisfaction.

Governments outside the United States tend to impose strict price controls and reimbursement approval policies, which may adversely affect our prospects for generating revenue.

Outside the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly EU Member States and EFTA countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time (6 to 12 months or longer) after the receipt of marketing approval for a product. The EU provides options for EU Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status.

Moreover, to obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidate to other available therapies. This Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.

In December 2021, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, was adopted in the EU. This Regulation entered into force in January 2022 and began to apply on January 12, 2025, through a phased implementation. The Regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation permits EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we or our partners are unable to maintain favorable pricing and reimbursement status in EU Member States for drug candidates that we or our partners may successfully develop and for which we or our partners may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. In light of the fact that the United Kingdom has left the EU, Regulation No 2021/2282 on HTA does not apply in the United Kingdom. However, the MHRA is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium, the National Institute for Health and Care Excellence, and the All-Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products, including, effective as of March 31, 2025, relaunching the Innovative Licensing and Access Pathway with more predicable timelines and closer involvement of the National Health Service.

In addition, certain governmental authorities may conduct reviews of reimbursement previously provided and assert for various reasons that amounts need to be repaid. For example, in October 2021 our distributor/exploitant in France for our previously marketed product Kolbam (which has since been divested) informed us that they had received a notice that the price previously paid for Kolbam during its period on the market in France had been recalculated by the agency responsible for pharmaceutical pricing in France. Such notice was confirmed by a decision in October 2023, asserting percentages of our turnover owed for repayment. In April 2024, we filed an appeal with the Competent Administrative Court regarding this matter. In October 2024, we received an invoice from the government authority for approximately $6.2 million, which we paid while we continue to pursue an appeal of the decision and the amount paid. While we cannot predict the amount that we may ultimately need to repay following ongoing review and future potential appeal proceedings, from 2015 through 2020, the period during which we had sales of Kolbam in France, our aggregate revenues from sales of Kolbam in France attributable to all purchasers/payers were approximately $8 million. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels or subject to re-assessment and recoupment procedures, our prospects for generating revenue outside of the United States, if any, could be adversely affected and our business may suffer.

We may not be able to rely on orphan drug exclusivity for our products.

Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs, providing eligibility for orphan drug exclusivity upon regulatory approval if certain jurisdictional-specific conditions are met. For example, FILSPARI has been granted orphan drug designation for the treatment of IgAN and has been awarded seven years of orphan drug exclusivity in the United States (running from the date of accelerated approval) to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, and has been granted a separate seven years of Orphan Drug Exclusivity in the U.S. (running from the date of full approval) to slow kidney function decline in adults with primary IgAN who are at risk for disease progression, excluding the use provided for in the aforementioned Orphan Drug Exclusivity granted in connection with the accelerated approval. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, that product is entitled to a period of marketing exclusivity, which precludes the applicable regulatory authority from approving another marketing application for the same drug for the same indication for that time period. The applicable period is seven years in the United States and ten years in the EU or, in the case of orphan drugs for which a pediatric investigation plan has been completed, 12 years. Even though we have been awarded orphan drug designation in the United States and the EU for sparsentan for the treatment of IgAN and FSGS and for pegtibatinase for the treatment of HCU, we may not be able to maintain it in the EU and the orphan drug designation may not result in orphan drug exclusivity in the United States for FSGS or the EU if approved. For example, if a competitive product that contains the same active moiety and treats the same disease as our product is shown to be clinically superior to our product, any orphan drug exclusivity we have obtained will not block the approval of such competitive product and we may effectively lose orphan drug exclusivity. Similarly, if a competitive product that contains the same active moiety and treats the same disease as our product candidate is approved for orphan drug exclusivity before our product candidate, we may not be able to obtain approval for our product candidate until the expiration of the competitive product's orphan drug exclusivity unless our product candidate is shown to be clinically superior to the competitive product.

Guidelines and recommendations published by various organizations may impact the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. However, professional societies, industry groups, practice management groups, insurance carriers, physicians, private foundations and other organizations involved in various diseases or conditions from time to time may also publish guidelines or recommendations to healthcare providers, administrators and payers, and patient communities. Recommendations by government agencies or those other groups/organizations may relate to such matters as clinical guidelines, usage and reimbursement of our products by government and private payers. Recommendations or guidelines that are followed by patients, healthcare providers and payers could impact the use of our products in positive or negative ways. In addition, recommendations or guidelines may not be followed by patients, healthcare providers or payers, and thus any such positive recommendations or guidelines may not have a positive impact on the use of our products. Any such recommendations or guidelines may be updated over time as the treatment landscape evolves, and future changes to guidelines or recommendations could have a material adverse impact on the use of our products. Any recommendations or

guidelines, or changes thereto, that result in decreased use or reimbursement of our products could materially and adversely affect our product sales, business and operating results.

Risks Related to the Development of our Product Candidates

Our clinical trials are expensive and time-consuming and may fail to demonstrate the safety and efficacy of our product candidates.

Before obtaining regulatory approval for the sale of any of our current or future product candidates, we must subject these product candidates to extensive nonclinical and clinical testing to demonstrate their safety and efficacy for humans. Clinical trials are expensive, time-consuming and may take years to complete.

We may experience numerous unforeseen events during, or as a result of, preclinical or nonclinical testing and the clinical trial process that could delay or prevent our ability to obtain, or impact our willingness to pursue, regulatory approval or commercialize our product candidates, including:

- our preclinical or nonclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical testing or clinical trials or we may abandon projects that we expect to be clinically promising in light of cost or strategic considerations;
- regulators may require us to conduct studies of the long-term effects associated with the use of our product candidates;
- regulators, institutional review boards or ethics committees may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA or any non-United States regulatory authority may impose conditions on us regarding the scope or design of our clinical trials or may require us to resubmit our clinical trial protocols to institutional review boards or ethics committees for re-inspection due to changes in the regulatory environment;
- the number of patients required for our clinical trials may be larger than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;
- our third-party contractors or clinical investigators may fail to comply with regulatory requirements or fail to meet their contractual obligations to us in a timely manner;
- we might have to suspend, vary or terminate one or more of our clinical trials if we, regulators or institutional review boards or ethics committees determine that the participants are being exposed to unacceptable health risks;
- regulators, institutional review boards or ethics committees may require that we hold, suspend, vary or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials or the anticipated commercialization costs may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct our clinical trials may be insufficient or inadequate, or more expensive than we originally anticipated, or we may not be able to reach agreements on acceptable terms with prospective suppliers or clinical research organizations; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

We will only obtain regulatory approval to commercialize a product candidate if we can demonstrate to the satisfaction of the FDA, and in the case of foreign commercialization, to the applicable foreign regulatory authorities, in well-designed and conducted clinical trials, that our product candidates are safe and effective and otherwise meet the appropriate standards required for approval for a particular indication.

Conducting clinical trials effectively in pursuit of regulatory approval requires significant resources, and the costs of conducting clinical trials varies depending on a number of factors, including the dosage of the study therapy, trial size and duration. These costs may prove greater than we originally anticipated, which may result in us choosing to abandon or forgo clinical trials that we deem clinically promising as we actively strategize over time with respect to the allocation of our resources.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether any nonclinical tests or clinical trials will be initiated as planned, will need to be restructured or will be completed on schedule, if at all. Significant nonclinical or clinical trial delays also could shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. In

addition, such delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining, or may not be able to obtain, marketing approval for one or more of our product candidates;
- obtain approval for indications that are not as broad as intended or entirely different than those indications for which we sought approval; and
- have the product removed from the market after obtaining marketing approval.

For example, in our pivotal Phase 3 DUPLEX Study of sparsentan in FSGS, although we achieved the pre-specified interim FSGS partial remission of proteinuria endpoint after 36 weeks of treatment, the study did not achieve the primary efficacy eGFR slope endpoint over 108 weeks of treatment. While we have continued to engage with the FDA to explore a potential path forward for an sNDA, including through a Type C meetings in December 2023 and February 2025, and while the FDA has accepted our sNDA seeking traditional approval of FILSPARI for FSGS and has indicated that an advisory committee meeting was not needed, there is no guarantee that the FDA will grant approval of FILSPARI for FSGS. In addition, a collaborative international effort referred to as the PARASOL project was initiated in late 2023 with a goal to define the quantitative relationships between short-term changes in biomarkers (proteinuria and GFR) and long-term outcomes in order to support the use of alternative proteinuria-based endpoints as a basis for accelerated and traditional approval. Even though representatives of regulatory agencies participated in the discussions, there is no guarantee that the outcome of those discussions will be reflected in any future formal determination by such regulatory agencies. There is no guarantee that the PARASOL group will achieve its intended goal, or that, even if it does, that sparsentan will be approved for FSGS. In January 2026, we announced that the FDA extended the review timeline of our sNDA for FILSPARI in FSGS, and the new PDUFA target action date is April 13, 2026. The extension follows the recent submission of responses requested by the FDA to further characterize the clinical benefit of FILSPARI. The FDA determined that the additional responses constituted a Major Amendment to the sNDA and extended the action date accordingly.

We may not be able to initiate or continue clinical trials in the rare diseases on which we are focused if we are unable to locate a sufficient number of eligible patients willing and able to participate in the clinical trials required by the FDA or foreign regulatory authorities. In addition, as other companies and researchers may be concurrently developing therapies for the same or similar indications that we are focused on, we could face competition for a limited number of patients, investigators and clinical trial sites willing to participate in clinical trials. Our inability to enroll and maintain a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful.

Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful. For example, while we saw trends in favor of sparsentan in the two-year confirmatory endpoint analysis in the DUPLEX Study in FSGS, the positive eGFR results from the open-label portion of the DUET study of sparsentan in FSGS were not replicated in the Phase 3 clinical trial with statistical significance. Similarly, the positive nonclinical data we have seen from pegtibatinase being tested in a mouse model of homocystinuria and the positive topline results we reported in December 2021 and May 2023 from the ongoing Phase 1/2 clinical trial of pegtibatinase may not be replicated in future studies. We cannot assure that any current or future clinical trials of sparsentan or pegtibatinase will ultimately be successful. Before obtaining regulatory approval to conduct clinical trials of our product candidates, we must conduct extensive nonclinical tests to demonstrate the safety of our product candidates in animals. Nonclinical testing is expensive, difficult to design and implement, and can take many years to complete. In addition, during the clinical development process, additional nonclinical toxicology studies are routinely conducted concurrently with the clinical development of a product candidate. If any of our product candidates show unexpected findings in concurrent toxicology studies, we could experience potentially significant delays in, or be required to abandon, development of that product candidate. A failure of one or more of our nonclinical studies can occur at any stage of testing.

Communications and/or feedback from regulatory authorities related to our current or planned future clinical trials does not guarantee any particular outcome from or timeline for regulatory review, and expedited regulatory review pathways may not actually lead to faster development or approval.

Communications and/or feedback from regulatory authorities, including the FDA or EMA, related to our current or future clinical trials does not guarantee any particular outcome from or timeline for regulatory review for such clinical trials, and expedited regulatory review pathways may not actually lead to faster development or approval.

In 2018 we initiated the Phase 3 DUPLEX Study under the Subpart H pathway for potential accelerated approval in the United States, and potential conditional marketing authorization in the EU, in both jurisdictions based on change in proteinuria. Recognition of change in proteinuria as a

surrogate endpoint in kidney disease is a relatively new regulatory development, and, as the field continues to evolve, new learnings may impact regulatory viewpoints.

In May 2023, we announced that the DUPLEX Study did not achieve its two-year primary endpoint with statistical significance over the active control irbesartan. While we have continued to engage with the FDA to explore a potential path forward for an sNDA, including through a Type C meetings in December 2023 and February 2025, and the FDA has accepted our sNDA seeking traditional approval of FILSPARI for FSGS and has indicated that an advisory committee is not needed, there is no guarantee that the FDA will grant approval of FILSPARI for FSGS. Similarly there is no guarantee that our collaborator CSL Vifor will be able to establish a pathway to a potential submission of sparsentan for FSGS in Europe based on the results from the DUPLEX Study, that the EMA will support an application for sparsentan in FSGS, or that sparsentan will be approved for FSGS in Europe. In January 2026, we announced that the FDA extended the review timeline of our sNDA for FILSPARI in FSGS, and the new PDUFA target action date is April 13, 2026. The extension follows the recent submission of responses requested by the FDA to further characterize the clinical benefit of FILSPARI. The FDA determined that the additional responses constituted a Major Amendment to the sNDA and extended the action date accordingly.

In December 2023, we 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 tHcy levels. In September 2024, we announced a voluntary pause of enrollment in the HARMONY Study. The voluntary enrollment pause was enacted following our determination that the desired drug substance profile was not achieved in the initial scale-up process. While we have made process improvements and have manufactured material at the larger scale, and while we have restarted enrollment activities for the Phase 3 HARMONY Study, and while the FDA has granted Fast Track and Breakthrough Therapy designations to pegtibatinase for the treatment of HCU, there is no guarantee that our pivotal Phase 3 HARMONY Study will be conducted or completed on the anticipated timeline or be successful, or that pegtibatinase will be approved for HCU in the future.

Obtaining access to an expedited program (such as Fast Track and Breakthrough Therapy designations) may not in fact lead to faster development timelines or achieve faster review or approval than conventional FDA procedures. We may experience delays in approval timelines attributable to, among other things, acquiring sufficient supply of our product to conduct clinical trials, identifying and resolving issues relating to chemistry, manufacturing and controls, or conducting additional nonclinical or clinical studies. In addition, the FDA may withdraw access to an expedited program if it believes the access or designation is no longer supported by the data from our program.

Interim, topline and preliminary data from our clinical trials that we announce or publish may change materially as more patient data become available and audit and verification procedures are complete.

From time to time, we may publicly disclose preliminary or topline or interim data from our clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment and dosing continues and more patient data become available. Adverse differences between preliminary or interim data and final or confirmatory data could significantly harm our business prospects.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular therapy, therapeutic candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We and/or a collaborative partner are or will be subject to ongoing regulatory obligations and continued regulatory review for our approved products and any product candidates that receive regulatory approval.

In September 2024, the FDA granted full approval of FILSPARI to slow kidney function decline in adults with primary IgAN who are at risk of disease progression. Any future regulatory approvals that sparsentan or any of our other product candidates receives may be subject to significant limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate.

In addition, our products, including FILSPARI, and any of our product candidates that are approved by the FDA or a comparable foreign regulatory authority, are or will be subject to extensive and ongoing regulatory requirements, including for the manufacturing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export, recordkeeping, conduct of potential post-marketing studies and post-market submission requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices and good clinical practices, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, undesirable side effects caused by the product, problems encountered by our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, either before or after product approval, may result in, among other things:

- restrictions on the marketing, manufacturing, or distribution of the product;
- requirements to include additional warnings on the label;
- requirements to create or enhance a medication guide outlining the risks to patients;
- withdrawal of the product from the market;
- voluntary or mandatory product recalls;
- requirements to change the way the product is administered or for us to conduct additional clinical trials;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension, variation or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- harm to our reputation.

For example, we have certain post-marketing requirements and commitments associated with FILSPARI. Further, we face risks relating to those post-marketing obligations, as well as the commercial acceptance of FILSPARI. If the regulatory approval for FILSPARI and/or Thiola are withdrawn for any reason, it would have a material adverse impact on our sales and profitability. Furthermore, if the regulatory approval for Chenodal and/or Cholbam are withdrawn for any reason, it would reduce the chance that we will receive any or all of the milestone payments from the sale of our bile acid product portfolio in August 2023.

The third-party clinical investigators and contract research organizations that we rely upon to conduct our clinical trials may not be diligent, careful or timely, and may make mistakes, in the conduct of our trials.

We depend on third-party clinical investigators and contract research organizations (“CROs”) to conduct our clinical trials under agreements with us. The CROs play a significant role in the conduct of our clinical trials. Failure of the CROs to meet their obligations could adversely affect clinical development of our product candidates. The third-party clinical investigators are not our employees and we cannot control the timing or amount of resources they devote to our studies. If their performance is substandard, it could delay or prevent approval of our FDA applications. Moreover, these third-party investigators and CROs may also have relationships with other commercial entities, some of which may compete with us. If third-party investigators and CROs allocate their resources to assist our competitors at our expense, it could harm our competitive position. The introduction of new third parties into our ongoing clinical trials increases the risks associated with our dependence on third parties, including the risk that substandard performance by, or competing interests of, such third parties could have a negative impact on our clinical trials.

Risks Related to our Products and Product Candidates

Our products may not achieve or maintain expected levels of market acceptance or commercial success.

The success of our products is dependent upon achieving and maintaining market acceptance. Commercializing products is time consuming, expensive and unpredictable. There can be no assurance that we will be able to, either by ourselves or in collaboration with our partners or through our licensees, successfully commercialize new products or current products or gain market acceptance for such products. New product candidates that appear promising in development may fail to reach the market or may have only limited or no commercial success.

Further, the discovery of significant problems with a product similar to one of our products that implicate (or are perceived to implicate) an entire class of products could have an adverse effect on sales of the affected products. Accordingly, new data about our products, or products similar to our products, could negatively impact demand for our products due to real or perceived side effects or uncertainty regarding efficacy and, in some cases, could result in product withdrawal.

Our current products, including FILSPARI, and any product candidates that receive marketing approval, that we or a collaboration partner bring to the market may not gain market acceptance by physicians, patients, third-party payers, and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our current products and product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the efficacy and potential advantages over alternative treatments;
- the pricing of our product candidates;
- the relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage and reimbursement.

As part of the NDA review process for sparsentan for IgAN, the FDA initially required us to include a REMS and a boxed warning on the label regarding mandatory birth control for patients of child-bearing potential regarding risk of embryo-fetal toxicity, as has been required for certain other approved endothelin antagonists, and a REMS and boxed warning on the label for liver monitoring regarding potential risk of hepatotoxicity, as has been required for certain other approved endothelin antagonists. Initially, as part of the liver monitoring REMS, monthly monitoring of each patient was required for the first year a patient was on treatment, and quarterly thereafter. In August 2025, we announced that the FDA approved updated REMS labeling for FILSPARI, reducing the frequency of liver function monitoring to every three months from the onset of treatment with FILSPARI, and removing the embryo-fetal toxicity monitoring requirement from the REMS. While we intend to utilize our continued clinical trial experience with FILSPARI and post-marketing data gathering commitment to potentially support lifting of the liver monitoring REMS in the future following sufficient experience with FILSPARI and if supported by the data, there is no guarantee that such efforts will be successful.

Even if a potential or current product displays a favorable efficacy and safety profile in nonclinical and clinical trials, market acceptance of the product will not be known until after it is launched. The efforts by us or any applicable collaboration partner to educate patients, the medical community, and third-party payers on the benefits of our products may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by the conventional marketing technologies employed by our competitors.

The market opportunities for our products and product candidates may be smaller than we believe they are.

Certain of the diseases that our current and future product candidates are being developed to address, such as IgAN, FSGS and HCU, are relatively rare. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, may not be accurate.

Currently, most reported estimates of the prevalence of IgAN, FSGS and HCU are based on studies of small subsets of the population of specific geographic areas, which are then extrapolated to estimate the prevalence of the diseases in the broader world population. As new studies are performed the estimated prevalence of these diseases may change. There can be no assurance that the prevalence of IgAN, FSGS or HCU in the study populations accurately reflect the prevalence of these diseases in the broader world population.

If our estimates of the prevalence of IgAN, FSGS or HCU or of the number of patients who may benefit from treatment with sparsentan or pegtibatinase prove to be incorrect or if regulatory approval is conditioned on label restrictions that limit the approved patient population, the market opportunities for our product candidates may be smaller than we believe they are, our prospects for generating revenue may be adversely affected and our business may suffer.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or commercialization.

Undesirable side effects caused by our product candidates could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale.

In addition, if any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product:

- regulatory authorities may require the addition of restrictive labeling statements;
- regulatory authorities may withdraw, suspend or vary their approval of the product; and
- we may be required to change the way the product is administered or conduct additional clinical trials.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product candidate, which in turn could delay or prevent us from generating significant revenues from its sale or adversely affect our reputation.

We do not currently have patent protection for certain of our commercial products. If we are unable to obtain and maintain protection for the intellectual property relating to our technology and products, their value will be adversely affected.

Our success will depend in large part on our ability to obtain and maintain protection in the United States and other countries for the intellectual property covering, or incorporated into, our technology and products. The patent situation in the field of biotechnology and pharmaceuticals generally is highly uncertain and involves complex legal, technical, scientific and factual questions. We do not have, and do not expect to obtain, patent protection for the original formulation of Thiola. Additionally, although we have a license to a granted U.S. patent covering the treatment of cystinuria by administering Thiola EC with food (U.S. Patent No. 11,458,104, "the '104 patent"), certain generic manufacturers have been able to obtain "skinny-label" approvals of generic versions of tiopronin EC as described below. More generally, we may not be able to obtain additional issued patents relating to our technology or products. Even if issued, patents issued to us or our licensors may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, which could limit our ability to stop competitors from marketing similar products or reduce the term of patent protection we may have for our products. In addition, in certain circumstances with respect to method of use patents, an ANDA applicant may certify that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. To date, several generic options for the 100mg and 300mg versions of Thiola EC have been approved by the FDA and become available. Accordingly, Thiola EC is subject to generic competition. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Patent laws vary by country. Some countries have compulsory licensing laws under which a patent owner may be required to grant licenses to third parties. Some countries do not grant or enforce patents related to medical treatments, or limit enforceability in the case of a public emergency. In addition, many countries limit the enforceability of patents against government agencies or government contractors. If we are unable to obtain or enforce patents related to medical treatments in certain countries, or we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our business may be adversely affected.

The intellectual property systems in other countries can be destabilized as a result of political events, during which the ability to obtain, maintain and enforce intellectual property protection in the affected country may be uncertain and evolving. For example, as a result of the ongoing war between Ukraine and Russia, Russian officials have suggested that they may treat patents or patent applications owned by parties from certain countries, including the United States, as unenforceable and/or provide for zero compensation compulsory licenses to such patents or patent applications. Recent court decisions in Russia have raised questions about the strength of trademark protections in Russia. The U.S. government's response to political events may also negatively affect our ability to obtain, maintain and enforce intellectual property protection in the affected country. For example, the U.S. government has issued sanctions against Russia related to the ongoing war in Ukraine, and as a result of these sanctions, it may not be possible to pay fees necessary for prosecution and maintenance of Russian patent applications and patents in the absence of licenses or exclusions set forth by the U.S. government authorizing transactions in connection with intellectual property. Payments for trademark protection may be similarly impacted. The U.S. Department of the Treasury has issued General License No. 31, authorizing such transactions to allow filing, prosecution and maintenance of Russian patents and trademarks. Uncertainties regarding political events, including the ongoing war between Ukraine and Russia, as well as any resulting losses of intellectual property protection, could harm our business.

Our product FILSPARI was covered by U.S. Patent No. 6,638,937, which expired in 2019 and to which we had an exclusive license. In addition, U.S. Patent No. 9,662,312, to which we also have an exclusive license and which was granted on May 30, 2017 and expires in 2030, covers the use of sparsentan for treating glomerulosclerosis, including FSGS. U.S. Patent No. 9,993,461, to which we also have an exclusive license and which was granted on June 12, 2018 and expires in 2030, covers the use of sparsentan for treating IgAN as well as glomerulosclerosis, including FSGS. While we have additional pending U.S. and foreign patent applications directed to sparsentan and its uses, there is no guarantee that any pending or future

patent applications will result in issued patents, issue on a timeline that provides material protection, or, if issued, contain claims of commercially meaningful scope.

For products we develop based on a new chemical entity not previously approved by the FDA, we expect that in addition to the protection afforded by our patent filings that we will be able to obtain five years regulatory exclusivity via the provisions of the Food, Drug, and Cosmetic Act ("FDC Act") and possibly seven years regulatory exclusivity via the orphan drug provisions of the FDC Act. In the case of sparsentan, the periods of regulatory exclusivity may, if certain conditions are satisfied, be extended by six months on the basis of pediatric exclusivity, thereby resulting in exclusivity periods of 5.5 years and 7.5 years, respectively. In addition, companies may be able to obtain up to five years patent term extension (to compensate for regulatory approval delay) for one patent covering such a product for its FDA-approved use. Such a patent, like the periods of regulatory exclusivity, also may be extended by a further six months on the basis of pediatric exclusivity if certain conditions are satisfied. While we have filed an application for patent term extension of U.S. Patent No. 9,993,461, and subsequently filed a supplement to this application to reflect the FDA -determined regulatory review period for sparsentan, which, if granted could extend the term of U.S. Patent No. 9,993,461 to January 2033, there is no guarantee that such patent term extension will be granted to such date, or at all. In addition, while we intend to seek pediatric exclusivity for FILSPARI based on our ongoing development efforts, which, if granted, could extend the term of such patent by an additional six months, the granting of pediatric exclusivity requires a series of regulatory interactions to reach agreement with the FDA, and there is no guarantee that our pediatric development efforts will support a path to pediatric exclusivity or that pediatric exclusivity will be granted by the FDA on a timeline that confers benefit on the term of patent coverage or regulatory exclusivity for FILSPARI, or at all.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we or our licensors were the first to make the inventions covered by each of our pending patent applications;
- we or our licensors were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents issued to us or our licensors that provide a basis for commercially viable products will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies that are patentable;
- we will file patent applications for new proprietary technologies promptly or at all;
- the claims we make in our patents will be upheld by patent offices in the United States and elsewhere;
- our patents will not expire prior to or shortly after commencing commercialization of a product; and
- the patents of others will not have a negative effect on our ability to do business.

We have a license agreement with Ligand Pharmaceuticals for the rights to sparsentan which we are initially developing for the treatment of IgAN and FSGS. This license subjects us to various commercialization, reporting and other obligations. If we were to default on our obligations, we and our licensees (including CSL Vifor and Chugai) could lose our rights to sparsentan. We have obtained a U.S. patent and European patent each covering the use of sparsentan for treating glomerulosclerosis, including FSGS, as well as a second U.S. patent and a second European patent each covering both the use of sparsentan for treating IgAN and the use of sparsentan for treating glomerulosclerosis, including FSGS. In November 2020, a third party filed an opposition to our second European patent (European Patent No. EP3222277, “the ‘277 EP Patent”), in the EPO. While we are vigorously defending the ‘277 EP Patent against the opposition, there is no guarantee that we will be successful in doing so.

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind the actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in our or their issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. If a third party has also filed a United States patent application prior to the effective date of the relevant provisions of the America Invents Act (i.e. before March 16, 2013) covering our product candidates or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that our efforts could be unsuccessful, resulting in a loss of our United States patent position.

We cannot assure you that third parties will not assert patent or other intellectual property infringement claims against us with respect to technologies used in our products. If patent infringement suits were brought against us, we may be unable to commercialize some of our products which could severely harm our business. Litigation proceedings, even if not successful, could result in substantial costs and harm our business.

We expect to rely on orphan drug status to develop and commercialize certain of our products and product candidates, but our orphan drug designations may not confer marketing exclusivity or other expected commercial benefits.

We expect to rely on orphan drug exclusivity for sparsentan and potential future product candidates that we may develop. Orphan drug status currently confers seven years of marketing exclusivity in the United States under the FDC Act, and up to ten years of marketing exclusivity in the EU for a particular product in a specified indication or, in the case of orphan drugs for which a pediatric investigation plan has been completed, 12 years. The FDA and European Commission have granted orphan designation for sparsentan for the treatment of IgAN and FSGS, and pegtibatinase for the treatment of homocystinuria. While we have been granted these orphan designations, we will not be able to rely on these designations to exclude other companies from manufacturing or selling these molecules for the same indication beyond these time frames. Furthermore, in the EU, orphan drug status is re-evaluated in connection with the marketing authorization review process and a product candidate must re-qualify as of such time in order to maintain orphan drug status and benefit from the potential regulatory exclusivity periods related to marketing authorizations granted to orphan products. The period of market exclusivity in the EU may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, a marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) the applicant consents to a second original orphan medicinal product application, (ii) the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

For any product candidate for which we have been granted orphan drug designation in a particular indication, it is possible that another company also holding orphan drug designation for the same product candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires. Even if we are the first to obtain marketing authorization for an orphan drug indication in the United States, there are circumstances under which a competing product may be approved for the same indication during the seven-year period of marketing exclusivity, such as if the later product is shown to be clinically superior to our orphan product, or if the later product is deemed a different product than ours. Further, the seven-year marketing exclusivity would not prevent competitors from obtaining approval of the same product candidate as ours for indications other than those in which we have been granted orphan drug designation, or for the use of other types of products in the same indications as our orphan product.

Any therapies we develop may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, thereby harming our business.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "PPACA"), was signed into law, which intended to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. There have been executive, judicial, Congressional, and political challenges and amendments to certain aspects of the PPACA. For example, on July 4, 2025, the One Big Beautiful Bill Act, or OBBBA, was signed into law, which narrowed access to PPACA marketplace exchange enrollment and declined to extend the PPACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired PPACA subsidies. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how any potential future healthcare reform measures of the current administration will impact the PPACA and our business.

Additionally, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and, due to subsequent legislative amendments, will stay in effect until 2032 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals and imaging centers.

In addition, in the EU, in April 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. In April 2024, the Parliament adopted its related position and on 4 June 2025 the European Council agreed on its position. The Council, the Parliament and the European Commission have begun trilogue negotiations with a view to reaching an agreement on the package. A decrease in data and market exclusivity opportunities for our product candidates in the EU could make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status.

If we are unable to obtain and maintain coverage and adequate reimbursement from governments or third-party payers for any products that we may develop or if we are unable to obtain acceptable prices for those products, our prospects for generating revenue and achieving profitability will suffer.

Our prospects for generating revenue and achieving profitability will depend heavily upon the availability of coverage and adequate reimbursement for the use of our approved product candidates from governmental and other third-party payers, both in the United States and in other markets. Reimbursement by a third-party payer may depend upon a number of factors, including the third-party payer's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining reimbursement approval for a product from each government or other third-party payer is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to each payer. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement. Additionally, we might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to such payers' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Even when a payer determines that a product is eligible for reimbursement, the payer may impose coverage limitations that preclude payment for some uses that are approved by the FDA or non-United States regulatory authorities. Also, prior authorization for a product may be required. In addition, there is a risk that full reimbursement may not be available for high-priced products. Moreover, eligibility for coverage does not imply that any product will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Further, coverage policies and third-party payer reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

A primary trend in the United States healthcare industry and elsewhere is toward cost containment. We expect the changes made by PPACA, other legislation impacting the Medicare program and the 340B program, and the increasing emphasis on managed care to continue to put pressure on pharmaceutical product pricing. As these concerns continue to grow over the need for tighter oversight, there remains the possibility that the Heath Resources and Services Administration or another agency under the HHS will propose regulations or that Congress will explore changes to the 340B program through legislation. There have also been a number of initiatives pending at the state and federal level that could negatively impact the reimbursement for products approved under the accelerated approval pathway in the United States by restricting patient access or establishing differential payment models. Certain states are also in the process of establishing Patient Drug Affordability Boards with the authority in some cases to set upper payment limits.

Further, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices, including several recent U.S. congressional inquiries and federal and state legislation designed to, among other things, increase drug pricing transparency, expedite generic competition, review relationships between pricing and manufacturer patient assistance programs, and reform government program drug reimbursement methodologies. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. In addition, HHS has been empowered to negotiate the price of certain single-source biologics that have been on the market for at least 11 years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop, which could have an adverse effect on our operating results and our overall financial condition.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs.

In addition, the current administration is pursuing policies to reduce regulations and expenditures across government including at the HHS, the FDA, Centers for Medicare & Medicaid Services ("CMS") and related agencies and has made significant staff reductions at the FDA and other agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and

repatriation of foreign revenues. Other recent actions and proposals include for example, (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs for Medicare through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing MFN pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's recent Strategy Report, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Finally, Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program. We cannot predict which additional measures may be adopted or the impact of current and additional measures on the marketing, pricing and demand for our products, which could have a material adverse effect on our business, financial condition and results of operations.

Any reduction in reimbursement from Medicare, Medicaid or other government-funded programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our therapies. Additionally, we are currently unable to predict what additional legislation or regulation, if any, relating to the healthcare industry may be enacted in the future or what effect recently enacted federal legislation or any such additional legislation or regulation would have on our business.

We face potential product liability exposure far in excess of our limited insurance coverage.

The use of any of our potential products in clinical trials, and the sale of any approved products, may expose us to liability claims. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling our products. We have obtained limited product liability insurance coverage for our clinical trials in the amount of $10 million per occurrence and $35 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage as we obtain marketing approval for additional product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance. On occasion, juries have awarded large judgments in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us would decrease our cash reserves and could cause our stock price to fall.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. Our operating results will suffer if we fail to compete effectively.

Several of our competitors have substantially greater financial, research and development, distribution, manufacturing and marketing experience and resources than we do and represent substantial long-term competition for us. Other companies may succeed in developing and marketing products that are more effective and/or less costly than any products that may be developed and marketed by us, or that are commercially accepted before or perceived as preferred relative to any of our products, or that obtain preferential formulary and reimbursement status. Factors affecting competition in the pharmaceutical and therapeutic industries vary, depending on the extent to which a competitor is able to achieve a competitive advantage based on its proprietary technology and ability to market and sell therapeutics. The industry in which we compete is characterized by extensive research and development efforts and rapid technological progress. In particular, the competitive landscape for IgAN is rapidly evolving and is expected to continue to evolve as multiple new modalities advance in development and potentially gain approval. Furthermore, although we believe that our orphan drug status and proprietary position with respect to sparsentan may give us a competitive advantage, new developments are expected to continue and there can be no assurance that discoveries by others will not render our products and product candidates noncompetitive. More detailed information is available under the heading "Competition" in Item 1 of Part I of this Annual Report on Form 10-K.

Furthermore, competitors could enter the market with generic versions of our products. For example, a generic option for the 100mg version of the original formulation of Thiola (tiopronin tablets) was approved by the FDA in May 2021 and a second 100mg version of the original formulation of Thiola (tiopronin tablets) was approved by the FDA in June 2022. In addition, several generic options for the 100mg and 300mg versions of Thiola EC have been approved by the FDA and become available.

Our competitive position also depends on our ability to enter into strategic alliances with one or more large pharmaceutical and contract manufacturing companies, attract and retain qualified personnel, develop effective proprietary products, implement development and marketing plans, obtain patent protection, secure adequate capital resources and successfully sell and market our approved products. There can be no assurance that we will be able to successfully achieve all of the foregoing objectives.

Use of third parties to manufacture our products and product candidates may increase the risk that we will not have sufficient quantities of our product and product candidates or such quantities at an acceptable cost, and clinical development and commercialization of our product and product candidates could be delayed, prevented or impaired.

We do not own or operate manufacturing facilities for clinical or commercial production of our products or product candidates. We have limited personnel with experience in drug manufacturing and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We outsource all manufacturing and packaging of our nonclinical, clinical, and commercial products to third parties. The manufacture of pharmaceutical products in general, and biologics in particular, requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production and in maintaining required quality control. These problems include difficulties with production costs and yields and quality control, including stability of the product candidate.

In September 2024, we announced a voluntary pause of enrollment in the Phase 3 HARMONY Study evaluating pegtibatinase for the treatment of classical HCU. The voluntary enrollment pause enabled us to address necessary process improvements in manufacturing scale-up to support the initial commercial scale manufacturing as well as full enrollment in the HARMONY Study. The voluntary enrollment pause was enacted following our determination that the desired drug substance profile was not achieved in the initial scale-up process. While we have made process improvements and have manufactured material at the larger scale, and while we restarted enrollment activities for the pivotal Phase 3 HARMONY Study in the first quarter of 2026, there is no guarantee that the Phase 3 HARMONY Study will be conducted or completed on the anticipated timeline or be successful. In addition, external factors including supply chain risks, geopolitical factors, and matters related to the staffing, resources and prioritization at the FDA and other government agencies, among others, could have impacts on our anticipated timeline.

We intend to rely on third-party manufacturers for the long-term commercial supply of FILSPARI and for our development stage product candidates. We expect the manufacturers of each product or product candidate to, at least initially and potentially for a significant period of time, be single source suppliers to us. Reliance on third-party manufacturers entails risks to which we may not be subject if we manufactured our product candidates or products ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- limitations on supply availability resulting from capacity and scheduling constraints of the third parties;
- less control over cost increases resulting from inflationary pressures affecting raw materials and other supply chain components;
- impact on our reputation in the marketplace if manufacturers of our products fail to meet the demands of our customers;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control; and
- the possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

The failure of any of our contract manufacturers to maintain high manufacturing standards could result in injury or death of clinical trial participants or patients using our products. Such failure could also result in product liability claims, product recalls, product seizures or withdrawals, delays or failures in testing or delivery, cost overruns or other problems that could seriously harm our business or profitability.

Our contract manufacturers are required to adhere to FDA regulations setting forth cGMP and comparable foreign regulatory authority requirements. These regulations cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our product candidates and any products that we may commercialize. Our manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our manufacturers are subject to unannounced inspections by the FDA, state regulators and similar regulators outside the United States to monitor and ensure compliance with cGMP. We are ultimately responsible for ensuring that our API and finished products are manufactured in accordance with cGMP regulations and similar regulatory requirements outside the United States, and it is therefore critical that we maintain effective management practices and oversight with respect to our third-party manufacturers, including routine auditing. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including shutdown of the third-party vendor or invalidation of drug product lots or processes, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect regulatory approval and supplies of our product candidates.

Our product and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. A health epidemic or pandemic and associated vaccine or treatment development and manufacturing efforts may increase demand for the services supplied by many third-party manufacturers, including some of those that we utilize for our products and product candidates, which may result in decreased availability of manufacturing slots at many such facilities. If the third parties that we engage to manufacture products for our

developmental or commercial products should halt or cease to continue to do so for any reason, we likely would experience interruptions in cash flows and/or delays in advancing our clinical trials while we identify and qualify replacement suppliers, and we may be unable to obtain replacement supplies on terms that are favorable to us. Later relocation to another manufacturer will also require notification, review and other regulatory approvals from the FDA and other regulators and will subject our production to further cost and instability in the availability of our product candidates. In addition, if we are not able to obtain adequate supplies of our products and product candidates, or the drug substances used to manufacture them, it will be more difficult for us to sell our products and to develop our product candidates. This could greatly reduce our competitiveness and negatively affect our results of operations.

Our current and anticipated future dependence upon others for the manufacture of our products and product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize our marketed products and any other products that may obtain regulatory approval on a timely and competitive basis.

Materials necessary to manufacture our products and product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our products and product candidates.

We rely on the manufacturers of our products and product candidates to purchase from third-party suppliers the materials necessary to produce the compounds or biologic substances for our nonclinical and clinical studies and rely on these other manufacturers for commercial distribution if we obtain marketing approval for any of our product candidates. Suppliers may not sell these materials to our manufacturers at the time we need them or on commercially reasonable terms and all such prices are susceptible to fluctuations in price and availability due to transportation costs, government regulations, price controls, and changes in economic climate or other foreseen circumstances. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. In addition, inflation and global supply chain disruptions, as well as past disruptions related to COVID-19 and potential future disruptions related to a future health epidemic or pandemic, wars, armed conflicts, tariffs and global geopolitical tension, including between the U.S. and China, have had and may continue to have a negative impact on our manufacturers' ability to acquire the materials necessary for our business. Changes in legislation could potentially impact our ability to secure the materials we need for our products and product candidates. For example, the United States has recently passed legislation, namely the BIOSECURE Act (the "BIOSECURE Act"), to prohibit U.S. federal executive agencies from procuring or obtaining any biotechnology equipment or service produced or provided by a "biotechnology company of concern" or entering into or renewing a contract, loan, or grant with an entity that uses such biotechnology equipment or services. Specifically, on December 18, 2025, President Trump signed the National Defense Authorization Act for fiscal year 2026 into law, which includes the BIOSECURE Act. The BIOSECURE Act prohibits the U.S. government from procuring or obtaining biotechnology equipment or services produced or provided by a "biotechnology company of concern" ("BCC"); entering into, extending, or renewing government contracts with an entity that directly or indirectly uses biotechnology equipment or services from a BCC in performance of that federal contract; and/or issuing grants or loans to purchase, obtain, or use biotechnology equipment or services produced by a BCC. The BIOSECURE Act also prohibits U.S. government loan and grant recipients from using federal loan or grant money to enter into contracts with entities that use equipment from BCCs in the performance of any federal prime contract or subcontract. Companies designated as a BCC include those that are identified on the U.S. Department of Defense's annual List of Chinese Military Companies, also known as the 1260H List, and the U.S. government also has the ability to designate entities as BCCs through a separate designation process. There is a "safe harbor" provision providing that the restrictions do not apply to equipment or services that were formerly but are no longer provided by a BCC, as well as a "grandfathering" provision providing that the prohibitions shall not apply for a five-year period to biotechnology equipment or services produced or provided under a contract or agreement entered into before the applicable effective date. Given the BIOSECURE Act, we may be restricted in our ability to work with certain Chinese biotechnology companies to the extent we would contract with, or otherwise receive funding from, the U.S. government. Although none of our current suppliers are presently designated, future designations or implementing regulations could require us to seek alternative suppliers, which could increase costs or delay our development and manufacturing timelines. Moreover, we currently do not have any agreements for the commercial production of these materials. If our manufacturers are unable to obtain these materials for our nonclinical and clinical studies, product testing and potential regulatory approval of our product candidates would be delayed, significantly impacting our ability to develop our product candidates. If our manufacturers or we are unable to purchase these materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would materially affect our ability to generate revenues from the sale of our product candidates. For example, in 2021 a membrane used in pegtibatinase drug substance manufacturing became more difficult to acquire due to the same or similar membranes being used in certain of the COVID-19 vaccine manufacturing processes. Additionally, in September 2024, we announced a voluntary pause of enrollment in the Phase 3 HARMONY Study to enable us to address necessary process improvements in manufacturing scale-up to support initial commercial scale manufacturing as well as full enrollment in the HARMONY Study. The voluntary enrollment pause was enacted following our determination that the desired drug substance profile was not achieved in the initial scale-up process. From time to time we continue to, and may in the future, face supply challenges or shortages of other materials necessary to manufacture pegtibatinase or our other products and product candidates. If our risk mitigation plans are not successful in overcoming these challenges, our pegtibatinase program or other products and product candidates, could be delayed.

Risks Related to Our Business

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

We operate in a global economy, and our business depends on a global supply chain for the development, manufacturing, and distribution of our pharmaceutical products, and for the advancement of our pre/nonclinical and clinical development programs. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty.

We source quantities of active pharmaceutical ingredients ("APIs"), precursor chemicals, and specialized equipment from international suppliers, including from manufacturers in China, consistent with broader industry practices. While the impact of tariff policies on our business has been minimal to date, current or future tariff policies, particularly those affecting China and pharmaceutical products, could further increase our costs, and may affect profitability, particularly in formulary-based markets where pricing flexibility may be limited. Recent and potential future changes in international trade policies, particularly regarding U.S.-China trade relations and pharmaceutical-specific tariffs, present potential risks to our future operations and financial performance.

The ongoing trade tensions between the United States and other countries including China have resulted in multiple rounds of tariffs affecting pharmaceutical ingredients, manufacturing equipment, and related supplies. The evolving tariff and trade landscape contributes to planning challenges for global pharmaceutical operations. Changes in tariff classifications, country-of-origin requirements, or customs procedures can occur with limited notice. This uncertainty complicates our long-term investment decisions regarding manufacturing facilities, supply chain optimization, and research and development locations.

Recent policy discussions have included potential targeted tariffs or other trade measures specifically aimed at pharmaceutical products and ingredients as part of broader healthcare cost control or national security initiatives. Pharmaceuticals and biologics face regulatory and technical constraints that make rapid supply chain adjustments challenging, complex and costly. Identifying and qualifying a new alternative supplier with available capacity and capabilities— whether in the U.S. or in another country with a more favorable tariff regime—requires a substantial monetary investment and investment of personnel and other resources, including those related to contracting, qualification, technology transfer, and regulatory approvals, and the process may take an extended period of time to complete.

While the impact of tariff policies on our business has been minimal to date, current or future tariffs may result in increased research and development expenses, including with respect to raw materials, APIs, laboratory equipment and research materials and components. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to development timelines. Increased costs and extended development timelines could affect competitiveness relative to companies operating in regions with more favorable trade relationships and could impact investor confidence.

The complexity of announced or future tariffs may also increase the risk of enforcement actions related to trade compliance. Foreign governments may adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities. These developments could affect our ability to compete internationally or engage with global suppliers, customers and partners. Retaliatory actions, such as changes to intellectual property protection, increased enforcement, or delays in regulatory approvals, could result in legal and operational risks.

In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain. While we actively monitor these risks and manage our supply chain accordingly, prolonged economic or geopolitical disruptions could adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this report.

Many of the trade, tariff, pricing, and related policy actions described herein remain subject to significant uncertainty, including with respect to their scope, duration, implementation, and enforceability. Such measures may be modified, delayed, suspended, repealed, or invalidated through administrative action, changes in policy priorities, or judicial challenges, and it is uncertain whether, when, or to what extent any such measures will ultimately be implemented or apply to our products, suppliers, or operations. Although we have taken and may continue to take certain actions intended to reduce potential exposure to supply chain or cost impacts, including efforts to diversify suppliers, there can be no assurance that such actions will be effective, timely, or sufficient to mitigate any adverse effects arising from these policies.

Our limited operating history makes it difficult to evaluate our future prospects, and our profitability in the future is uncertain.

We face the problems, expenses, difficulties, complications and delays, many of which are beyond our control, associated with any business in its early stages and have a limited operating history on which an evaluation of our prospects can be made. Such prospects should be considered in light of the risks, expenses and difficulties frequently encountered in the establishment of a business in a new industry, characterized by a number of market entrants and intense competition, and in the shift from development to commercialization of new products based on innovative technologies.

We have experienced significant growth over the past five years in the number of our employees and the scope of our operations. We have expanded our sales and marketing, compliance and legal functions in addition to expansion of all functions to support a commercial organization. We have also expanded our operations in connection with the commercial launch of FILSPARI in the United States, including by adding additional members to our sales force. To appropriately manage for our future, we must continue to implement and improve our managerial, operational and financial systems, continue to recruit, train and retain qualified personnel as needed, and successfully integrate any changes into our existing business. To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical, commercial and management personnel, and we face significant competition for experienced personnel.

Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit, train and retain qualified personnel, including in connection with the ongoing commercial launch of FILSPARI in the United States. The management of changes to our operations may lead to significant costs and may divert our management and business development resources. Any inability on the part of our management to manage growth or other changes in our organization could delay the execution of our business plans or disrupt our operations.

Factors that may inhibit our efforts to commercialize our products without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or educate adequate numbers of physicians to prescribe our products;
- the lack of complementary products to be offered by our sales personnel, which may put us at a competitive disadvantage against companies with broader product lines;
- unforeseen costs associated with expanding our own sales and marketing team for new products or with entering into a partnering agreement with an independent sales and marketing organization; and
- efforts by our competitors to commercialize competitive products.

Moreover, though we generate revenues from product sales arrangements, we may incur significant operating losses over the next several years. Our ability to achieve profitable operations in the future will depend in large part upon successful in-licensing of products approved by the FDA, selling and manufacturing these products, completing development of our products, obtaining regulatory approvals for these products, and bringing these products to market. The likelihood of the long-term success of our company must be considered in light of the expenses, difficulties and delays frequently encountered in the development and commercialization of new therapeutics, competitive factors in the marketplace, as well as the regulatory environment in which we operate.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors.

We depend on a highly experienced and skilled workforce to grow and operate our business. If we are unable to attract, retain and engage our employees, we may not be able to grow effectively.

The execution of our strategic objectives and future success will depend upon our continued ability to identify, hire, develop, motivate and retain a highly qualified workforce. We depend on contributions from our employees, and, in particular, our senior management team, to execute efficiently and effectively. Our success further depends on our ability to attract, retain and motivate highly skilled mid-level and senior managers as well as team members at various levels in the scientific, development, medical and commercial areas of the business, particularly in connection with our ongoing commercial launch of FILSPARI in the United States.

Our headquarters are based in San Diego, California. This region is home to many other biopharmaceutical companies and many academic and research institutions. Competition for qualified key talent in our market is intense and may limit our ability to hire and retain employees on acceptable terms, or at all. As a result, we may not be able to retain our existing employees or hire new employees quickly enough to meet our needs.

To induce valuable employees to remain at our company, in addition to salary, cash incentives and other employee benefits, we have provided stock options and restricted stock unit ("RSU") awards that vest over time. The value to employees of stock options and RSU awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Current market conditions and the potential for extreme stock price volatility exacerbates this risk. Despite our

efforts to retain valuable employees, members of our management, scientific, development and commercial teams may terminate their employment with us on short notice. All of our employees have at-will employment, which means that they could leave our employment at any time, with or without notice. We do not maintain “key person” insurance policies on the lives of any of our employees.

If we fail to effectively manage our hiring and retention needs, our ability to meet our strategic objectives and our business and operating results may be adversely impacted.

Health epidemics or pandemics could materially adversely affect our business, results of operations and financial condition.

A health epidemic or pandemic poses the risk that we or our clinical trial subjects, employees, contractors, collaborators, suppliers and vendors may be prevented from conducting certain clinical trials or other business activities for an indefinite period of time, including due to travel restrictions, quarantines, “stay-at-home” and "shelter-in-place" orders or shutdowns that have been or may be requested or mandated by governmental authorities, or that our or their ability to conduct operations will be negatively impacted by staffing shortages while employees quarantine as a result of exposure to or transmission of the virus. In addition, a health epidemic or pandemic could impact personnel at third-party manufacturing facilities in the United States and other countries, including China, or the availability or cost of materials, which could potentially disrupt the supply chain for our commercial products, our product candidates or the comparator products in our ongoing clinical trials.

The timelines and conduct of our ongoing clinical trials previously have been affected by COVID-19 and we may experience similar delays or interruptions due to other health epidemics or pandemics in the future. For example, in 2020 we experienced a reduction in the rates of patient enrollment in our ongoing clinical trials as a result of the COVID-19 pandemic. New health epidemics or pandemics may emerge that result in similar or more severe disruptions to our business, which could adversely impact our business and operating results.

We will likely experience fluctuations in operating results and could incur substantial losses.

We expect that our operating results will vary significantly from quarter-to-quarter and year-to-year as a result of investments in research and development, specifically our clinical and nonclinical development activities. We anticipate that certain of our expenses will continue to increase, depending on factors including but not limited to: the continuation and cost of our clinical trials and the research and development of additional product candidates; the costs involved in seeking and obtaining marketing approvals for our products, and in maintaining quality systems standards for our products; the timing of, and costs involved in, commercial activities, including product marketing, sales and distribution, costs related to our operational, financial, and management information systems and personnel, including personnel to support product development efforts and our obligations as a public company.

To attain and sustain profitability, we must succeed in developing and commercializing therapies with significant market potential. This will require us to be successful in a range of challenging activities, including the discovery of product candidates, successful completion of nonclinical testing and clinical trials of our product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We may not be successful enough in these activities to generate revenues that are substantial enough to recoup the expenses we have expended in conducting these activities to achieve profitability. Pursuant to the Ligand License Agreement, we are obligated to pay to Ligand an escalating annual royalty between 15% and 17% of net sales of FILSPARI and any other products containing sparsentan or related compounds, which will impact our potential future profit from the commercialization of FILSPARI in the United States and sparsentan for the treatment of IgAN in the EU as well as sparsentan for the treatment of FSGS, if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become or remain profitable could depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the market price of our common stock may also cause a loss of a part or all of your investment.

Negative publicity regarding any of our products could impair our ability to market any such product and may require us to spend time and money to address these issues.

If any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to consumers and/or subject to FDA or comparable foreign regulatory authority enforcement action, our ability to successfully market and sell our products could be impaired. Because of our dependence on patient and physician perceptions, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our products or any similar products distributed by other companies could limit the commercial potential of our products and expose us to potential liabilities.

We may not have sufficient insurance to cover our liability in any current or future litigation claims either due to coverage limits or as a result of insurance carriers seeking to deny coverage of such claims.

We face a variety of litigation-related liability risks. Our certificate of incorporation, bylaws, other applicable agreements, and/or Delaware law require us to indemnify (and advance expenses to) our current and past directors and officers and employees from reasonable expenses related to the defense of any action arising from their service to us, including circumstances under which indemnification is otherwise discretionary. While our directors and officers are included in a director and officer liability insurance policy ("D&O insurance"), which covers all our directors and officers in

some circumstances, our insurance coverage does not cover all of our indemnification obligations and may not be adequate to cover any indemnification or other claims against us. In addition, the underwriters of our present coverage may seek to avoid coverage in certain circumstances based upon the terms of the respective policies. If we incur liabilities that exceed our coverage under our D&O insurance or incur liabilities not covered by our insurance, we would have to self-fund any indemnification amounts owed to our directors and officers and employees in which case our results of operations and financial condition could be materially adversely affected. Further, if D&O insurance becomes prohibitively expensive to maintain in the future, we may be unable to renew such insurance on economic terms or unable to renew such insurance at all. The potential lack of D&O insurance may make it difficult for us to retain and attract talented and skilled directors and officers to serve our company, which could adversely affect our business.

We may need substantial funding and may be unable to raise capital when needed.

We expect our general and research and development expenses to increase in connection with our ongoing and planned activities, particularly as we conduct later-stage clinical trials of our product candidates. In addition, in connection with the commercial launch of FILSPARI in the United States, we have begun to incur significant commercialization expenses and expect to continue to incur significant commercialization expenses for FILSPARI and any other future approved products, including for product sales and marketing, securing commercial quantities of product from our manufacturers, and product distribution. Our expenses have and may continue to increase as a result of inflation in the United States and abroad. We currently have no additional commitments or arrangements for any additional financing to fund the research and development and commercial launch of our product candidates. General market conditions, including high interest rates and stock price volatility, actual or anticipated bank failures, new or increased tariffs, and ongoing issues arising global geopolitical tensions, including the wars and other armed conflicts, as well as market conditions affecting companies in the life sciences industry in general, may make it difficult for us to seek financing from the capital markets on attractive terms, or at all.

Management believes our ability to continue our operations depends on our ability to sustain and grow revenue, results of operations and our ability to access capital markets when necessary to accomplish our strategic objectives. Management believes that we may incur losses in the immediate future. We expect that our operating results will vary significantly from quarter-to-quarter and year-to-year as a result of investments in research and development, specifically our clinical and nonclinical development activities. We expect to finance our cash needs from cash on hand and results of operations, and depending on results of operations we may either need additional equity or debt financing, or need to enter into strategic alliances on products in development to continue our operations until we can achieve sustained profitability and positive cash flows from operating activities. Additional funds may not be available to us when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to reduce or eliminate research development programs or commercial efforts.

Our future capital requirements will depend on many factors, including:

- the timing, progress, cost and results of our clinical trials, preclinical studies and other discovery and research and development activities;
- the timing of, and costs involved in, seeking and obtaining marketing approvals for our products, and in maintaining quality systems standards for our products;
- the timing of, and costs involved in, commercial activities, including product marketing, sales and distribution;
- our ability to successfully commercialize FILSPARI for the treatment of IgAN, and to obtain regulatory approval for, and successfully commercialize, sparsentan for FSGS and our other or future product candidates;
- increases or decreases in revenue from our marketed products, including decreases resulting from generic entrants or health epidemics or pandemics;
- debt service obligations on the 2029 Notes;
- the number and development requirements of other product candidates that we pursue;
- our ability to manufacture sufficient quantities of our products to meet expected demand;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property related claims;
- our ability to enter into collaboration, licensing or distribution arrangements and the terms and timing of these arrangements;
- the potential need to expand our business, resulting in additional payroll and other overhead expenses;
- the potential in-licensing of other products or technologies;

- the emergence of competing products and technologies and other adverse market developments;
- the extent to which we acquire or invest in businesses, products and technologies; and
- the potential impacts of inflation and resulting cost increases.

The market price for shares of our common stock may be volatile and purchasers of our common stock could incur substantial losses.

The price of our stock is likely to be volatile. The stock market in general, and the market for biotechnology companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock has been in the past, and may be in the future, influenced by many factors, including:

- results of clinical trials of our product candidates or those of our competitors;
- our entry into or the loss of a significant collaboration;
- regulatory or legal developments in the United States and other countries, including changes in the health care payment systems;
- our ability to obtain and maintain marketing approvals from the FDA or similar regulatory authorities outside the United States;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- general economic, industry and market conditions, including the impacts thereon of inflation and high interest rates, actual or anticipated bank failures, new or increased tariffs, wars, armed conflicts and global geopolitical tensions;
- results of clinical trials conducted by others on therapies that would compete with our product candidates;
- developments or disputes concerning patents or other proprietary rights;
- public concern over our product candidates or any products approved in the future;
- litigation;
- communications from government officials regarding health care costs or pharmaceutical pricing;
- future sales or anticipated sales of our common stock by us or our stockholders; and
- the other factors described in this "Risk Factors" section.

In addition, the stock markets, and in particular, the Nasdaq Stock Market, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many pharmaceutical companies. The realization of any of the above risks or any of a broad range of other risks, including those described in these "Risk Factors" could have a dramatic and material adverse impact on the market price of our common stock.

We may not receive some or all of the potential milestone and/or royalty payments from our corporate and licensing transactions.

From time to time, we engage in corporate transactions and licensing transactions that include potential milestone payments and/or royalties. For example, on July 16, 2023, we entered into a Purchase Agreement with Mirum, pursuant to which we agreed to sell to Mirum, subject to the terms of the Purchase Agreement, our bile acid product portfolio including the Products. The closing of the transaction occurred on August 31, 2023. A portion of the consideration for the sale is in the form of milestone payments that will only be payable upon the achievement of certain milestones based on specified amounts of annual net sales of the Products. We are also party to license agreements with CSL Vifor and Renalys (which was acquired by Chugai in November 2025) pursuant to which we are entitled to receive certain payments contingent on the future achievement of specified milestones, and royalty payments based on potential future sales in specified licensed territories. There is a risk that any or all of the milestone

events under these various agreements might not be achieved, that our licensees may not achieve sales that would entitle us to royalty payments, and that any or all of the consideration tied to the achievement of the milestone events and/or royalties might not be received.

In the fourth quarter of 2025, our partner Renalys was acquired by and merged into Chugai, and as a result of the acquisition, Chugai gained exclusive rights to develop and commercialize sparsentan in Japan, South Korea, and Taiwan. Travere received a portion of the upfront payment due to the fact that it was a minority shareholder in Renalys prior to the acquisition, and Travere is also eligible to receive future payments upon the achievement of specified regulatory milestones for sparsentan and royalties on net sales in Japan, South Korea, and Taiwan. There is no guarantee that we will receive any or all of the consideration that is due upon closing or tied to the regulatory milestones or net sales.

We may be unable to successfully integrate new products or businesses we may acquire.

We may in the future expand our product pipeline by pursuing acquisition of pharmaceutical products. If an acquisition is consummated, the integration of the acquired business, product or other assets into our company may also be complex and time-consuming and, if such businesses, products and assets are not successfully integrated, we may not achieve the anticipated benefits, cost-savings or growth opportunities. Potential difficulties that may be encountered in the integration process include the following:

- integrating personnel, operations and systems, while maintaining focus on producing and delivering consistent, high quality products;
- coordinating geographically dispersed organizations;
- distracting employees from operations;
- retaining existing customers and attracting new customers; and
- managing inefficiencies associated with integrating the operations of the acquired company or product into our own operations.

Furthermore, these acquisitions and other arrangements, even if successfully integrated, may fail to further our business strategy as anticipated, expose us to increased competition or challenges with respect to our products or geographic markets, and expose us to additional liabilities associated with an acquired business, product, technology or other asset or arrangement. Any one of these challenges or risks could impair our ability to realize any benefit from our acquisitions or arrangements after we have expended resources on them.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

Our business exposes us to potential liability risks inherent in the research, development, manufacturing and marketing of pharmaceutical products. If any of our product candidates in clinical trials or commercialized products harm people, we may be subject to costly and damaging product liability claims. We have clinical trial insurance and commercial product liability coverage. However, this insurance may not be adequate to cover all claims. We may be exposed to product liability claims and product recalls, including those which may arise from misuse or malfunction of, or design flaws in, such products, whether or not such problems directly relate to the products we have provided. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- damage to our reputation;
- regulatory investigations that could require costly recalls or product modifications;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients, including awards that substantially exceed our product liability insurance, which we would then be required to pay from other sources, if available, and would damage our ability to obtain liability insurance at reasonable costs, or at all, in the future;
- loss of revenue;
- the diversion of management’s attention from managing our business; and

- the inability to commercialize any products that we may develop.

A successful product liability claim or a series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our available cash and adversely affect our business.

We may become involved in litigation matters, which could result in substantial costs, divert management's attention and otherwise have a material adverse effect on our business, operating results or financial condition.

From time to time we may become involved in certain litigation matters, including those described in Note 11 of the Consolidated Financial Statements included in this report. Although we intend to vigorously defend our interests in each matter, there is no guarantee that we will be successful and we may have to pay damages awards or otherwise may enter into settlement arrangements in connection with such matters. Any such payments or settlement arrangements could have material adverse effects on our business, operating results or financial condition. Even if we are successful in defending our interests in each matter, litigation with respect to such matters could result in substantial costs and significant adverse impact on our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

We are subject to significant ongoing regulatory obligations and oversight, which may result in significant additional expense and may limit our commercial success.

We are subject to significant ongoing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, the manufacture, quality control, labeling, packaging, safety surveillance, adverse event reporting, storage and recordkeeping for our products are subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with any of our products, a regulatory authority may impose restrictions on our products, our contract manufacturers or us. If we, our products and product candidates, or the manufacturing facilities for our products and product candidates fail to comply with applicable regulatory requirements, a regulatory authority, including the FDA, may send enforcement letters, mandate labeling changes, suspend, vary or withdraw regulatory approval, suspend, vary or terminate any ongoing clinical trials, refuse to approve pending applications or supplements filed by us, suspend or impose restrictions on manufacturing operations, request a recall of, seize or detain a product, seek criminal prosecution or an injunction, or impose civil or criminal penalties or monetary fines. In such instances, we could experience a significant drop in the sales of the affected products, our product revenues and reputation in the marketplace may suffer, and we could become the target of lawsuits.

We are also subject to regulation by supranational, national, regional, state and local agencies and regulatory authorities, including but not limited to the FDA, the CMS, Department of Justice, the Federal Trade Commission, the HHS Office of Inspector General and other regulatory bodies. The FDC Act, Social Security Act, Public Health Service Act and other federal and state statutes and regulations, and comparable foreign regulatory acts, govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including nonclinical testing, clinical research, approval, production, labeling, sale, distribution, post-market surveillance, advertising, dissemination of information, promotion, marketing, and pricing to government purchasers and government health care programs. Our manufacturing partners are subject to many of the same requirements.

Companies may not promote drugs for “off-label” uses—that is, uses that are not described in the product’s labeling and that differ from those approved by the FDA or other applicable regulatory authorities. However, a company may share truthful and not misleading information that is otherwise consistent with the product’s labeling. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management’s attention could be diverted from our business operations and our reputation could be damaged.

The federal health care program Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements that pharmaceutical companies have with prescribers, purchasers and formulary managers, among others. Further, the PPACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Although there are a number of statutory exceptions and regulatory safe harbors under the federal Anti-Kickback Statute protecting certain common manufacturer business arrangements and activities from prosecution, the exceptions and safe harbors are drawn narrowly and an arrangement must meet all of the conditions specified in order to be fully protected from scrutiny under the federal Anti-Kickback Statute. We seek to comply with the exceptions and safe harbors whenever possible, but our practices, such as our patient assistance programs and discounts with certain customers, may not in all cases meet all of the criteria for protection from Anti-Kickback liability and may be subject to scrutiny.

The federal false claims laws, including the federal False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Additionally, the civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have

presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Many pharmaceutical and other health care companies have been investigated and have reached substantial financial settlements with the federal government under the federal False Claims Act for a variety of alleged marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company's products; and inflating prices reported to private price publication services, which may be used by states to set drug payment rates under government health care programs. Companies have been prosecuted for causing false claims to be submitted because of the marketing of their products for unapproved uses. Pharmaceutical and other health care companies have also been prosecuted on other legal theories of Medicare and Medicaid fraud.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. It is not clear whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of any Travere products, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We also could become subject to government investigations and related subpoenas. Such subpoenas are often associated with previously filed qui tam actions, or lawsuits filed under seal under the federal False Claims Act. Qui tam actions are brought by private plaintiffs suing on behalf of the federal government for alleged violations of the federal False Claims Act. The time and expense associated with responding to such subpoenas, and any related qui tam or other actions, may be extensive, and we cannot predict the results of our review of the responsive documents and underlying facts or the results of such actions. Responding to government investigations, defending any claims raised, and any resulting fines, restitution, damages and penalties, settlement payments or administrative actions, as well as any related actions brought by stockholders or other third parties, could have a material impact on our reputation, business and financial condition and divert the attention of our management from operating our business.

The number and complexity of both federal and state laws continues to increase, and additional governmental resources are being added to enforce these laws and to prosecute companies and individuals who are believed to be violating them. In particular, the PPACA includes a number of provisions aimed at strengthening the government's ability to pursue Anti-Kickback and False Claims Act cases against pharmaceutical manufacturers and other healthcare entities, including substantially increased funding for healthcare fraud enforcement activities, enhanced investigative powers, amendments to the federal False Claims Act that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim violations and public reporting of certain payments and transfers of value by certain pharmaceutical manufacturers to physicians and teaching hospitals nationwide. We anticipate that government scrutiny of pharmaceutical sales and marketing practices will continue for the foreseeable future and subject us to the risk of further government investigations and enforcement actions. Responding to a government investigation or enforcement action would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The U.S. Foreign Corrupt Practices Act, and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to government officials for the purpose of obtaining or retaining business. Our policies mandate compliance with these anti-bribery laws. We operate in parts of the world that have experienced governmental corruption to some degree and in certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices or may require us to interact with doctors and hospitals, some of which may be state controlled, in a manner that is different than in the United States. We cannot assure that our internal control policies and procedures will protect us from reckless or criminal acts committed by our employees or agents. Violations of these laws, or allegations of such violations, could disrupt our business and result in criminal or civil penalties or remedial measures, any of which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common stock to decline.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), created new federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, the PPACA amended the intent standard for certain healthcare fraud provisions under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Additionally, the federal Physician Payments Sunshine Act within the PPACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biologicals and medical supplies to report annually information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

Also, many states have similar fraud and abuse statutes or regulations, including state anti-kickback and false claims laws, that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Further, certain states require implementation of commercial compliance programs and marketing codes, compliance with the pharmaceutical industry's voluntary compliance

guidelines, and compliance with the applicable compliance guidance promulgated by the federal government. Other various state level requirements include restricting payments or the provision of other items of value that may be made to healthcare providers and other potential referral sources; restricting various marketing practices; requiring prescription drug companies to report expenses relating to the marketing and promotion of drug products; requiring the posting of information relating to clinical studies and their outcomes; requiring the registration of sales representatives; requiring the reporting of certain information related to drug pricing; and requiring drug manufacturers to track and report information related to payments, gifts, compensation, and other items of value to physicians and other healthcare providers.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to significant penalties, including imprisonment, criminal fines, civil monetary penalties, administrative penalties, disgorgement, exclusion from participation in federal healthcare programs, contractual damages, injunctions, recall or seizure of products, total or partial suspension of production, reputational harm, administrative burdens, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar agreement to resolve allegation of non-compliance with these laws, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We are also subject to foreign requirements comparable to those established above. Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

If we are not able to obtain and maintain required regulatory approvals, we will not be able to commercialize our products, and our ability to generate revenue will be materially impaired.

Our product candidates, once approved, and the activities associated with their manufacture, marketing, distribution, and sales are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to adhere to regulations set out by these bodies for one or more of our commercial products could prevent us from commercializing the product candidate in the jurisdiction of the regulatory authority. We have only limited experience in meeting the regulatory requirements incumbent on the sale of drugs in the United States and elsewhere, and expect to rely on third parties to assist us in these processes. If these third parties fail to adequately adhere to the regulations governing drug distribution and promotion, we may be unable to sell our products, which could have a material effect on our ability to generate revenue.

Our product candidates and the activities associated with their development and commercialization, including testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate in the jurisdiction of the regulatory authority. We have only limited experience in filing and prosecuting the applications necessary to obtain regulatory approvals and expect to rely on third-party contract research organizations to assist us in this process.

Securing FDA approval requires the submission of extensive nonclinical and clinical data and supporting information to the FDA for each therapeutic indication to establish the product candidate's safety and efficacy. Securing FDA approval also requires the submission of information about the product manufacturing process to, and successful inspection of manufacturing facilities by, the FDA. Our future products may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use. Comparable requirements are applicable outside the United States.

Our product candidates may fail to obtain regulatory approval for many reasons, including:

- our failure to demonstrate to the satisfaction of the FDA or comparable regulatory authorities that a product candidate is safe and effective for a particular indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable regulatory authorities for approval;
- our inability to demonstrate that a product candidate's benefits outweigh its risks;
- our inability to demonstrate that the product candidate presents an advantage over existing therapies;
- the FDA's or comparable regulatory authorities' disagreement with the manner in which we interpret the data from nonclinical studies or clinical trials;
- failure of the third-party manufacturers with which we contract for clinical or commercial supplies to satisfactorily complete an FDA or comparable foreign regulatory authority pre-approval inspection of the facility or facilities at which the product is manufactured to assess

compliance with the FDA's cGMP regulations or comparable foreign regulatory authority requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and

- a change in the approval policies or regulations of the FDA or comparable regulatory authorities or a change in the laws governing the approval process.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA and non-United States regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional nonclinical, clinical or other studies. In addition, varying interpretations of the data obtained from nonclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post approval commitments that render the approved product not commercially viable. Any FDA or other regulatory approval of our product candidates, once obtained, may be suspended, varied or withdrawn, including for failure to comply with regulatory requirements or if clinical or manufacturing problems follow initial marketing.

We and the third parties with whom we work are subject to stringent and changing U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "process") personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data (collectively, "sensitive information"). Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer health data laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH, through its implementing regulations, makes certain of HIPAA's privacy and security standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains or transmits protected health information for or on behalf of a covered entity for a function or activity regulated by HIPAA as well as their covered subcontractors.

Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments or risk assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 ("CCPA"), as amended, applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices, and affords California residents certain privacy rights related to their personal data, such as those noted herein. The CCPA allows for fines for certain noncompliance and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other U.S. comprehensive privacy laws exempt some data processed in the context of clinical trials, but these laws increase compliance costs and potential liability with respect to certain other personal data we maintain about residents in certain states. Similar laws are being considered in several other states, as well as at the local level, and we expect more jurisdictions to pass similar laws in the future.

In addition, numerous U.S. states have enacted new laws governing the privacy of consumer health data. For example, Washington's My Health My Data Act broadly defines consumer health data, places restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states have passed, are considering, and may adopt similar laws.

Additionally, under various privacy laws and other obligations, we are required to obtain certain consents to process personal data. For example, some of our data processing practices may be challenged under wiretapping laws, since we obtain consumer information from third parties through various methods, including via cookies or third-party marketing pixels. These practices may be subject to increased challenges by class action

plaintiffs. Our inability or failure to obtain consent for these practices could result in adverse consequences, including class action litigation and mass arbitration demands.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR") (EU GDPR and UK GDPR, collectively "GDPR"), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or "LGPD") (Law No. 13,709/2018), and China's Personal Information Protection Law ("PIPL") impose strict requirements for processing personal data. For example, the GDPR imposes significant and complex burdens on processing personal data, which is relevant to our operations in the context of our conduct of clinical trials and is of interest to relevant regulators. Under the GDPR, government regulators can impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, or 4% of annual global revenue, whichever is greater. Further, under the GDPR, individuals may initiate litigation related to processing of their personal data, as well as consumer protection organizations authorized at law to represent data subjects' interests.

In addition, privacy advocates and industry groups around the world have proposed, and may propose, standards with which we are legally or contractually bound to comply, and may become subject to in the future. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. Additionally, we publish privacy policies, marketing materials and other statements, such as compliance with certain certifications, regarding data privacy and security. Regulators in the United States are increasingly scrutinizing these statements. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the United Kingdom ("UK") have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent localization and cross-border transfer laws, which could make it more difficult to transfer information across jurisdictions or prevent us from conducting business in certain countries. Although there are currently various mechanisms that are used to transfer personal data from the EEA and UK to the United States in compliance with these laws, such as the EU Standard Contractual Clauses ("EU SCCs"), the UK's International Data Transfer Agreement / International Data Transfer Addendum to the EU SCCs, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the applicable frameworks), these mechanisms may be subject to legal challenges, and there is no assurance that we can satisfy or rely on the Data Privacy Framework to lawfully transfer personal data to the United States.

If we are unable to implement a valid compliance mechanism for cross-border personal data transfers, or if the requirements for a legally-compliant transfer are too onerous, we may face significant adverse consequences, including increased exposure to regulatory actions, substantial fines and injunctions against processing or transferring personal data from Europe. Inability to import personal data from Europe to the United States may significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with third parties with whom we work (such as CROs, service providers, contractors and other companies) that are subject to such cross-border data transfer or localization laws; the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Additionally, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

In Europe, the Network and Information Security Directive ("NIS 2") regulates the cyber resilience and incident response capabilities of entities operating in a number of sectors, including the health sector. Although NIS 2 has not yet been transposed into domestic law in Ireland, we may be required to comply with its provisions. Achieving compliance with NIS 2 may require significant investment of our time and resources.

Our obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing in an increasingly stringent fashion, creating uncertainty. Additionally, these obligations are subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties with whom we work. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our

personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third party with whom we work to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including proceedings against us by governmental entities or others. If we or any of the third parties with whom we work fail to comply or are perceived to have failed to comply with applicable obligations, we or they could be subject to a range of regulatory actions, litigation (including class actions), or mass arbitration demands that could affect our or our partners' ability to commercialize our products and conduct necessary research and development, and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any threatened or actual government enforcement action or litigation could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Compliance with applicable federal, state, and foreign laws is difficult and time consuming, and companies that violate them may face substantial penalties. The potential sanctions include significant criminal fines, civil monetary penalties, administrative penalties, disgorgement, exclusion from participation in federal health care programs, individual imprisonment, injunctions, recall or seizure of products, total or partial suspension of production, reputational harm, administrative burdens, interruption or cessation of clinical trials, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, diminished profits and future earnings, and the curtailment or restructuring of our operations, and other sanctions. Because of the breadth of these laws, it is possible that some of our business activities could be subject to challenge under one or more of these laws. Such a challenge, irrespective of the underlying merits of the challenge or the ultimate outcome of the matter, could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Moreover, clinical trial subjects and other individuals about whom we or the third parties with whom we work obtain personal data, as well as the third parties with whom we work who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If our information technology systems or data, or those of third parties with whom we work, are or were compromised, we could experience adverse impacts resulting from such compromise, including, but not limited to, regulatory investigations or actions; litigation; fines and penalties; interruptions to our commercial operations, clinical trials or other operations; harm to our reputation; loss of revenue or profits; loss of sales; and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work process sensitive information.

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer "hackers," threat actors, personnel (such as through theft or misuse), "hacktivists", organized criminal threat actors, sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyberattacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyberattacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products. For example, we work with third parties to support our business located in unstable regions and regions experiencing (or expected to experience) geopolitical or other conflicts, including in Israel, where businesses have experienced an increase in cyberattacks in relation to the Israel/Hamas conflict. We and the third parties with whom we work are subject to a variety of other evolving threats, including, but not limited to, social-engineering attacks (including through deep fakes, which are increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, attacks enhanced or facilitated by artificial intelligence, and other similar threats. In particular, ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, ability to provide our products, disruption of clinical trials, loss of data (including data related to clinical trials), loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws prohibit such payments). Additionally, hybrid and remote work has increased risks to our information technology systems and data, as our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit, and in public locations. Future or past business transactions (such as acquisitions or integrations) could also expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely upon third parties and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. We also rely on third parties to provide certain products, including active pharmaceutical ingredients or API, to operate our business, including in China. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in

place. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information security systems (such as our hardware and/or software, including that of third parties with whom we work), but we have not in the past and may not in the future be able to detect, mitigate, and remediate all such vulnerabilities including on a timely basis. Despite our efforts, there can be no assurance that these vulnerability mitigation measures will be effective. It may also be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Further, we have experienced, and may in the future experience, delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. If exploited, certain vulnerabilities can result in a security incident. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

Certain of the previously identified or similar threats have in the past, and may in the future, cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. We have experienced, and may in the future experience, security incidents involving our systems and the systems of third parties with whom we conduct business. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our products. We expend resources and may have to modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Applicable data security and public company disclosure obligations require us, or we may voluntarily choose, to notify relevant stakeholders of certain security incidents, including affected individuals, customers, regulators and investors, or to take other actions in certain circumstances, such as providing credit monitoring and identity theft protection services. Whether a cybersecurity incident is reportable to our investors may not be straightforward, may take considerable time to determine, and may be subject to change as the investigation of the incident progresses, including changes that may significantly alter any initial disclosure that we provide. Such disclosures and related actions can be costly, and the disclosures or the failure to comply with such applicable requirements, could lead to adverse consequences. Any incidents or perceived incidents involving our systems (or those of a third party with whom we work) may lead to adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; loss of customer, investor or partner confidence in the effectiveness of our cybersecurity measures; monetary fund diversions; the expenditure of significant capital and other resources; diversion of management attention; interruptions in our operations (including availability of data); financial loss and other similar harms. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Some of our contracts do not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. In addition, our insurance coverage may not be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices or that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Sensitive information of us or our customers could also be leaked, disclosed, or revealed as a result of or in connection with our employee's, personnel's, or third parties with whom we work use of generative AI technologies.

Risks related to the use of artificial intelligence technologies could adversely affect our business, financial condition and/or operating results.

Our employees and personnel use generative artificial intelligence, machine learning and other artificial intelligence technologies (together, "AI/ML") and/or automated decision-making technologies to perform their work, and the disclosure and use of personal data in AI/ML technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws and regulations regulating AI/ML and/or automated decision-making technologies. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use AI/ML and/or automated decision-making technologies in the future, it could make our business less efficient and result in competitive disadvantages. Any sensitive information (including confidential, competitive, proprietary, or personal data) that we input into a third-party generative AI/ML platform could be leaked or disclosed to others, including if sensitive information is used to train the third parties' AI/ML model. Additionally, where an AI/ML model ingests personal data and makes connections using such data, those technologies may

reveal other personal or sensitive information generated by the model. Moreover, AI/ML models may create flawed, incomplete, or inaccurate outputs, some of which may appear correct. This may happen if the inputs that the model relied on were inaccurate, incomplete or flawed (including if a bad actor "poisons" the AI/ML with bad inputs or logic), or if the logic of the AI/ML is flawed (a so-called "hallucination"). We may use AI/ML outputs to make certain decisions. Due to these potential inaccuracies or flaws, the model could be biased and could lead us to make decisions that could bias certain individuals (or classes of individuals), and adversely impact their rights, employment, and ability to obtain certain pricing, products, services, or benefits.

Several jurisdictions around the globe, including Europe and certain U.S. states, have proposed, enacted, or are considering laws governing AI/ML, including the EU's AI Act and the Colorado AI Act. For example, the EU AI Act sets out a risk-based framework, subjecting certain AI technologies to numerous compliance obligations, including transparency, conformity and risk assessment, monitoring and human oversight requirements. Under the EU AI Act, non-compliant companies may be subject to administrative fines of up to 35 million Euros or 7% of a company's total worldwide annual turnover for the preceding financial year, whichever is the higher. Certain of our activities subject us to the EU AI Act and depending on how the EU AI Act is implemented and interpreted, we may have to adapt our business practices, contractual arrangements, and services to comply with such obligations. We expect other jurisdictions will adopt similar laws. Additionally, certain privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision making, which may be incompatible with our use of AI/ML. These obligations may make it harder for us and our employees and personnel to use AI/ML, lead to regulatory fines or penalties, require us to change our business practices or make changes to the AI/ML that we use, or prevent or limit our use of AI/ML. For example, the FTC has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI/ML where they allege the company has violated privacy and consumer protection laws. If we cannot use AI/ML or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage.

Additionally, sensitive information of the Company or our employees or other individuals could be leaked, disclosed, or revealed as a result of or in connection with our employee's, personnel's, or vendor's use of AI/ML technologies.

Uncertainties in the interpretation and application of existing, new and proposed tax laws and regulations could materially affect our tax obligations and effective tax rate.

The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws or regulations proposed or implemented by the current or a future U.S. presidential administration, Congress, or taxing authorities in other jurisdictions, including jurisdictions outside of the United States, could materially affect our tax obligations and effective tax rate. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes may adversely impact our business, financial condition, results of operations, and cash flows.

The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, tax rates, new or revised tax laws, or interpretations of tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

In July 2025, the OBBBA was signed into law, and it (along with other recent U.S. federal tax reform) has resulted in significant changes to the taxation of business entities including, among other changes, changes to the taxation of income derived from international operations, changes in the deduction and amortization of research and development expenditures, and limitations on the deductibility of business interest. Future guidance from the Internal Revenue Service and other tax authorities with respect to any legislation may affect us, and certain aspects of such legislation could be repealed or modified or sunset in future years.

Our ability to use net operating loss carryforwards and certain other tax attributes to offset future taxable income and taxes may be subject to limitations.

Our U.S. federal net operating losses ("NOLs") generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards in a taxable year is limited to 80% of taxable income in such year. As of December 31, 2025, we had federal NOL carryforwards of $232.6 million. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change U.S. tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We continue to evaluate potential historical ownership changes and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control.

As a result, our federal NOL carryforwards may be subject to a percentage limitation if used to offset income in tax years following an ownership change. In addition, it is possible that we have in the past undergone, and in the future may undergo, additional ownership changes that could limit our ability to use all of our pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2023 and before 2027. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which would harm our future operating results by effectively increasing our future tax obligations.

Changes in funding for the FDA, the SEC and other government agencies or regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new therapies to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, including in the fourth calendar quarter of 2025, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. In addition, there have been significant staff reductions at the FDA and other agencies, some of which are or may be subject to legal challenges. If a prolonged government shutdown occurs, or if the FDA or EDA experience resource constraints, it could significantly impact the ability of the applicable regulatory agency to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Comparable considerations may be applicable in relation to foreign regulatory authorities.

Our business could be negatively impacted by environmental, social and corporate governance (ESG) matters or our reporting of such matters.

In recent years, there has been an increased focus from certain investors, employees, partners, and other stakeholders concerning ESG matters. While we have internal efforts directed at ESG matters and preparations for potential increased future disclosures, we may be perceived by certain stakeholders as not acting responsibly in connection with these matters, which could negatively impact us. Various policymakers within and outside of the U.S., including the State of California and the European Union, among others, have adopted (or are considering adopting) requirements for certain companies to undertake various actions, including disclosures, on climate-related or other ESG-related matters. These requirements are not uniform and may not be interpreted or applied uniformly, which may increase the cost and complexity of compliance and any associated risks. Some of these initiatives have been subject to legal challenges, delays, stays, or changes in enforcement posture, and their ultimate scope, applicability, and timing remain uncertain. The ESG landscape has been evolving rapidly, and it can be difficult to predict future developments. If other climate-related disclosure rules or other ESG rules become effective or become applicable to us, they may significantly increase our compliance and reporting costs and may also result in disclosures that certain investors or other stakeholders deem to negatively impact our reputation and/or that harm our stock price.

The withdrawal of the United Kingdom from the European Union, commonly referred to as "Brexit," may adversely impact our ability to obtain regulatory approvals of our product candidates in the United Kingdom, result in restrictions or imposition of taxes and duties for importing our product candidates into the United Kingdom, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the United Kingdom.

The UK withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has changed the regulatory relationship between the UK and the EU. The MHRA is now the UK's standalone regulator for medicinal products and medical devices. The United Kingdom is no longer subject to EU regulations. Northern Ireland continues to follow certain limited EU regulatory rules, but not in relation to medicinal products.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the CTD, as implemented into UK national law through secondary legislation. On January 17, 2022, the MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials. The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation, and such changes were laid before Parliament on December 12, 2024. and signed into law on April 11, 2025. The changes include risk-proportionate regulation of clinical trials, with low-risk trials able to receive faster approval through automatic authorisation, a streamlined approval process that integrates both regulatory and ethics committee approvals,

leading to a single UK decision for clinical trials, and new legal obligations mandating the registration of clinical trials in public registries and the publication of trial results within 12 months of trial conclusion.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU centralized procedure marketing authorization can no longer be established in the UK. As a result, since this date, companies established in the UK cannot use the EU centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain a marketing authorization to market products in the UK. All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorization, effective in Great Britain only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. Northern Ireland remained within the scope of EU authorizations in relation to centrally authorized medicinal products until January 1, 2025. However, on January 1, 2025, a new arrangement as part of the so-called "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework also removes EU licensing processes and EU labelling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines.

The MHRA has also introduced changes to national marketing authorization procedures. This includes introduction of procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment route, a rolling review procedure and the International Recognition Procedures which entered into application on January 1, 2024. Since January 1, 2024, the MHRA may rely on the International Recognition Procedure, or IRP, when reviewing certain types of marketing authorization applications. This procedure is available for applicants for marketing authorization who have already received an authorization for the same product from a reference regulator. These include the FDA, the EMA, and national competent authorities of individual EEA countries. A positive opinion from the EMA and CHMP, or a positive end of procedure outcome from the mutual recognition or decentralized procedures are considered to be authorizations for the purposes of the IRP.

There is no pre-marketing authorization orphan designation for medicinal products in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding marketing authorization application. The criteria are essentially the same as those in the EU, but have been tailored for the market. This includes the criterion that prevalence of the condition in the United Kingdom, rather than the EU, must not be more than five in 10,000. Upon the grant of a marketing authorization with orphan status, the medicinal product will benefit from up to 10 years of market exclusivity from similar products in the approved orphan indication. The start of this market exclusivity period will be set from the date of first approval of the product in the United Kingdom.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third-party manufacturers, CROs and other contractors and consultants, could be subject to disruptions resulting from earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, health epidemics or pandemics, wars and other geopolitical conflicts, and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our corporate headquarters are located in San Diego, California, an area prone to wildfires and earthquakes. These and other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Any disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business.

In addition, we rely on third-party manufacturers, some of whom are located in China, to manufacture API for FILSPARI and certain of our product candidates. Any disruption in production or inability of our manufacturers in China to produce or ship adequate quantities to meet our needs, whether as a result of a natural disaster or other causes (such as staffing shortages, or a health epidemic or pandemic), could impair our ability to meet commercial demand for FILSPARI, to operate our business on a day-to-day basis and to continue our research and development of our product candidates. In addition, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments (such as tariffs on products or materials that we use that are manufactured in China), political unrest or unstable economic conditions in China. Any recall of the manufacturing lots or similar action regarding our API used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our product candidates and impair our competitive position.

If material weaknesses in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results, which could adversely affect our stock price and result in an inability to maintain compliance with applicable stock exchange listing requirements.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. If material weaknesses in our internal control over financial reporting are discovered or occur in the future, or if we are unable to maintain effective internal control over financial reporting or disclosure controls and procedures for any reason, our ability to record, process and report financial information accurately, and to prepare financial statements within required time periods, could be adversely affected, which could subject us to litigation or investigations requiring management resources and payment of legal and other expenses and negatively impact the price of our common stock. In addition, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Furthermore, investor perceptions of our company may suffer as a result of any material weakness in our internal controls, and this could cause a decline in the market price of our stock. Any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results, result in an adverse opinion on our internal control over financial reporting from our independent registered public accounting firm, and harm our reputation.

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. In addition, on May 1, 2023, the FDIC seized First Republic Bank and sold its assets to JPMorgan Chase & Co. It is uncertain whether the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including concerns or uncertainty relating to tariffs and their potential impact on the economy, levels of interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.

We maintain the majority of our cash and cash equivalents in accounts at banking institutions in the United States that we believe are of high quality. Cash held in these accounts often exceed the FDIC insurance limits. If such banking institutions were to fail, we could lose all or a portion of amounts held in excess of such insurance limitations. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

Risks Related to our Indebtedness and Financial Condition

Our indebtedness could adversely affect our financial condition.

As of December 31, 2025, we had approximately $316 million of total debt outstanding, all of which is classified as long term. As a result of our indebtedness, a portion of our cash flow will be required to pay interest and principal on the 2029 Notes if the notes are not converted to shares of common stock prior to maturity. We may not generate sufficient cash flow from operations or have future borrowings available to enable us to repay our indebtedness or to fund other liquidity needs.

Our indebtedness pursuant to the 2029 Notes could have important consequences. For example, it could:

- make it more difficult for us to satisfy our obligations with respect to any other debt we may incur in the future;
- increase our vulnerability to general adverse economic and industry conditions;
- require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness and related interest, thereby reducing the availability of our cash flow to fund working capital, capital expenditures and other general corporate purposes;
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;
- increase our cost of borrowing;
- place us at a competitive disadvantage compared to our competitors that may have less debt; and
- limit our ability to obtain additional financing for working capital, capital expenditures, acquisitions, debt service requirements or general corporate purposes.

We expect to use cash flow from operations and outside financings to meet our current and future financial obligations, including funding our operations, debt service and capital expenditures. Our ability to make these payments depends on our future performance, which will be affected by financial, business, economic and other factors, many of which we cannot control. Our business may not generate sufficient cash flow from operations in the future, which could result in our being unable to repay indebtedness, or to fund other liquidity needs. If we do not generate sufficient cash from operations, we may be forced to reduce or delay our business activities and capital expenditures, sell assets, obtain additional debt or equity capital or restructure or refinance all or a portion of our debt, including the 2029 Notes, on or before maturity. We cannot make any assurances that we will be able to accomplish any of these alternatives on terms acceptable to us, or at all. In addition, the terms of existing or future indebtedness may limit our ability to pursue any of these alternatives. In addition, we may from time to time seek to retire or purchase our outstanding debt, including the 2029 Notes, through cash purchases and/or exchanges for equity securities, in open market purchases, privately negotiated transactions or otherwise. Such repurchases or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions, and other factors. The amounts involved in any such transactions, individually or in the aggregate, may be material. Further, any such purchases or exchanges may result in us acquiring and retiring a substantial amount of such indebtedness, which could impact the trading liquidity of such indebtedness.

We may be unable to raise the funds necessary to repurchase the 2029 Notes for cash following a fundamental change, or to pay any cash amounts due upon conversion, and our future indebtedness may limit our ability to repurchase the 2029 Notes or pay cash upon their conversion.

Noteholders may require us to repurchase their 2029 Notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the 2029 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. In addition, upon conversion, we would satisfy part or all of our conversion obligation in cash unless we elected to settle conversions solely in shares of our common stock.

We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the 2029 Notes or pay the cash amounts due upon conversion of the 2029 Notes. In addition, applicable law, regulatory authorities and the agreements governing our future indebtedness may restrict our ability to repurchase the 2029 Notes or pay the cash amounts due upon conversion of the 2029 Notes. Our failure to repurchase the 2029 Notes or to pay the cash amounts due upon conversion of the 2029 Notes when required will constitute a default under the base and supplemental indentures that govern the 2029 Notes, which we refer to collectively as the “indenture.” We may not have sufficient funds to satisfy all amounts due under the other indebtedness and the 2029 Notes.

A default under the 2029 Notes may have a material adverse effect on our financial condition.

If an event of default under the 2029 Notes occurs, the principal amount of the 2029 Notes, as applicable, plus accrued and unpaid interest (including additional interest, if any) may be declared immediately due and payable, subject to certain conditions set forth in the indenture governing such notes. Events of default include, but are not limited to:

- failure to pay (for more than 30 days) interest when due;
- failure to pay principal when due;
- failure to deliver shares of common stock upon conversion of a 2029 Note;
- failure to provide notice of a fundamental change;
- acceleration on our other indebtedness in excess of $10 million (other than indebtedness that is non-recourse to us); or
- certain types of bankruptcy or insolvency involving us.

Accordingly, the occurrence of a default under the 2029 Notes, unless cured or waived, may have a material adverse effect on our results of operations.

Provisions of the 2029 Notes could discourage an acquisition of us by a third party.

Certain provisions of the 2029 Notes could make it more difficult or more expensive for a third party to acquire us. Upon the occurrence of certain transactions constituting a fundamental change, holders of the 2029 Notes will have the right, at their option, to require us to repurchase all of their 2029 Notes or any portion of the principal amount of such Notes in integral multiples of $1,000. We may also be required to increase the conversion rate for conversions in connection with certain fundamental changes.

Conversion of the Notes may dilute the ownership interest of existing stockholders, including holders who had previously converted their 2029 Notes.

To the extent we issue shares of common stock upon conversion of the 2029 Notes, the conversion of some or all of the 2029 Notes will dilute the ownership interests of existing stockholders. Any sales in the public market of shares of the common stock issuable upon such conversion could adversely affect prevailing market prices of shares of our common stock. In addition, the existence of the 2029 Notes may encourage short selling by market participants because the conversion of the 2029 Notes could depress the price of shares of our common stock.

General Risk Factors

Unstable market, economic and geopolitical conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have experienced extreme volatility and disruptions, including as a result of inflation and high interest rates, bank failures, tariffs, other restrictive trade policies, wars, armed conflicts and global geopolitical tension, and may experience disruptions in the future. These disruptions can result in severely diminished liquidity and credit availability, increased inflation, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recessions and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment, higher inflation, or unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our operations, growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans.

Other international and geopolitical events could also have a serious adverse impact on our business. For instance, in February 2022, Russia initiated military action against Ukraine. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions. While we cannot predict the broader consequences, the conflict and retaliatory and counter-retaliatory actions could materially adversely affect global trade, currency exchange rates, inflation, regional economies, and the global economy, which in turn may increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and data related to patients and clinical trials (“Information Systems and Data”).

Various members of our management team, IT department and other employees, including but not limited to the individuals on our cybersecurity incident management team, help identify, assess and manage our cybersecurity threats and risks, with the assistance of a third-party IT managed service provider. We manage, identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment and risk profile using various methods including, for example: through the use of automated tools in certain environments, including but not limited to tools for monitoring, geolocation, remote wiping, threat detection, intrusion detection and prevention (including through the use of machine learning, a form of artificial intelligence), patch management, distributed denial of service ("DDoS") protection and forensics; conducting (directly or through third parties) regular audits and threat assessments for internal and external threats; subscribing to reports and services that identify cybersecurity threats; analyzing reports of certain threats and actors; conducting vulnerability assessments in certain environments to identify vulnerabilities; evaluating our and our industry’s risk profile; conducting routine tabletop incident response exercises; and evaluating certain threats reported to us. With the help of our managed services provider, we have implemented a Security Operations Center ("SOC") service to provide continuous 24/7 monitoring and incident response across our network infrastructure.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident response plans and procedures, disaster recovery/business continuity plans, risk assessments, implementation of security standards and certifications, encryption of certain data, network security controls on certain networks, data segregation, Wi-Fi segregation, access controls for certain environments, physical security, asset management, tracking and disposal, systems monitoring, vendor risk management program, employee training and penetration testing.

Our assessment and management of cybersecurity risks are integrated into our enterprise risk management program. Cybersecurity risk is addressed as part of our overall risk governance framework, and members of our management team, IT department and other relevant functional teams collaborate to prioritize risk mitigation efforts, address threats that may have a material impact on our business, and report regularly to our board of directors on cybersecurity matters.

We engage third-party service providers to assist us to identify, assess, and manage material risks from cybersecurity threats, including for example managed cybersecurity service providers, threat intelligence service providers, dark web monitoring services, and other cybersecurity software providers.

We use third-party service providers to perform a variety of functions throughout our business, including but not limited to application providers, hosting companies, contract manufacturing organizations and contract research organizations. We have a vendor management program to oversee, identify and manage cybersecurity risks associated with our use of certain of these providers. The program includes a risk assessment for vendors that may include, depending on the vendor and nature of services being performed, security questionnaires, review of the vendor's written security program, review of security assessments, audits and reports, vulnerability scans related to the vendor, security assessment calls with the vendor's security personnel, and the imposition of certain contractual obligations on the vendor, among other elements, in accordance with the processes outlined in our internal vendor selection, management, and oversight process policy and other internal guidelines. More specifically, the level of assessment may depend on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including the risk factor captioned “If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse impacts resulting from such compromise, including, but not limited to, regulatory investigations or actions; litigation; fines and penalties; interruptions to our commercial operations, clinical trials or other operations; harm to our reputation; loss of revenue or profits; loss of sales and other adverse consequences.”

Governance

Our Nominating / Corporate Governance Committee has oversight of our cybersecurity risk management program and reports to our board of directors on cybersecurity matters.

Our cybersecurity risk assessment and management processes are implemented and maintained by various members of our management team, IT department and other employees, including but not limited to the individuals on our cybersecurity incident management team, which includes individuals who have a diverse combination of relevant expertise, experience, education and training, with representation from our IT, legal, human resources, compliance, risk and privacy functions, among others. Our team includes individuals with relevant experience in enterprise risk management and disclosure controls and procedures. Additionally, certain members of our IT department have experience managing cybersecurity programs and are specifically assigned cybersecurity oversight.

Certain members of our management team and IT department are responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, communicating key priorities to relevant personnel, approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response processes are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including in some cases to our executive team. Our cybersecurity incident management team, and other individuals as needed, work to help us mitigate and remediate cybersecurity incidents of which we are notified. In addition, our incident response processes include a procedure for reporting certain cybersecurity incidents to the board of directors and/or the Nominating / Corporate Governance Committee.

The Nominating / Corporate Governance Committee receives regular reports from management concerning our cybersecurity risk management program, and also receives various summaries and/or presentations related to cybersecurity threats, risks and mitigation.

ITEM 2. PROPERTIES

As of December 31, 2025, we leased the following location to conduct our business:

Location	Address	Lease Expiration	Square Feet
San Diego, California	3611 Valley Centre Drive, Suite 300	August 31, 2028	103,677

In November 2024, we entered into an arrangement to sublet 26,455 square feet of our San Diego office space beginning in January 2025 and ending in August 2028.

We believe our current facilities are adequate to conduct our business, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

For additional information regarding our lease agreements, see Note 18 of the Consolidated Financial Statements included in this report.

ITEM 3. LEGAL PROCEEDINGS

The information required by this Item is incorporated herein by reference to the Notes to the Consolidated Financial Statements--Note 11 Commitments and Contingencies: Legal Proceedings in Item 15 of this Annual Report on Form 10-K.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

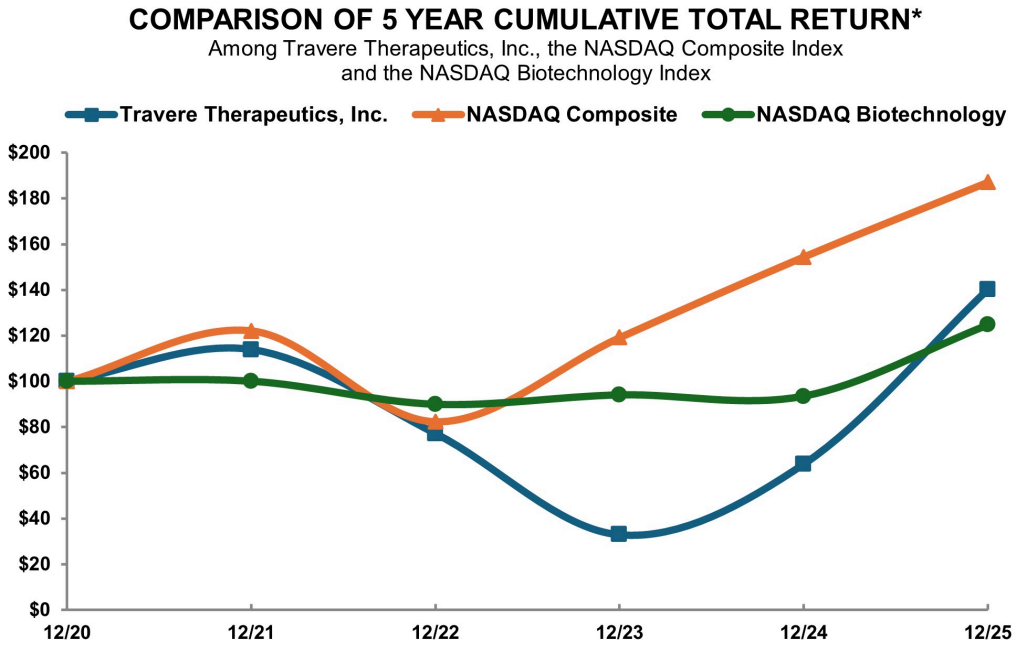
Our common stock is listed for quotation on the Nasdaq Global Market under the trading symbol “TVTX” and is part of the Nasdaq Biotechnology Index (Nasdaq: NBI).

As of February 13, 2026, we had approximately 158 holders of record of our common stock.

Performance Graph

The following information is not deemed to be “soliciting material” or to be “filed” with the Securities and Exchange Commission or subject to Regulation 14A or 14C under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or the liabilities of Section 18 of the Exchange Act, and will not be deemed incorporated by reference into any filing we make under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation by reference language in such filing, except to the extent we specifically incorporate it by reference into such filing.

Our common stock is traded on the Nasdaq Global Market and is a component of both the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The total return for our common stock and for each index assumes the reinvestment of dividends, although dividends have never been declared on our common stock, and is based on the returns of the component companies weighted according to their capitalizations as of the end of each monthly period. The Nasdaq-Composite tracks the aggregate price performance of equity securities of companies traded on the Nasdaq National Market. The Nasdaq Biotechnology Index contains securities and tracks the aggregate price performance of equity securities of Nasdaq-listed companies classified according to the Industry Classification Benchmark as either Biotechnology or Pharmaceuticals which also meet other eligibility criteria. The comparisons shown in the graph are based upon historical data and we caution that the stock price performance shown in the graph is not indicative of, nor intended to forecast, the potential future performance of our stock.



*$100 invested on 12/31/20 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

Dividends

Since inception we have not paid any dividends on our common stock. We currently do not anticipate paying any cash dividends in the foreseeable future on our common stock. Although we intend to retain our earnings, if any, to finance the exploration and growth of our business, our Board of Directors will have the discretion to declare and pay dividends in the future. Payment of dividends in the future will depend upon our earnings, capital requirements and other factors which our Board of Directors may deem relevant.

Recent Sales of Unregistered Equity Securities

During the year ended December 31, 2025, we did not issue or sell any unregistered securities not previously disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

Securities Authorized for Issuance under Equity Compensation Plans

See Item 12 of Part III of this Annual Report on Form 10-K for information about our equity compensation plans which is incorporated by reference herein.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our equity securities during the three months ended December 31, 2025.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Our discussion and analysis of our financial condition and results of operations for 2025 as compared to 2024 are discussed below and should be read in conjunction with our audited Consolidated Financial Statements, including the notes thereto. For a discussion of our financial condition and results of operations for 2024 as compared to 2023, except as set forth below, please refer to Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our 2024 Annual Report on Form 10-K, which discussion is incorporated by reference herein.

Overview

We are a biopharmaceutical company headquartered in San Diego, California, focused on identifying, developing and delivering life-changing therapies to people living with rare kidney and metabolic diseases. Our approach centers on advancing our innovative pipeline with multiple late-stage clinical programs targeting rare diseases with significant unmet medical needs. Upon approval of any of our late-stage programs, we intend to leverage the skills of our talented commercial organization which has successfully identified, supported and treated patients prescribed our approved products for over ten years.

FILSPARI® (sparsentan)

On September 5, 2024, the FDA granted full approval of FILSPARI® (sparsentan) to slow kidney function decline in adults with primary Immunoglobulin A nephropathy (IgAN) who are at risk of disease progression. FILSPARI had previously been granted accelerated approval in February 2023 based on the surrogate marker of proteinuria. Full approval was based on positive long-term confirmatory results from the PROTECT Study demonstrating that FILSPARI significantly slowed kidney function decline over two years compared to irbesartan.

FILSPARI is the only oral, once-daily, non-immunosuppressive medication that directly targets glomerular injury in the kidney by blocking two critical pathways of IgAN disease progression (endothelin-1 and angiotensin II).

The two-year efficacy data contained in the FDA-approved label is a modified intention to treat (ITT) analysis and evaluates data from all patients regardless of treatment discontinuation. In the final analysis of the 404 randomized patients, FILSPARI significantly reduced the rate of decline in kidney function from baseline to Week 110 compared to irbesartan. In the ITT analysis included in the label, the mean eGFR slope from baseline to Week 110 was -3.0 mL/min/1.73 m^2/year for FILSPARI and -4.2 mL/min/1.73 m^2/year for irbesartan, corresponding to a statistically significant treatment effect of 1.2 mL/ min/1.73 m^2/year (p=0.0168). The positive treatment effects on proteinuria compared to the active control irbesartan that were observed at Week 36 were durable out to the two-year measurement period. Additional results from the PROTECT Study demonstrated the

benefit of FILSPARI on absolute eGFR accrued over time and by Week 110 resulted in a 3.8 mL/min/1.73 m^2 difference in the mean change from baseline between FILSPARI and irbesartan.

Results from the PROTECT Study showed that FILSPARI was well tolerated with a clearly defined safety profile that has been consistent across all clinical trials conducted to date.

FILSPARI is a dual endothelin angiotensin receptor antagonist ("DEARA"). Pre-clinical data have shown that blockade of both endothelin type A and angiotensin II type 1 pathways in forms of rare chronic kidney disease, reduces proteinuria, protects podocytes and prevents glomerulosclerosis and mesangial cell proliferation. FILSPARI has been granted seven years of Orphan Drug Exclusivity in the U.S. (running from the date of accelerated approval) for the reduction of proteinuria in adults with primary IgAN at risk of rapid disease progression, and has been granted a separate seven years of Orphan Drug Exclusivity in the U.S. (running from the date of full approval) to slow kidney function decline in adults with primary IgAN who are at risk for disease progression, excluding the use provided for in the aforementioned Orphan Drug Exclusivity granted in connection with the accelerated approval.

IgAN is characterized by hematuria, proteinuria, and variable rates of progressive renal failure. With an estimated prevalence of up to 150,000 people in the United States and greater numbers in Europe and Asia, IgAN is the most common primary glomerular disease. Most patients are diagnosed between the ages of 16 and 35, with up to 40% progressing to kidney failure within 15 years. FILSPARI is the first non-immunosuppressive therapy approved for IgAN and is the only oral, once-daily, non-immunosuppressive therapy approved for this condition that directly targets glomerular injury in the kidney by blocking two critical pathways of IgAN disease progression (endothelin-1 and angiotensin II). We estimate more than 70,000 patients in the United States to be addressable under FILSPARI's full approval indication.

Data to support the approval of FILSPARI was generated from the Phase 3 PROTECT Study, the largest head-to-head interventional study to date in IgAN. It is a global, randomized, multicenter, double-blind, parallel-arm, active-controlled clinical trial that evaluated the safety and efficacy of 400mg of sparsentan, compared to 300mg of irbesartan, in 404 patients ages 18 years and up with IgAN and persistent proteinuria despite available angiotensin converting enzyme ("ACE") inhibitor or angiotensin receptor blockers ("ARB") therapy, and is currently ongoing in the open label extension phase of the study.

FILSPARI is available only through a risk evaluation and mitigation strategy (REMS) approved by the FDA for liver monitoring regarding potential risk of hepatotoxicity, as has been required for certain other approved endothelin antagonists. Initially, as part of the liver monitoring REMS, monthly monitoring of each patient was required for the first year a patient was on treatment, and quarterly thereafter. In August 2025, the FDA approved updated REMS labeling, reducing the frequency of liver monitoring to every three months from the onset of treatment and also removing the embryo-fetal toxicity monitoring requirement from the REMS.

In April 2024, we and our partner CSL Vifor announced that the European Commission had granted conditional marketing authorization (“CMA”) for FILSPARI (sparsentan) for the treatment of adults with primary IgAN with a urine protein excretion ≥1.0 g/day (or urine protein-to-creatinine ratio ≥0.75 g/g), and in April 2025, we and CSL Vifor announced that the European Commission had converted the CMA into a standard marketing authorization (“MA”) for FILSPARI for the treatment of adults with primary IgAN with a urine protein excretion ≥1.0 g/day (or urine protein-to-creatinine ratio ≥0.75 g/g). The MA was granted for all member states of the European Union, as well as in Iceland, Liechtenstein and Norway. As a result of the standard MA approval, we received a regulatory milestone payment of $17.5 million in May 2025 under the terms of the License Agreement. FILSPARI became commercially available in Europe under the CMA in August 2024, with an initial launch in Germany and Austria. In October 2024, we and CSL Vifor announced that Swissmedic has granted temporary marketing authorization for FILSPARI for the treatment of adults with primary IgAN with a urine protein excretion ≥1.0 g/day (or urine protein-to-creatinine ratio ≥0.75 g/g). In April 2025, the MHRA in the UK converted its conditional approval of FILSPARI in IgAN to standard approval. In the fourth quarter of 2025, we received a $40.0 million market access milestone payment from CSL Vifor.

In January 2024, we announced our entry into an exclusive licensing agreement with Renalys Pharma, Inc. ("Renalys"), to bring sparsentan for the treatment of IgAN to patients in Japan and other countries in Asia. In December 2024, Renalys announced that sparsentan received Orphan Drug Designation from the Japanese Ministry of Health, Labour and Welfare for the indication of primary IgA nephropathy as of November 27, 2024. In the fourth quarter of 2025, Renalys announced positive topline results from its Phase 3 study of sparsentan in Japanese patients with IgAN. Renalys has also announced that it has reached an agreement with the PMDA regarding development plans for two other Phase 3 clinical trials of sparsentan, one investigating the use of sparsentan in FSGS and the other in Alport syndrome, in Japan. In the fourth quarter of 2025, Renalys was acquired by and merged into Chugai Pharmaceutical Co., Ltd. (“Chugai”). Through the acquisition, Chugai gained exclusive rights to develop and commercialize sparsentan in Japan, South Korea, and Taiwan. As a minority shareholder in Renalys, we received $10.2 million at the closing of the transaction and we are also eligible to receive multiple milestones according to the progress of sparsentan regulatory approval, and consideration linked to sparsentan's net sales in the applicable territory. Under the terms of the licensing agreement, Chugai is responsible for development, regulatory matters, and commercialization in the licensed territories. Chugai plans to file for regulatory approval for sparsentan in Japan in 2026.

Clinical-Stage Programs:

Sparsentan for the treatment of FSGS

Sparsentan has been granted Orphan Drug Designation for the treatment of FSGS in the U.S. and the EEA.

FSGS is a leading cause of kidney failure and nephrotic syndrome. There are currently no FDA-approved pharmacologic treatments for FSGS and there remains a high unmet need for patients living with FSGS as off-label treatments such as ACE/ARBs, steroids, and immunosuppressant agents are effective in only a subset of patients and use of some of these off-label treatments may be further inhibited by their safety profiles. Every year approximately 5,400 patients are diagnosed with FSGS and we estimate that there are more than 40,000 FSGS patients in the United States and a similar number in Europe. We believe that there are up to 30,000 FSGS patients in the United States that are potentially addressable with FILSPARI, if approved.

In 2016, we generated positive data from our Phase 2 DUET study in FSGS. In 2018, we announced the initiation of the Phase 3 clinical trial designed to serve as the basis for an NDA and MAA filing for sparsentan for the treatment of FSGS (the "DUPLEX Study"). The DUPLEX Study is a global, randomized, multicenter, double-blind, parallel-arm, active-controlled clinical trial evaluating the safety and efficacy of sparsentan in 371 patients. The DUPLEX Study protocol provided for an unblinded analysis of at least 190 patients to be performed after 36 weeks of treatment to evaluate the interim efficacy endpoint - the proportion of patients achieving a FSGS partial remission of proteinuria endpoint (FPRE), which is defined as urine protein-to-creatinine ratio (UPCR) ≤1.5 g/g and a >40% reduction in UPCR from baseline, at week 36. In February 2021, we announced that the ongoing Phase 3 DUPLEX Study achieved its pre-specified interim FSGS partial remission of proteinuria endpoint following the 36-week interim period. 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). Following engagement with the FDA on the interim proteinuria analysis and a subsequent eGFR data-cut, we elected to forego the previously planned submission for accelerated approval and pursue a potential traditional approval upon completion of the DUPLEX Study.

In May 2023, we announced topline primary efficacy results from the pivotal Phase 3 DUPLEX Study of sparsentan in FSGS. The confirmatory primary endpoint of the DUPLEX Study designed to support traditional regulatory approval was the rate of change in eGFR over 108 weeks of treatment. At the end of the 108-week double-blind period, sparsentan was observed to have a 0.3 mL/min/1.73m^2 per year (95% CI: -1.74, 2.41) favorable difference on eGFR total slope and a 0.9 mL/min/1.73m^2 per year (95% CI: -1.27, 3.04) favorable difference on eGFR chronic slope compared to the active control irbesartan, which was not statistically significant. After 108 weeks of treatment, sparsentan achieved a mean reduction in proteinuria from baseline of 50%, compared to 32% for irbesartan. Although the DUPLEX Study did not achieve its two-year primary endpoint with statistical significance over the active control irbesartan, we are encouraged by the results, including the pre-specified secondary endpoints on proteinuria and exploratory endpoints, including renal outcomes, which trended favorably for sparsentan. In addition, a review of the safety results through 108 weeks of treatment indicate sparsentan was generally well-tolerated and the overall safety profile in the study to date was generally consistent between treatment groups.

In December 2023, we announced that we had completed a planned Type C meeting with the FDA to discuss results from the Phase 3 DUPLEX Study of sparsentan in FSGS. The FDA acknowledged the high unmet need for approved therapies as well as the challenges in studying FSGS but indicated that the two-year results from the Phase 3 DUPLEX Study alone were not sufficient to support an sNDA submission. The FDA acknowledged the work being done by the larger nephrology community to better understand proteinuria and eGFR as endpoints in clinical trials of FSGS and indicated a willingness to continue to engage with us on a potential path forward for sparsentan in FSGS following our consideration of additional evidence. Subsequently, a collaborative international effort referred to as the PARASOL project was initiated with a goal to define the quantitative relationships between short-term changes in biomarkers (proteinuria and GFR) and long-term outcomes in order to support the use of alternative proteinuria-based endpoints as a basis for accelerated and traditional approval. The PARASOL project is led by several patient advocacy organizations focused on glomerular diseases, with participation from regulators and industry representatives. The principal finding from PARASOL was that in FSGS, reduction in proteinuria over 24 months is strongly associated with a reduction in the risk of kidney failure, and responder definitions based on thresholds of proteinuria are both biologically plausible and strongly supported by epidemiological data. Following the PARASOL public workshop in the fourth quarter of 2024, in which a multi-stakeholder group of rare kidney disease experts aligned around a potential proteinuria-based clinical trial endpoint for FSGS, we scheduled a Type C meeting with the FDA to discuss a potential regulatory pathway for a sparsentan FSGS indication. In February 2025, we announced that we had completed a Type C meeting with the FDA and in March 2025, we announced that we had submitted an sNDA to the FDA seeking traditional approval of FILSPARI for the treatment of FSGS. In May 2025, we announced that the FDA accepted the sNDA, assigned a PDUFA target action date of January 13, 2026, and initially indicated that it planned to hold an advisory committee meeting to discuss the application. In September 2025, following further review of the sNDA, the FDA informed us that an advisory committee meeting was no longer needed. In January 2026, we announced that the FDA extended the review timeline of the sNDA, and that the new PDUFA target action date is April 13, 2026. The extension followed the recent submission of responses requested by the FDA to further characterize the clinical benefit of FILSPARI. The FDA determined that the additional responses constituted a Major Amendment to the sNDA and extended the action date accordingly. The sNDA remains under review by the FDA with a PDUFA target action date of April 13, 2026.

The sNDA is supported by two of the largest and most rigorous head-to-head interventional studies conducted to date in FSGS, the Phase 3 DUPLEX Study and the Phase 2 DUET Study. In these studies, FILSPARI demonstrated rapid, superior and sustained reductions in proteinuria when compared with maximum labeled dose irbesartan across adult and pediatric patients. As published in the New England Journal of Medicine, DUPLEX showed statistically significant and clinically meaningful proteinuria remission at 36 weeks that was durable through 2 years. The treatment

effect of FILSPARI strengthened at more stringent thresholds down to complete remission. Patients who achieved partial or complete proteinuria remission in the DUPLEX Study, irrespective of the treatment arm, had a 67% to 77% lower risk of kidney failure, respectively. The results from these studies are in alignment with the findings of the independent PARASOL workgroup that support the importance of proteinuria in FSGS. If approved, FILSPARI could become the first and only FDA-approved medicine indicated for FSGS.

Together with CSL Vifor and Chugai, we continue to evaluate the potential for a regulatory pathway forward for sparsentan in FSGS in Europe and Japan.

Under the terms of our exclusive license to CSL Vifor, CSL Vifor is responsible for all commercialization activities in its licensed territories. We remain responsible for the clinical development of sparsentan in the applicable territories. If sparsentan receives marketing authorization in any of the territories covered by the exclusive license to Chugai, Chugai will be responsible for all development, regulatory matters, and commercialization activities in such licensed territories. We will retain all rights to sparsentan in the United States and rest of world outside of the territories licensed to CSL Vifor and Chugai, provided that CSL Vifor has a right of negotiation to expand the licensed territories into Canada and/or Mexico.

Pegtibatinase

Pegtibatinase 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 complications. We estimate that there are approximately 7,000 to 10,000 addressable HCU patients globally. Pegtibatinase has been granted Rare Pediatric Disease, Fast Track and Breakthrough Therapy designations by the FDA, as well as orphan drug designation in the United States and European Union.

In December 2021, we announced positive topline results from the Phase 1/2 COMPOSE Study, a double blind, randomized, placebo-controlled dose escalation study to assess its safety, tolerability, pharmacokinetics, pharmacodynamics and clinical effects in patients with classical HCU. Pegtibatinase demonstrated dose-dependent reductions in total homocysteine (tHcy) during the 12 weeks of treatment, and in the highest dose cohort to date evaluating 1.5 mg/kg of pegtibatinase twice weekly (BIW), treatment with pegtibatinase resulted in rapid and sustained reductions in total homocysteine (tHcy) through 12 weeks of treatment, including a 55.1% mean relative reduction in tHcy from baseline as well as maintenance of tHcy below a clinically meaningful threshold of 100 µmol. Additionally, in a dose-dependent manner in the study to date, methionine levels were substantially reduced and cystathionine levels were substantially elevated following treatment with pegtibatinase, suggesting that pegtibatinase acts in a manner similar to the native CBS enzyme.

In May 2023, we announced positive topline results from the sixth cohort of the Phase 1/2 COMPOSE Study, which was initiated to inform and refine formulation work for future development and commercial purposes and to further evaluate the dose response curve for pegtibatinase, and to further inform our pivotal development program to ultimately support potential approval of pegtibatinase for the treatment of HCU. In this cohort, five patients were randomized in a blinded fashion to receive 2.5 mg/kg of lyophilized pegtibatinase or placebo twice weekly (BIW), with four patients assigned to the treatment group. In this highest dose cohort to date, treatment with pegtibatinase resulted in rapid and sustained reductions in total homocysteine (tHcy), with a 67.1% mean relative reduction in tHcy from baseline, as well as maintenance of mean tHcy below the clinically meaningful threshold of 100 µmol, over weeks 6 to 12. In the double-blind period, pegtibatinase was generally well-tolerated, with no discontinuations due to treatment-related adverse events.

In December 2023, we 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. In the beginning of 2024, the first patients were dosed in the HARMONY Study.

In September 2024, we announced a voluntary pause of enrollment in the Phase 3 HARMONY Study. The voluntary enrollment pause was enacted following our determination that the desired drug substance profile was not achieved in the initial scale-up process, and it enabled us to address necessary process improvements in manufacturing scale-up to support initial commercial scale manufacturing as well as full enrollment in the HARMONY Study. Currently enrolled patients will be able to continue on study medication as scheduled for the duration of the trials in which they are participating. Following further optimization of the manufacturing process in 2025, we restarted enrollment activities for the pivotal Phase 3 HARMONY Study in the first quarter of 2026.

We acquired pegtibatinase as part of the November 2020 acquisition of Orphan Technologies Limited.

Other Commercial Products:

Thiola and Thiola EC (tiopronin)

Thiola and Thiola EC are approved by the FDA for the treatment of cystinuria, a rare genetic cystine transport disorder that causes high cystine levels in the urine and the formation of recurring kidney stones. Due to the larger stone size, cystine stones may be more difficult to pass, often requiring surgical procedures to remove. More than 80 percent of people with cystinuria develop their first stone by the age of 20. More than 25 percent will develop cystine stones by the age of 10. Recurring stone formation can cause loss of kidney function in addition to substantial pain and loss of productivity associated with renal colic and stone passage. While a portion of people living with the disease are able to manage symptoms through diet and fluid intake, the prevalence of cystinuria in the U.S. is estimated to be 10,000 to 12,000, indicating that there may be as many as 4,000 to 5,000 affected individuals with cystinuria in the U.S. that would be candidates for Thiola or Thiola EC.

In June 2019 we announced that the FDA approved 100mg and 300mg tablets of Thiola EC, an 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.

In May 2021, a generic option for the 100mg version of the original formulation of Thiola (tiopronin tablets) became available and in June 2022, a second option for the 100mg version of the original formulation of Thiola (tiopronin tablets) was approved. These generic versions of the original formulation of Thiola have impacted our sales, and these or additional generic versions of either formulation could have a material adverse impact on sales. To date, several generic options for the 100mg and 300mg versions of Thiola EC have been approved by the FDA and become available. Accordingly, Thiola EC is subject to generic competition.

Sale of Bile Acid Product Portfolio

In July 2023, we entered into an Asset Purchase Agreement (the “Purchase Agreement”) with Mirum Pharmaceuticals, Inc. ("Mirum Pharmaceuticals" or “Mirum”), pursuant to which Mirum agreed to purchase substantially all of the assets primarily related to our business of development, manufacture (including synthesis, formulation, finishing or packaging) and commercialization of Chenodal and Cholbam (also known as Kolbam, and together with Chenodal, the “Products”), collectively, the "bile acid business". In August 2023, we consummated the transactions contemplated by the Purchase Agreement (the "Closing"). In connection with the Closing, we received an upfront cash payment of $210.0 million. Pursuant to the Purchase Agreement, after the Closing, we are eligible to receive up to $235.0 million upon the achievement of certain milestones based on specified amounts of annual net sales (tiered from $125.0 million to $500.0 million) of the Products. Mirum achieved the first such milestone based on its annual net sales in 2025, we recognized a milestone payment of $25.0 million during 2025, and expect to receive payment in the second quarter of 2026, as a result of such achievement.

For the year ended December 31, 2023 we recognized a $226.0 million gain, net of tax, on the transaction as a component of net income from discontinued operations in the Consolidated Statements of Operations. The bile acid business has been classified as a discontinued operation for all periods presented and is excluded from the following discussion of the results of our continuing operations in the results of operations. Refer to Note 19 of our Consolidation Financial Statements for additional information.

Strategic Reorganization

In December 2023, we implemented an approximate 20% workforce reduction focused on non-field-based employees in an effort to align our resources on the ongoing FILSPARI launch and the pivotal Phase 3 HARMONY Study to support the potential approval of pegtibatinase as the first potential disease-modifying treatment for HCU. These restructuring adjustments are expected to result in an estimated annualized savings of approximately $25.0 million beginning in 2024. As of December 31, 2024, we had recognized total costs of $13.8 million in connection with the restructuring and no such expenses were incurred for the year ended December 31, 2025.

Critical Accounting Estimates

Management makes certain judgments and uses certain estimates and assumptions when applying accounting principles generally accepted in the United States (“GAAP”) in the preparation of our Consolidated Financial Statements. We evaluate our estimates and judgments on an ongoing basis and base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary from what we anticipate and different assumptions or estimates about the future could change our reported results. We believe the following accounting policies are the most critical to us, in that they require our most difficult, subjective or complex judgments in the preparation of our Consolidated financial statements. For further information, see Note 2, Summary of Significant Accounting Policies, to our Consolidated Financial Statements, which outlines our application of significant accounting policies.

Revenue Recognition

We recognize revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("ASC 606"), the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect substantially all the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

We recognize revenues from product sales when the customer obtains control of the product, which occurs upon delivery to our customer. We receive payments from our product sales based on terms that generally are within 30 days of delivery of product to the patient.

Revenues from product sales are recorded at the net sales price, which includes provisions resulting from discounts, rebates and co-pay assistance that are offered to its customers, health care providers, payers and other indirect customers relating to the sale of our products. In order to determine the transaction price, we estimate, utilizing the expected value method, the amount of variable consideration to which we will be entitled. These provisions are based on the amounts earned or to be claimed on the related sales and are classified as a reduction of accounts receivable (if the amount is payable to the customer) or as a current liability (if the amount is payable to a party other than a customer). Calculating these provisions involves estimates and judgments. Where appropriate, these reserves take into consideration our historical experience, current contractual and statutory requirements and specific known market events and trends. Overall, these reserves reflect our best estimates of the amount of consideration to which it is entitled based on the terms of the contract. If actual results in the future vary from the provisions, we will adjust the provision, which would affect net product revenue and earnings in the period such variances become known. For the years ended December 31, 2025 and 2024, the Company recorded adjustments to net product revenue of $1.1 million and $0.5 million, respectively, related to performance obligations satisfied in previous periods.

Government Rebates: We calculate the rebates that we will be obligated to provide to government programs and deduct these estimated amounts from our gross product sales at the time the revenues are recognized. Allowances for government rebates and discounts are established based on an estimated allocation of payers and the government-mandated discounts applicable to government-funded programs. Rebate discounts are included in accrued expenses in the accompanying consolidated balance sheets.

Commercial Rebates: We calculate the rebates we incur according to any contracts with certain commercial payers and deduct these amounts from our gross product sales at the time the revenues are recognized. Allowances for commercial rebates are established based on actual payer information, which is reasonably estimated at the time of delivery for applicable products. Rebate discounts are included in accrued expenses in the accompanying consolidated balance sheets.

Prompt Pay Discounts: We offer discounts to certain customers for prompt payments. We accrue for the calculated prompt pay discount based on the gross amount of each invoice for those customers at the time of sale.

Other Fees: We pay service fees to certain customers based on a contractually fixed percentage of the wholesale acquisition cost and fees for data. Other fees are recorded as an offset to revenue based on contractual terms at the time revenue from the sale is recognized.

Product Returns: Consistent with industry practice, we offer our customers a limited right to return product purchased directly from us, which is principally based upon the product’s expiration date. Historically, returns have been immaterial.

Co-pay Assistance: We offer a co-pay assistance program, which is intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the estimated cost per claim associated with product that has been recognized as revenue.

Payments received under collaboration and licensing agreements may include non-refundable fees at the inception of the arrangements, milestone payments for specific achievements and royalties on the sale of products. At the inception of arrangements that include milestone payments, we use judgment to evaluate whether the milestones are probable of being achieved and estimates the amount to include in the transaction price utilizing the most likely amount method. If it is probable that a significant revenue reversal will not occur, the estimated amount is included in the transaction price. Milestone payments that are not within our or the licensee’s control, such as regulatory approvals, are considered to be constrained due to a high degree of uncertainty and are not included in the transaction price until such uncertainty is resolved. At the end of each reporting period, we re-evaluate the probability of achievement of development milestones and any related constraint and adjust the estimate of the overall transaction price, if necessary. Our evaluation concluded that all such milestones not recognized as of December 31, 2025 associated with our collaboration and licensing agreements remained constrained and therefore no adjustment to the respective transaction price was necessary. We recognize aggregate sales-based milestones and royalty payments from product sales of which the license is deemed to be the predominant item to which the royalties relate, at the later of when the related sales occur or when the performance obligation to which the sales-based milestone or royalty has been allocated has been satisfied.

We utilize significant judgment to develop estimates of the stand-alone selling price for each distinct performance obligation based upon the relative stand-alone selling price. Variable consideration that relates specifically to our efforts to satisfy specific performance obligations is allocated entirely to those performance obligations. The stand-alone selling price for license-related performance obligations requires judgment in developing assumptions to project probability-weighted cash flows based upon estimates of forecasted revenues, clinical and regulatory timelines and discount rates. The stand-alone selling price for clinical development performance obligations is based on forecasted expected costs of satisfying a performance obligation plus an appropriate margin.

If the licenses to intellectual property are determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to benefit from the license. For licenses that are not distinct from other promises, we apply judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the related revenue recognition accordingly.

The selection of the method to measure progress towards completion requires judgment and is based on the nature of the products or services to be provided. Revenue is recorded proportionally as costs are incurred. We generally utilize the cost-to-cost method of progress because it best measures the transfer of control to the customer which occurs as we incur costs. Under the cost-to-cost measure of progress, the extent of progress towards completion is measured based on the ratio of costs incurred to date to the total estimated costs at completion of the performance obligation. We use judgment to estimate the total costs expected to complete the clinical development performance obligations, which include subcontractor costs, labor, materials, other direct costs and an allocation of indirect costs. We evaluate these cost estimates and the progress each reporting period and adjust the measure of progress, if necessary.

Changes in assumptions where management utilizes significant judgment could have a material impact on the revenue we recognize.

Clinical Trial Expenses

We record expenses in connection with our clinical trials under contracts with contract research organizations ("CROs") that support conducting and managing clinical trials, as well as contract manufacturing organizations ("CMOs") for the manufacture of drug product supplies to support clinical development. The financial terms and activities of these agreements vary from contract to contract and may result in uneven expense levels. Generally, these agreements set forth activities that drive the recording of expenses such as start-up, initiation activities, enrollment, treatment of patients, or the completion of other clinical trial activities, and in the case of CMOs, costs associated with the production of drug product supplied and the procurement of raw materials to be consumed in the manufacturing process.

Expenses related to clinical trials are accrued based on our estimates of the progress of services performed, including actual level of patient enrollment, completion of patient studies and progress of the clinical trials or the delivery of goods. The assumptions we use represent our best estimates of the activity and expenses at the time of our accrual and involve inherent uncertainties and the application of our judgment. Upon settlement, these costs may differ materially from the amounts accrued in our consolidated financial statements. Our historical accrual estimates have not been materially different from our actual amounts. We currently have four Phase 3 clinical trials in process that are in varying stages of activity, with ongoing non-clinical support trials that are significant and changes in estimates could have a material impact on expenses we recognize.

Recently Issued Accounting Pronouncements

See Note 2 to the Consolidated Financial Statements for discussion.

Results of Operations

Unless noted otherwise, the discussion below, and the revenue and expense amounts discussed below, are based on and relate to our continuing operations.

Revenue

For further background on our net product sales and license and collaboration revenue, see Revenue Recognition under our Critical Accounting Estimates.

The following table provides information regarding revenue, including net product sales and license and collaboration revenue (*in thousands*):

	Year Ended December 31,		
	2025	2024	Change
FILSPARI	$ 322,005	$ 132,222	$ 189,783
Tiopronin products	88,455	94,485	(6,030)
Total net product sales	410,460	226,707	183,753
License and collaboration revenue	80,268	6,468	73,800
Total revenue	$ 490,728	$ 233,175	$ 257,553

Net product sales

The $183.8 million increase in total net product sales for the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to growth in sales of FILSPARI. The decrease in net sales of our tiopronin products was driven by increased competition.

License and collaboration revenue

The $73.8 million increase in license and collaboration revenue for the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to market access and regulatory milestones totaling $57.5 million associated with CSL Vifor, recognition of Renalys deferred revenue of $9.3 million, $5.9 million for royalties earned in 2025 on net sales of FILSPARI and sales totaling $4.7 million of active pharmaceutical ingredients to CSL Vifor. We recognize costs related to the sale of active pharmaceutical ingredients in cost of goods sold.

Operating Expenses

The following table provides information regarding operating expenses (*in thousands*):

	Year Ended December 31,		
	2025	2024	Change
Cost of goods sold - product sales	$ 5,813	$ 7,446	$ (1,633)
Cost of goods sold - license and collaboration	4,526	298	4,228
Total cost of goods sold	10,339	7,744	2,595
Research and development	206,011	217,496	(11,485)
Selling, general and administrative	337,202	264,119	73,083
In-process research and development	—	65,205	(65,205)
Restructuring	—	2,438	(2,438)
Total operating expenses	$ 553,552	$ 557,002	$ (3,450)

Cost of goods sold

Cost of goods sold includes the cost of inventory sold, third party manufacturing and supply chain costs, product shipping and handling costs, and provisions for excess and obsolete inventory.

Prior to the February 2023 FDA accelerated approval of FILSPARI (sparsentan), we expensed the production of active pharmaceutical ingredients purchased to support the commercial launch of FILSPARI in research and development expenses. For the year ended December 31, 2025, sales of FILSPARI primarily consisted of zero-cost inventories, and therefore cost of goods sold did not increase proportionally to the increase in product sales. As of December 31, 2025 the zero-cost inventory remaining was immaterial.

For the year ended December 31, 2025 compared to the year ended December 31, 2024, our cost of goods sold - license and collaboration increased by $4.2 million, primarily due to the sale of active pharmaceutical ingredients to CSL Vifor in 2025.

Research and development expenses

Research and development costs include expenses related to sparsentan, pegtibatinase and our other pipeline programs. We expense all research and development costs as they are incurred. Our research and development costs are comprised of salaries and bonuses, benefits, non-cash share-based compensation, license fees, milestones under license agreements, costs paid to third-party contractors to perform research, conduct clinical trials, and develop drug materials and delivery methods, manufacture drug product supplies to support clinical development, and associated overhead expenses and facilities costs. We charge direct internal and external program costs to the respective development programs. We also incur indirect costs that are not allocated to specific programs because such costs benefit multiple development programs and allow us to increase our pharmaceutical development capabilities. These consist of internal shared resources related to the development and maintenance of systems and processes applicable to all of our programs.

We currently have four Phase 3 clinical trials in process that are in various stages of activity, with ongoing non-clinical support trials. As such, clinical trial expenses will vary depending on all the factors set forth above and may fluctuate significantly from quarter to quarter and year to year.

We routinely engage vendors and service providers for scientific research, clinical trial, regulatory compliance, manufacturing and other consulting services. We also make grants to research and non-profit organizations to conduct research which may lead to new intellectual properties that we may subsequently license under separately negotiated license agreements. Such grants may be funded in lump sums or installments.

The following table provides information regarding research and development expenses (*in thousands*):

	For the Year Ended December 31,		
	2025	**2024**	**Change**
External service provider costs:			
Sparsentan	$ 50,712	$ 58,023	$ (7,311)
Pegtibatinase	56,324	68,280	(11,956)
General and other product candidates	18,884	17,350	1,534
Total external service provider costs	125,920	143,653	(17,733)
Internal personnel costs	80,091	73,843	6,248
Total research and development	$ 206,011	$ 217,496	$ (11,485)

For the year ended December 31, 2025 compared to the year ended December 31, 2024, our research and development expenses decreased by $11.5 million. External service provider costs decreased by $17.7 million, which was largely driven by a decrease in costs associated with the development of pegtibatinase due to the pause of the HARMONY Study in September 2024 and a decrease in costs associated with the development of sparsentan as our Phase 3 programs advance towards completion. Internal personnel costs to support all programs increased by $6.2 million.

Selling, general and administrative expenses

Selling, general and administrative expenses consist of salaries and bonuses, benefits, non-cash share-based compensation, legal and other professional fees, rent, depreciation and amortization, travel, insurance, business development, sales and marketing programs, and other operating expenses.

For the year ended December 31, 2025 compared to the year ended December 31, 2024, our selling, general and administrative expenses increased by $73.1 million, primarily as a result of an increase in intangible asset amortization from capitalized FILSPARI royalties, an increase in commercial investment to support FILSPARI in IgAN following full approval by the FDA in September 2024 and commercial investments in preparation for the potential launch of FSGS, if approved.

In-process research and development expense

In March 2024, we recognized a non-recurring $65.2 million charge in in-process research and development (IPR&D) expense upon the achievement of a development milestone associated with our treatment candidate pegtibatinase, which was paid during the second quarter of 2024 and recorded within investing activities in the Consolidated Statements of Cash Flows. We acquired pegtibatinase as part of the November 2020 acquisition of Orphan Technologies Limited.

Other Income/Expenses

Other income/expenses consist of interest income and expense, finance expense and miscellaneous other income/expenses.

The following table provides information regarding other income (expenses) (*in thousands*):

	Year Ended December 31,		
	2025	2024	Change
Interest income	$ 12,721	$ 17,817	$ (5,096)
Interest expense	(10,748)	(11,182)	434
Other income (expense), net	11,578	(3,318)	14,896
Total other income, net	$ 13,551	$ 3,317	$ 10,234

The $10.2 million change in our total other income, net for the year ended December 31, 2025 compared to the year ended December 31, 2024, is primarily attributable to a $10.2 million gain on the sale of our equity investment in Renalys to Chugai during the year ended December 31, 2025.

Discontinued Operations

Results of discontinued operations are as follows (*in thousands*):

	Year Ended December 31,		
	2025	2024	Change
Income (loss) from discontinued operations, net of tax	$ 24,715	$ (915)	$ 25,630

The $25.6 million change in income (loss) from discontinued operations, net of tax for the year ended December 31, 2025 compared to the year ended December 31, 2024 is due to the recognition of a $25.0 million sales milestone from Mirum related to the achievement of an annual net sales milestone in 2025.

See Note 19 to our Consolidated Financial Statements for further discussion.

Liquidity and Capital Resources

We have financed our operations through a combination of borrowings, sales of our equity securities, and revenues generated from our commercialized products, along with proceeds from license and collaboration agreements and the divestiture of our bile acid business. We experienced significant growth in recent years in the number of our employees and the scope of our operations. We also expanded our sales and marketing, compliance and legal functions in addition to expansion of all functions to support a commercial organization, including by adding additional members to our sales force in connection with the commercial launch of FILSPARI in the United States for IgAN and for the potential commercial launch of FILSPARI in the United States for FSGS, if approved.

We believe that our available cash and short-term investments as of the date of this filing, together with anticipated cash generated from operations, will be sufficient to fund our anticipated level of operations beyond the next 12 months from the date of this filing. We expect that our operating results will vary from quarter-to-quarter and year-to-year depending upon various factors including revenues, selling, general and administrative expenses, and research and development expenses, particularly with respect to our clinical and preclinical development activities. Our ability to fund our operations in subsequent years will depend upon certain factors which are beyond our control and may require us to obtain additional debt or equity capital or refinance all or a portion of our debt, including the 2029 Notes, on or before maturity. Though we generate revenues from product sales, we may incur significant operating losses over the next several years. Our ability to achieve profitable operations in the future will depend in large part upon completing development of products in our pipeline, obtaining regulatory approvals for these products and bringing these products to market, along with potential in-licensing of additional products approved by the FDA and manufacturing and selling these products.

For the years ended December 31, 2025 and 2024, we had the following balances and financial performance (*in thousands*):

	Year Ended December 31,	
	2025	2024
Cash and cash equivalents	$ 93,035	$ 58,535
Marketable debt securities, at fair value	$ 229,761	$ 312,166
Convertible debt	$ 311,724	$ 378,988
Accumulated deficit	$ (1,472,713)	$ (1,447,167)
Stockholders' equity	$ 114,828	$ 59,077
Net working capital*	$ 277,661	$ 215,951
Net working capital ratio**	2.74	2.08

* Current assets less current liabilities
**Current assets divided by current liabilities

As of December 31, 2025, we had cash and cash equivalents of $93.0 million and available-for-sale marketable debt securities of $229.8 million. Substantial sources of funds since the beginning of 2025, as summarized further below, include milestone payments from CSL Vifor totaling $57.5 million and $10.2 million from the sale of Renalys stock to Chugai.

Over the next 12 months, our expected financial obligations include, but are not limited to, funding our operations, operating lease payments, interest payments on our outstanding debt, anticipated milestone payments, royalties on sales of our existing commercialized products, research and development expenses pertaining to clinical and preclinical development activities across our pipeline, expenses associated with the ongoing launch of FILSPARI and expenses associated with the preparations for a potential commercial launch of FILSPARI in FSGS. Sources of cash over this period include net revenues from sales of our products, the sale or maturity of investments in our portfolio of marketable debt securities, FILSPARI royalties and certain earned and potential milestone payments.

Beyond the next 12 months and over the foreseeable future, our known commitments and potential financial obligations will likely include ongoing operations funding, operating lease payments, interest payments on our outstanding debt, royalties on sales of our existing commercialized products, research and development expenses pertaining to clinical and preclinical development activities across our pipeline, milestone and royalty payments associated with FILSPARI, pegtibatinase, and other developmental programs based upon the achievement of certain agreement-specific criteria, along with sales-based royalties and the repayment of principal on the outstanding 2029 Notes, which mature on September 1, 2029. Potential sources of cash over this time horizon may include net revenues from sales of our existing products and, if commercialized, our pipeline products, licensing revenue, the sale or maturity of marketable debt securities in our investment portfolio, the refinancing of all or a portion of our debt, on or before maturity, or the issuance of additional debt or equity. In addition, depending on prevailing market conditions, our liquidity requirements, contractual restrictions, and other factors, we may also from time to time seek to retire or purchase our outstanding debt through cash purchases and/or exchanges for equity securities, in open market purchases, privately negotiated transactions or otherwise, and the amounts involved in such purchases and/or exchanges, individually or in the aggregate, may be material. We may not be able to successfully conduct financing or refinancing activity on favorable terms or at all.

Purchase Agreement Proceeds

Sale of Bile Acid Product Portfolio

In July 2023, we entered into the Purchase Agreement with Mirum, pursuant to which Mirum agreed to purchase substantially all of the assets primarily related to our business of development, manufacture and commercialization of the Products, which comprised our bile acid business. Upon the Closing of the transaction in August 2023, we received an upfront cash payment of $210.0 million. Pursuant to the Purchase Agreement, we are eligible to receive up to $235.0 million upon the achievement of certain milestones based on specified amounts of annual net sales (tiered from $125.0 million to $500.0 million) of the Products. Mirum achieved the first such milestone based on its annual net sales in 2025, and we expect to receive a milestone payment of $25.0 million in the second quarter of 2026, as a result of such achievement.

License and Collaboration Agreement with CSL Vifor

In September, 2021, we entered into a license agreement with CSL Vifor, pursuant to which we granted an exclusive license to CSL Vifor for the commercialization of FILSPARI in the licensed territories. Under the terms of the license agreement, we will be eligible for up to $135.0 million in aggregate regulatory and market access related milestone payments and up to $655.0 million in aggregate sales-based milestone payments for a total potential value of up to $845.0 million. Through December 31, 2025, we have received milestone payments totaling $57.5 million associated with the license agreement. We are also entitled to receive tiered double-digit royalties of up to 40 percent of annual net sales of sparsentan in the licensed territories.

See Note 4 to Consolidated Financial Statements for further discussion.

Licensing Agreement with Chugai

In January 2024, our license agreement with Renalys Pharma, Inc. came into effect. Under the terms of the agreement, we granted an exclusive license to Renalys for the development and commercialization of sparsentan in Japan and other specified countries in Asia. Pursuant to the terms of the agreement, we are eligible to receive up to $120.0 million in aggregate regulatory, development and sales-based milestone payments. We are also entitled to receive tiered double-digit to mid-20 percent royalties of annual net sales of sparsentan in the licensed territories. In addition, we received an option to purchase shares of common stock of Renalys, which we exercised in January 2024. In the fourth quarter of 2025, Renalys was acquired by and merged into Chugai. Through the acquisition, Chugai gained exclusive rights to develop and commercialize sparsentan in Japan, South Korea, and Taiwan. As a minority shareholder in Renalys, we received $10.2 million at the closing of the transaction and we are also eligible to receive multiple milestones according to the progress of sparsentan regulatory approval, and consideration linked to sparsentan's net salesin the applicable territory. Under the terms of the licensing agreement, Chugai is responsible for development, regulatory matters, and commercialization in the licensed territories.

See Note 4 to Consolidated Financial Statements for further discussion.

Equity Offerings

2024 Underwritten Public Offering of Common Stock

In November 2024, we sold an aggregate of approximately 9.0 million shares of our common stock in an underwritten public offering, at a price to the public of $16.00 per share of common stock. The net proceeds from the offering, after deducting the underwriting discounts and offering expenses, were approximately $134.7 million.

2023 Underwritten Public Offering of Common Stock

In February 2023, we sold an aggregate of approximately 9.7 million shares of our common stock and pre-funded warrants to purchase 1.25 million shares of our common stock in an underwritten public offering, at a price to the public of $21.00 per share of common stock and $20.9999 per pre-funded warrant. The pre-funded warrants are exercisable immediately, subject to certain beneficial ownership limitations which can be modified by the respective holders with at least 61 days' notice, and are exercisable for one share of our common stock. The exercise price of each pre-funded warrant is $0.0001 per share of common stock. The net proceeds to us from the offering, after deducting the underwriting discounts and offering expenses, were approximately $215.8 million. All of the pre-funded warrants were exercised in the third quarter of 2024, resulting in the issuance of 1.25 million shares of our common stock.

At-the-Market Equity Offering

In October 2024, we filed a prospectus supplement to the prospectus included in our registration statement on Form S-3 (File No. 333-281194), pursuant to which we may offer and sell, from time to time through Jefferies LLC, as agent (“Jefferies”), up to $100.0 million of our common stock pursuant to an Amended and Restated Open Market Sale Agreement ("ATM Agreement") with Jefferies dated October 2024. We have not sold any shares under the ATM Agreement.

Operating Leases

Future Minimum Rental Commitments

As of December 31, 2025, we have future minimum rental commitments totaling $18.5 million arising from our operating lease and sublease income totaling $3.5 million. These commitments represent the aggregate base rent through August 2028.

See Note 18 to Consolidated Financial Statements for further discussion.

Purchase Commitments

Manufactured Product

Certain of our contractual arrangements with contract manufacturing organizations ("CMOs") require binding forecasts or commitments to purchase minimum amounts for the manufacture of drug product supply, which may be material to our financial statements.

Royalties and Contingent Cash Payments

Ligand License Agreement

In 2012, we entered into an agreement with Ligand Pharmaceuticals, Inc. ("Ligand") for a worldwide sublicense to develop, manufacture and commercialize FILSPARI (the “Ligand License Agreement”). As consideration for the license, we are required to make substantial payments upon the achievement of certain milestones, totaling up to $114.1 million. Through December 31, 2025, we have paid $47.2 million for contractual milestones achieved under the Ligand License Agreement. Pursuant to the terms of the Ligand License Agreement, we are obligated to pay to Ligand an escalating royalty between 15% and 17% of net sales of FILSPARI and any other products containing FILSPARI or related compounds, with payments due quarterly. We began incurring costs associated with such royalties following the February 2023 approval of FILSPARI.

The Ligand License Agreement will continue until neither party has any further payment obligations under the agreement and is expected to continue for up to 20 years from the effective date. Ligand may terminate the Ligand License Agreement due to (i) our insolvency, (ii) our material uncured breach of the agreement, (iii) our failure to use commercially reasonable efforts to develop and commercialize FILSPARI as described above or (iv) certain other conditions. We may terminate the Ligand License Agreement due to a material uncured breach of the agreement by Ligand.

See Note 9 to our unaudited Consolidated Financial Statements for further discussion.

Mission License Agreement

In 2014, we entered into a license agreement with Mission Pharmacal ("Mission"), pursuant to which we obtained an exclusive, royalty-bearing license to market, sell and commercialize Thiola (tiopronin) in the United States and Canada, and a non-exclusive license to use know-how relating to Thiola to the extent necessary to market Thiola ("Mission License Agreement"). Under the terms of the Mission License Agreement, as subsequently amended, which runs through May 2029, we are obligated to pay to Mission the greater of $2.1 million, representing the guaranteed minimum royalty, or 20% of our Thiola net sales generated globally during each calendar year.

See Note 9 to Consolidated Financial Statements for further discussion.

Acquisition of Orphan Technologies Limited

In November 2020, we completed the acquisition of Orphan Technologies Limited (“Orphan”), including Orphan’s rare metabolic disorder drug pegtibatinase. We acquired Orphan by purchasing all of its outstanding shares. Under the Stock Purchase Agreement ("the Agreement"), we agreed to make contingent cash payments up to an aggregate of $427.0 million based on the achievement of certain development, regulatory and commercialization events as set forth in the Agreement, as well as additional tiered mid-single digit royalty payments based upon future net sales of any pegtibatinase products in the U.S. and Europe, subject to certain reductions as set forth in the Agreement, and a contingent payment in the event a pediatric rare disease voucher for any pegtibatinase product is granted. We made a $65.0 million payment in the second quarter of 2024 following the achievement of a development milestone.

French Rebate Accrual

In October 2021, our distributor in France for our previously marketed product Kolbam informed us that they had received a notice that the price previously paid for Kolbam during its period on the market in France had been recalculated by the agency responsible for pharmaceutical pricing in France. In October 2024, we received an invoice from the government authority in the amount of approximately $6.2 million for reimbursement of amounts previously paid for Kolbam, which we paid in November 2024. We have appealed the pricing decision and will pursue an appeal of the amount owed with the Competent Administrative Court.

Borrowings

Convertible Senior Notes Due 2029

On March 11, 2022, we completed a registered underwritten public offering of $316.3 million aggregate principal amount of 2.25% Convertible Senior Notes due 2029 (“2029 Notes”). We issued the 2029 Notes under an indenture, dated as of September 10, 2018, as supplemented by the second supplemental indenture, dated as of March 11, 2022 (collectively, the “2029 Indenture”). The 2029 Notes will mature on March 1, 2029, unless earlier repurchased, redeemed, or converted. The 2029 Notes are senior unsecured obligations of ours and bear interest at an annual rate of 2.25%, payable semi-annually in arrears on March 1 and September 1 of each year, beginning on September 1, 2022. The 2029 Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the issuance of other indebtedness or the issuance or repurchase of securities by us.

See Note 7 to Consolidated Financial Statements for further discussion.

Funding Requirements

We believe that our available cash and short-term investments as of the date of this filing will be sufficient to fund our anticipated level of operations beyond the next 12 months from the date of this filing. We expect to use cash flows from operations and, when necessary, outside financings, to meet our current and future financial obligations, including funding our operations, debt service and capital expenditures. Our ability to make these payments depends on our future performance, which will be affected by financial, business, economic, regulatory and other factors, many of which we cannot control. Factors that may affect financing requirements include, but are not limited to:

- the timing, progress, cost and results of our clinical trials, preclinical studies and other discovery and research and development activities;
- the timing and outcome of, and costs involved in, seeking and obtaining marketing approvals for our products, and in maintaining quality systems standards for our products;
- the timing of, and costs involved in, commercial activities, including product marketing, sales and distribution;
- our ability to successfully commercialize FILSPARI for the treatment of IgAN, and to obtain regulatory approval for, and successfully commercialize, sparsentan for FSGS and our other or future product candidates;
- increases or decreases in revenue from our marketed products, including decreases in revenue resulting from generic entrants, changes in reimbursement or rebates, and/or health epidemics or pandemics;
- payment obligations related to the 2029 Notes;
- the number and development requirements of other product candidates that we pursue;
- our ability to manufacture sufficient quantities of our products to meet expected demand;
- the costs of preparing, filing, prosecuting, maintaining and enforcing any patent claims and other intellectual property rights, litigation costs and the results of litigation;
- our ability to enter into collaboration, licensing or distribution arrangements and the terms and timing of these arrangements;
- the potential need to expand our business, resulting in additional payroll and other overhead expenses;
- the potential in-licensing of other products or technologies;
- the emergence of competing technologies or other adverse market or technological developments;
- the potential impacts of actions taken by the current administration, including but not limited to tariffs and changes at the FDA and other government agencies; and
- the impacts of inflation and resulting cost increases.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies.

Cash Flows from Continuing Operations

The following table summarizes our cash flows for the periods set forth below (*in thousands*):

	Year Ended December 31,		
	2025	**2024**	**2023**
Net cash provided by (used in) operating activities - continuing operations	$ 37,784	$ (230,024)	$ (325,357)
Net cash provided by (used in) investing activities - continuing operations	27,892	99,325	(151,626)
Net cash (used in) provided by financing activities - continuing operations	(33,467)	139,422	220,134
Cash flows provided by (used in) continuing operations	32,209	8,723	(256,849)
Cash flows (used in) provided by discontinued operations	—	(7,451)	251,356
Effect of exchange rate changes on cash	2,291	(913)	1,981
Net increase (decrease) in cash and cash equivalents	34,500	359	(3,512)
Cash and cash equivalents, beginning of year	58,535	58,176	61,688
Cash and cash equivalents, end of year	93,035	58,535	58,176
Marketable debt securities, at fair value	229,761	312,166	508,675
Total cash and cash equivalents and marketable debt securities	**$ 322,796**	**$ 370,701**	**$ 566,851**

Management considers marketable debt securities to be available to fund current operations, and they are classified as available for sale and included within current assets in our Consolidated Balance Sheets. Therefore, cash and short-term investments available to fund operations is $322.8 million as of December 31, 2025.

Cash Flows from Operating Activities

Cash provided by operating activities from continuing operations for the year ended December 31, 2025 was $37.8 million compared to cash used of $230.0 million for the year ended December 31, 2024. The change in cash provided was due to a $183.8 million increase in total net product sales, and an increase in license and collaboration revenue of $73.8 million.

Cash Flows from Investing Activities

Cash provided by investing activities from continuing operations for the year ended December 31, 2025 was $27.9 million compared to cash provided of $99.3 million for the year ended December 31, 2024. The change was due to a decrease in net proceeds from the sale and maturity of marketable debt securities and an increase in the purchase of intangible assets, offset by a $65.0 million payment to Orphan in the second quarter of 2024 following the achievement of a development milestone.

Cash Flows from Financing Activities

Cash used in financing activities from continuing operations for the year ended December 31, 2025 was $33.5 million compared to cash provided of $139.4 million for the year ended December 31, 2024. The change was due to the $68.9 million repayment of convertible notes upon maturity in September 2025 and the November 2024 issuance of common stock through an underwritten public offering that provided $134.7 million in net proceeds.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is related to changes in interest rates. As of December 31, 2025, we had cash equivalents and marketable debt securities of approximately $322.8 million, consisting of money market funds, U.S. government agency debt, corporate debt and commercial paper. This exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term debt securities. Our marketable debt securities are subject to interest rate risk and will fall in value if market interest rates continue to increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, a change in interest rates of 100 basis points on December 31, 2025 would have had approximately a $1.1 million impact on our investments.

The marketable debt securities held in our investment portfolio may subject us to credit risk, though our investment policy limits interest-bearing security investments to certain types of instruments issued by institutions with primarily investment grade credit ratings and places restrictions on maturities and concentration by asset class and issuer. Given these policy restrictions and our emphasis on preserving capital and liquidity while enhancing overall returns, we have not experienced material credit-related losses with our securities holdings.

We are also exposed to market risk related to changes in foreign currency exchange rates. From time to time, we enter into contracts with vendors that are located outside of the United States, which contracts are denominated in foreign currencies. We are subject to fluctuations in foreign currency rated in connection with these agreements. We do not currently hedge our foreign currency exchange rate risk.

Inflation generally affects us by increasing our salaries and fees paid to third-party contract service providers. Inflationary pressures have primarily impacted our operations through increased labor costs. While we continue to monitor the effects of macroeconomic factors, inflationary pressures have not affected our current outlook or business objectives.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Consolidated Financial Statements and supplementary data of Travere Therapeutics, Inc. required by this Item are described in Item 15 of this Annual Report on Form 10-K and are presented beginning on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) of the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rule 13a–15(e) and 15d-15(e)), as of the end of the year covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment

and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk. Management is responsible for establishing and maintaining adequate internal control over financial reporting for the company.

Management has used the framework set forth in the report entitled *Internal Control-Integrated Framework (2013 framework)* published by the Committee of Sponsoring Organizations of the Treadway Commission, known as COSO, to evaluate the effectiveness of our internal control over financial reporting. Based on this assessment, our Chief Executive Officer and Chief Financial Officer concluded that our internal control over financial reporting was effective as of December 31, 2025. Ernst & Young LLP ("EY"), our independent registered public accounting firm, has issued an attestation report on our internal control over financial reporting as of December 31, 2025, which is included herein.

Changes in Internal Control Over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any change to our internal control over financial reporting that occurred during the fourth quarter of 2025 and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. There have not been any changes in our internal control over financial reporting during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Travere Therapeutics, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Travere Therapeutics, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Travere Therapeutics, Inc. and subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2025 and the related notes and our report dated February 19, 2026 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Diego, California

February 19, 2026

ITEM 9B. OTHER INFORMATION

Trading Arrangements

During the fiscal quarter ended December 31, 2025, certain of our directors and/or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Regulation S-K, Item 408, as set forth below. Each 10b5-1 plan listed below is part of such individual's long-term asset diversification, tax and/or financial planning strategy, and has been entered into in accordance with the terms of our Insider Trading Policy. Under the terms of the plans, once the plans are in effect, the individuals listed below have no discretion or control over the timing or effectuation of any transactions in our securities pursuant to the plans, and sales will be made only if the stock meets the minimum price thresholds and/or other requirements specified in the applicable plan. Some of the planned sales relate to shares required to be sold by such individual to cover the tax withholding obligation in connection with the settlement of vested restricted stock units and/or performance restricted stock units. Each such director and/or officer continues to be subject to our stock ownership guidelines, and the execution of all potential sales under the plan would not by themselves cause any such individual to be out of compliance with the requirements of our stock ownership guidelines.

Trading Arrangements Adopted:

Name & Title	Date Adopted	Character of Trading Arrangement (1)	Aggregate Number of Shares of Common Stock to be Sold Pursuant to Trading Arrangement	Expiration Date (2)
Roy Baynes, member of our Board of Directors	November 17, 2025	Rule 10b5-1 Trading Arrangement	Up to 61,500 shares (3)	November 13, 2026
Timothy Coughlin, member of our Board of Directors	November 19, 2025	Rule 10b5-1 Trading Arrangement	Up to 13,250 shares (3)	February 25, 2027
Gary Lyons, chair of our Board of Directors	November 11, 2025	Rule 10b5-1 Trading Arrangement	Up to 8,000 shares (4)	May 17, 2026
Jeffrey Meckler, member of our Board of Directors	November 17, 2025	Rule 10b5-1 Trading Arrangement	Up to 8,000 shares (4)	May 18, 2026

1 Each trading arrangement marked as a "Rule 10b5-1 Trading Arrangement" is intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act (the "Rule").

2 Each trading arrangement permits transactions through and including the earlier to occur of (a) the completion of all sales and (b) the date listed in the table. Each trading arrangement marked as a "Rule 10b5-1 Trading Arrangement" only permits transactions upon expiration of the applicable mandatory cooling-off period under the Rule.

3 Includes shares underlying stock options expiring in May 2028.

4 Consists of shares of underlying stock options expiring in May 2026.

Trading Arrangements Terminated:

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this item and not included below will be contained under the captions "Election of Directors", "Information Regarding the Board of Directors and Corporate Governance" and "Executive Officers," in our Definitive Proxy Statement for our 2026 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2025 (the "Proxy Statement"). Such information is incorporated herein by reference.

We have adopted a Code of Business Conduct that applies to our directors and employees (including our principal executive officer, principal financial officer, principal accounting officer and controller), and have posted the text of the policy on our website (https://ir.travere.com/governance-documents). In addition, we intend to promptly disclose on our website in the future (i) the date and nature of any amendment (other than technical, administrative or other non-substantive amendments) to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and relates to any element of the code of ethics definition enumerated in Item 406(b) of Regulation S-K, and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals that relates to one or more of the elements of the code of ethics definition enumerated in Item 406(b) of Regulation S-K, the name of such person who is granted the waiver and the date of the waiver.

We have adopted insider trading policies and procedures governing the purchase, sale, and other dispositions of our securities by our directors, officers and employees, as well as Travere itself, that are reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to Travere.

ITEM 11. EXECUTIVE COMPENSATION

Information required by this item will be contained under the captions “Compensation Discussion and Analysis,” “Executive Compensation,” “Director Compensation Summary”, “Compensation Committee Interlocks and Insider Participation,” and "Compensation Committee Report" in the Proxy Statement. Such information is incorporated herein by reference, provided that the information required by Item 402(x) of Regulation S-K shall be set forth in under the heading “Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information” in the Proxy Statement and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information required by this item will be contained under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Securities Authorized for Issuance Under Equity Compensation Plans” in the Proxy Statement. Such information is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information required by this item will be contained under the caption “Transaction With Related Persons” and “Information Regarding the Board of Directors and Corporate Governance” in the Proxy Statement. Such information is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information required by this item will be contained under the caption “Principal Accountant Fees and Services” in the Proxy Statement. Such information is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The financial statements at page F-1 are incorporated by reference to a part of this Annual Report on Form 10-K.

Financial statement schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

(b) Exhibits: The exhibits to this report are listed in the exhibit index below.

Exhibit No.	Description
2.1*	Stock Purchase Agreement, dated October 21, 2020, by and among the Company, Orphan Technologies Limited and Citco Trustees (Cayman) Limited acting solely in its capacity as the sole trustee of The Fuhrer Family Trust (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the SEC on November 18, 2020).
2.2↓*	Asset Purchase Agreement, dated July 16, 2023, by and between Mirum Therapeutics, Inc. and the Company (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 17, 2023).
3.1	Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to Amendment No. 2 to the Company's General Form for Registration of Securities on Form 10-12G, filed with the SEC on October 28, 2010).
3.2	Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 11, 2015).
3.3	Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the SEC on November 16, 2020).
3.4	Certificate of Amendment to the Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on May 18, 2021).
3.5	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on November 16, 2020).
3.6	Certificate of Amendment of Bylaws of the Company, effective June 9, 2021 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 10, 2021).
4.1	Reference is made to Exhibits to 3.1, 3.2, 3.3, 3.4, 3.5 and 3.6.
4.2	Description of Common Stock (incorporated by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 24, 2022).
4.3	Base Indenture, dated September 10, 2018, between the Company and U.S. Bank National Association, as Trustee (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 10, 2018).
4.4	Second Supplemental Indenture, dated March 11, 2022, between the Company and U.S. Bank Trust Company, National Association, as Trustee (including the form of 2.25% Convertible Senior Note due 2029) (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed with the SEC on March 11, 2022).
10.1	Form of Indemnity Agreement (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 1, 2018).
10.2†	Employment Agreement, dated January 4, 2019, by and between the Company and Eric M. Dube (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K, filed with the SEC on February 26, 2019).
10.3†	Employment Agreement, effective September 1, 2022, between the Company and Christopher Cline (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A, filed with the SEC on August 17, 2022).
10.4†	Employment Agreement, dated February 13, 2017, and Amendment to Employment Agreement, dated April 11, 2017, by and between the Company and William Rote (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 1, 2018)
10.5†	Employment Agreement, dated February 6, 2017, and Amendment to Employment Agreement, dated April 11, 2017, by and between the Company and Elizabeth E. Reed (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 1, 2018)
10.6†	Employment Agreement, dated October 1, 2019, by and between the Company and Peter Heerma (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 5, 2020).
10.7†	Employment Agreement, effective January 1, 2022, between the Company and Jula Inrig, M.D. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 4, 2023).
10.8†	Non-Employee Director Compensation Program, as amended (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 1, 2025).
10.9†	The Company's 2026 Executive Officer Annual Bonus Plan.
10.10†	The Company's 2014 Incentive Compensation Plan as amended (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 9, 2015).
10.11†	The Company's 2015 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, filed with the SEC on May 18, 2017).

10.12†	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise for Inducement Grant Outside of 2015 Equity Incentive Plan (incorporated by reference to Exhibit 99.3 to the Company's current report on Form S-8, filed with the SEC on June 8, 2017).
10.13†	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement for Inducement Grant Outside of 2015 Equity Incentive Plan (incorporated by reference to Exhibit 99.4 to the Company's current report on Form S-8, filed with the SEC on June 8, 2017).
10.14†	The Company's 2017 Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.2 to the Company's Current report on Form 8-K, filed with the SEC on May 18, 2017).
10.15†	The Company's 2018 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, filed with the SEC on May 16, 2025).
10.16†	Form of Stock Option Grant Notice, Option Agreement and Exercise Notice for use under the Company's 2018 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 24, 2022).
10.17†	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement for use under the Company's 2018 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 24, 2022).
10.18†	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise for Inducement Grant Outside of 2018 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.2 to the Company's Registration Statement on Form S-8 (File No. 333-232857), filed with the SEC on July 26, 2019).
10.19†	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement for Inducement Grant Outside of 2018 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.3 to the Company's Registration Statement on Form S-8 (File No. 333-232857), filed with the SEC on July 26, 2019).
10.20+↓	Sublicense Agreement, dated February 16, 2012, by and among Ligand Pharmaceuticals Incorporated, a Delaware corporation, Pharmacopeia, Inc., a Delaware limited liability company, and the Company, a Delaware limited liability company (incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 24, 2022).
10.21*	Amendment No. 3 to Sublicense Agreement dated as of February 27, 2015, between the Company and Ligand Pharmaceuticals Incorporated (incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 24, 2022).
10.22*	Amendment No. 4 to Sublicense Agreement dated as of September 17, 2015, between the Company and Ligand Pharmaceuticals Incorporated (incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 24, 2022).
10.23*	Amendment No. 5 to Sublicense Agreement dated as of March 20, 2018, between the Company and Ligand Pharmaceuticals Incorporated (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on October 31, 2024).
10.24*	Trademark License and Supply Agreement, dated May 29, 2014, by and between the Company and Mission Pharmacal Company (incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K, filed with the SEC on February 20, 2024).
10.25	First Amendment to Trademark License and Supply Agreement, effective as of July 28, 2014, by and between Mission Pharmacal Company and the Company (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 29, 2014).
10.26	Addendum to Trademark License and Supply Agreement, dated October 19, 2015, by and between to Company and Mission Pharmacal (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on November 6, 2015).
10.27*	Third Amendment to Trademark License and Supply Agreement dated as of March 17, 2016, between the Company and Mission Pharmacal Company (incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K, filed with the SEC on February 20, 2024).
10.28*	Amendment One to the Third Amendment to Trademark License and Supply Agreement, dated September 12, 2016, by and between the Company and Mission Pharmacal Company (incorporated by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K, filed with the SEC on February 20, 2024).
10.29*	Amendment Two to the Third Amendment to Trademark License and Supply Agreement, dated November 3, 2017, by and between the Company and Mission Pharmacal Company (incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K, filed with the SEC on February 20, 2024).
10.30	Fourth Amendment to Trademark License and Supply Agreement dated as of November 28, 2018, between the Company and Mission Pharmacal (incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K, filed with the SEC on February 26, 2019).
10.31*	Fifth Amendment to Trademark License and Supply Agreement dated as of September 30, 2020, between the Company and Mission Pharmacal Company (incorporated by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K, filed with the SEC on February 20, 2024).
10.32↓*	Master Manufacturing Supply Agreement, dated September 30, 2020, between the Company and STA Pharmaceutical Hong Kong Limited, a subsidiary of WuXi AppTec (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on November 5, 2020).
10.33↓*	First Amendment to Master Manufacturing Supply Agreement, effective as of November 14, 2022, between the Company and STA Pharmaceutical Hong Kong Limited, a subsidiary of WuXi AppTec (incorporated by reference to Exhibit 10.37 to the Company's Annual Report on Form 10-K, filed with the SEC on February 23, 2023).
10.34↓*	License and Collaboration Agreement, dated September 15, 2021, by and among Orphan Technologies and Vifor (International) Ltd., and, solely with respect to Article 15, the Company (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on October 29, 2021).
10.35↓*	Amendment No. 1 to the License and Collaboration Agreement, effective as of October 5, 2022, by and between Travere Therapeutics Switzerland GmbH (formerly known as Orphan Technologies Limited) and Vifor (International) Ltd. (incorporated by reference to Exhibit 10.39 to the Company's Annual Report on Form 10-K, filed with the SEC on February 23, 2023).

10.36↓*	Amendment No. 2 to the License and Collaboration Agreement, effective as of June 24, 2025, by and between Travere Therapeutics Switzerland GmbH (formerly known as Orphan Technologies Limited) and Vifor (International) Ltd (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 6, 2025).
10.37↓*	Commercial Supply Agreement, dated December 21, 2021, between the Company and Catalent Pharma Solutions, LLC (incorporated by reference to Exhibit 10.40 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 24, 2022).
10.38	Office Lease, effective April 12, 2019, between the Company and Kilroy Realty, L.P. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 6, 2019).
10.39*	First Amendment to Office Lease, dated November 7, 2019, between the Company and Kilroy Realty, L.P. (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 8, 2020).
10.40	Third Amendment to Existing Office Lease and Second Amendment to Long Term Lease, dated May 29, 2020, between the Company and Kilroy Realty, L.P. (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K, filed with the SEC on June 8, 2020).
19.1	Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Company's Annual Report on Form 10-K, filed with the SEC on February 21, 2025).
21.1	List of subsidiaries of the Company.
23.1	Consent of Ernst & Young.
24.1	Power of Attorney (see signature page hereto).
31.1	Chief Executive Officer's Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Chief Financial Officer's Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Chief Executive Officer's Certification pursuant to Section 906 of Sarbanes Oxley Act of 2002.
32.2	Chief Financial Officer's Certification pursuant to Section 906 of Sarbanes Oxley Act of 2002.
97	Incentive Compensation Recoupment Policy (incorporated by reference to Exhibit 97 to the Company's Annual Report on Form 10-K, filed with the SEC on February 20, 2024).
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Taxonomy Extension Presentation Linkbase Document.
104	The cover page to this Annual Report on Form 10-K has been formatted in Inline XBRL.

† Indicates management contract or compensatory plan.

↓ Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC.

* Certain portions of this exhibit are omitted pursuant to Item 601(b)(10)(iv).

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 19, 2026

Travere Therapeutics, Inc.

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

POWER OF ATTORNEY

Know all persons by these presents, that each person whose signature appears below constitutes and appoints Eric Dube and Christopher Cline, and each of them, as his attorneys-in-fact and agents, each with power of substitution in any and all capacities, to sign any amendments to this annual report on Form 10-K, and to file the same with exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that the attorney-in-fact or his substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Eric Dube Eric Dube	Chief Executive Officer and Director (Principal Executive Officer)	February 19, 2026
/s/ Christopher Cline Christopher Cline	Chief Financial Officer (Principal Financial Officer)	February 19, 2026
/s/ Sandra Calvin Sandra Calvin	Senior Vice President and Chief Accounting Officer (Principal Accounting Officer)	February 19, 2026
/s/ Roy D. Baynes Roy D. Baynes	Director	February 19, 2026
/s/ Suzanne Bruhn Suzanne Bruhn	Director	February 19, 2026
/s/ Timothy Coughlin Timothy Coughlin	Director	February 19, 2026
/s/ Gary Lyons Gary Lyons	Chair of the Board	February 19, 2026
/s/ Jeffrey A. Meckler Jeffrey A. Meckler	Director	February 19, 2026
/s/ John A. Orwin John A. Orwin	Director	February 19, 2026
/s/ Sandra E. Poole Sandra E. Poole	Director	February 19, 2026
/s/ Ron Squarer Ron Squarer	Director	February 19, 2026
/s/ Ruth Williams-Brinkley Ruth Williams-Brinkley	Director	February 19, 2026

TRAVERE THERAPEUTICS, INC. AND SUBSIDIARIES

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Travere Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Travere Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 19, 2026 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Government rebate deductions from revenue

Description of the Matter

As described in Note 3 to the consolidated financial statements under the caption “Deductions from Revenue”, the Company calculates the rebates for Filspari that it will be obligated to provide to government programs and deducts these estimated amounts from its gross product sales at the time the revenues are recognized. Allowances for government rebates and discounts are established based on an estimated allocation of payers and the government-mandated discounts applicable to government-funded programs. Where appropriate, these allowances take into consideration the Company’s historical experience, current statutory requirements, and specific known market events and trends. Estimated government rebates are included in accrued expenses on the consolidated balance sheet.

Auditing the Filspari government rebate deductions from revenue was complex and required significant auditor judgment because the related accruals were dependent on certain subjective assumptions. Such subjective assumptions included estimated allocations of payers and estimated government-mandated discounts applicable to government-funded programs, each of which are adjusted for the Company’s historical experience, current statutory requirements, and specific known market events and trends, where appropriate.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of controls over the Company’s Filspari government rebate deductions from revenue process. This included testing controls over management’s review of the significant assumptions described above and other inputs into the estimation of government rebates, including the accuracy of data used in the calculation.

To test the Filspari government rebate deductions from revenue, our audit procedures included, among others, understanding and evaluating the significant assumptions and underlying data used in management’s calculations. Our testing of significant assumptions included a lookback analysis to evaluate the historical accuracy of management’s estimates by comparing actual activity to previous estimates and performing sensitivity analyses over the subjective assumptions to evaluate the completeness of the reserves. As a part of our procedures, we evaluated the reasonableness of the Company’s assumptions considering recent sales trends and regulatory factors related to Filspari government rebates.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2023.

San Diego, California

February 19, 2026

TRAVERE THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 93,035	$ 58,535
Marketable debt securities, at fair value	229,761	312,166
Accounts receivable, net	80,134	27,116
Inventory	5,875	6,200
Prepaid expenses and other current assets	28,760	12,685
Total current assets	437,565	416,702
Long-term inventory	30,280	35,656
Property and equipment, net	4,022	5,336
Operating lease right-of-use assets	10,576	14,295
Intangible assets, net	113,868	103,974
Other assets	8,880	18,162
Total assets	$ 605,191	$ 594,125
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 24,800	$ 23,534
Accrued expenses	126,035	86,028
Convertible debt, current portion	—	68,678
Operating lease liabilities, current portion	5,875	5,405
Other current liabilities	3,194	17,106
Total current liabilities	159,904	200,751
Convertible debt, less current portion	311,724	310,310
Operating lease liabilities, less current portion	11,134	17,191
Other non-current liabilities	7,601	6,796
Total liabilities	490,363	535,048
Commitments and Contingencies (See Note 11)		
Stockholders' Equity:		
Preferred stock $0.0001 par value; 20,000,000 shares authorized; no shares issued and outstanding as of December 31, 2025 and 2024	—	—
Common stock $0.0001 par value; 200,000,000 shares authorized; 90,922,868 and 87,452,835 issued and outstanding as of December 31, 2025 and 2024, respectively	9	9
Additional paid-in capital	1,588,721	1,506,315
Accumulated deficit	(1,472,713)	(1,447,167)
Accumulated other comprehensive loss	(1,189)	(80)
Total stockholders' equity	114,828	59,077
Total liabilities and stockholders' equity	$ 605,191	$ 594,125

The accompanying notes are an integral part of these consolidated financial statements.

TRAVERE THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2025	2024	2023
Net product sales	$ 410,460	$ 226,707	$ 127,537
License and collaboration revenue	80,268	6,468	17,701
Total revenue	490,728	233,175	145,238
Operating expenses:			
Cost of goods sold	10,339	7,744	11,450
Research and development	206,011	217,496	244,990
Selling, general and administrative	337,202	264,119	265,542
In-process research and development	—	65,205	—
Restructuring	—	2,438	11,394
Total operating expenses	553,552	557,002	533,376
Operating loss	(62,824)	(323,827)	(388,138)
Other income, net:			
Interest income	12,721	17,817	21,768
Interest expense	(10,748)	(11,182)	(11,334)
Other income (expense), net	11,578	(3,318)	1,594
Total other income, net	13,551	3,317	12,028
Loss from continuing operations before income tax provision	(49,273)	(320,510)	(376,110)
Income tax provision on continuing operations	(988)	(120)	(223)
Loss from continuing operations, net of tax	(50,261)	(320,630)	(376,333)
Income (loss) from discontinued operations, net of tax	24,715	(915)	264,934
Net loss	$ (25,546)	$ (321,545)	$ (111,399)
Per share data			
Basic and diluted:			
Net loss from continuing operations	$ (0.57)	$ (4.07)	$ (5.07)
Net income (loss) from discontinued operations	0.28	(0.01)	3.57
Net loss per common share	$ (0.29)	$ (4.08)	$ (1.50)
Weighted average common shares outstanding	89,211,813	78,888,861	74,267,418
Comprehensive loss:			
Net loss	$ (25,546)	$ (321,545)	$ (111,399)
Unrealized gain (loss) on defined benefit pension plan	219	328	(374)
Foreign currency translation (loss) gain	(945)	1,422	(1,871)
Unrealized (loss) gain on marketable debt securities	(383)	(374)	3,696
Comprehensive loss	$ (26,655)	$ (320,169)	$ (109,948)

The accompanying notes are an integral part of these consolidated financial statements.

TRAVERE THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
BALANCE - DECEMBER 31, 2022	64,290,570	$ 6	$ 1,059,975	$ (2,907)	$ (1,014,223)	$ 42,851
Share based compensation	—	—	43,985	—	—	43,985
Issuance of common stock under the equity incentive plan and proceeds from exercise	1,046,276	—	3,240	—	—	3,240
Employee stock purchase program purchase and expense	326,521	—	4,853	—	—	4,853
Equity offering, net of issuance costs of $12.6 million	9,703,750	1	191,198	—	—	191,199
Issuance of pre-funded common stock warrants, net of issuance costs of $1.6 million	—	—	24,630	—	—	24,630
Unrealized loss on defined benefit pension plan	—	—	—	(374)	—	(374)
Foreign currency translation adjustments	—	—	—	(1,871)	—	(1,871)
Unrealized gain on marketable debt securities	—	—	—	3,696	—	3,696
Net loss	—	—	—	—	(111,399)	(111,399)
BALANCE - DECEMBER 31, 2023	75,367,117	$ 7	$ 1,327,881	$ (1,456)	$ (1,125,622)	$ 200,810
Share based compensation	—	—	35,679	—	—	35,679
Issuance of common stock under the equity incentive plan and proceeds from exercise	1,455,575	1	4,452	—	—	4,453
Employee stock purchase program purchase and expense	395,768	—	3,566	—	—	3,566
Equity offering, net of issuance costs of $9.0 million	8,984,375	1	134,737	—	—	134,738
Exercise of pre-funded common stock warrants	1,250,000	—	—	—	—	—
Unrealized gain on defined benefit pension plan	—	—	—	328	—	328
Foreign currency translation adjustments	—	—	—	1,422	—	1,422
Unrealized loss on marketable debt securities	—	—	—	(374)	—	(374)
Net loss	—	—	—	—	(321,545)	(321,545)
BALANCE - DECEMBER 31, 2024	87,452,835	$ 9	$ 1,506,315	$ (80)	$ (1,447,167)	$ 59,077
Share based compensation	—	—	43,480	—	—	43,480
Issuance of common stock under the equity incentive plan and proceeds from exercise	3,254,517	—	34,745	—	—	34,745
Employee stock purchase program purchase and expense	215,516	—	4,181	—	—	4,181
Unrealized gain on defined benefit pension plan	—	—	—	219	—	219
Foreign currency translation adjustments	—	—	—	(945)	—	(945)
Unrealized loss on marketable debt securities	—	—	—	(383)	—	(383)
Net loss	—	—	—	—	(25,546)	(25,546)
BALANCE - DECEMBER 31, 2025	90,922,868	$ 9	$ 1,588,721	$ (1,189)	$ (1,472,713)	$ 114,828

The accompanying notes are an integral part of these consolidated financial statements

TRAVERE THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	For the year ended December 31,		
	2025	2024	2023
Cash Flows From Operating Activities:			
Net loss	$ (25,546)	$ (321,545)	$ (111,399)
Net income (loss) from discontinued operations	24,715	(915)	264,934
Net loss from continuing operations	(50,261)	(320,630)	(376,333)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	60,743	43,555	38,530
Share based compensation	44,868	36,913	44,246
In-process research and development	—	65,205	—
Loss on allowance for inventory	684	2,819	3,039
Amortization of debt discount and issuance costs	1,640	1,725	1,718
Amortization of discounts on investments	(4,436)	(4,535)	(7,456)
Other	(1,457)	7,944	(3,626)
Changes in operating assets and liabilities:			
Accounts receivable	(27,822)	(6,001)	(11,264)
Inventory	5,016	(3,771)	(39,420)
Income taxes	849	(41)	(35)
Prepaid expenses and other current and non-current assets	(7,658)	(3,164)	(4,657)
Change in lease assets and liabilities, net	(622)	(949)	(986)
Accounts payable	(85)	(17,563)	24,763
Accrued expenses	28,840	(31,061)	22,321
Deferred revenue, current and non-current	(2,815)	(6,116)	(15,779)
Other current and non-current liabilities	(9,700)	5,646	(418)
Net cash provided by (used in) operating activities - continuing operations	37,784	(230,024)	(325,357)
Net cash (used in) provided by operating activities - discontinued operations	—	(7,451)	45,336
Net cash provided by (used) in operating activities	37,784	(237,475)	(280,021)
Cash Flows From Investing Activities:			
Proceeds from the sale and maturity of marketable debt securities	323,595	326,334	334,575
Purchase of marketable debt securities	(237,142)	(125,757)	(443,942)
Purchase of intangible assets	(58,157)	(36,212)	(41,591)
Payment of milestone	—	(65,000)	—
Other	(404)	(40)	(668)
Net cash provided by (used in) investing activities - continuing operations	27,892	99,325	(151,626)
Net cash provided by investing activities - discontinued operations	—	—	207,402
Net cash provided by investing activities	27,892	99,325	55,776

	For the year ended December 31,		
	2025	2024	2023
Cash Flows From Financing Activities:			
Payment of guaranteed minimum royalty	(2,100)	(2,100)	(2,100)
Repayment of 2025 convertible senior notes	(68,904)	—	—
Proceeds from the issuance of common stock, net of issuance costs	—	134,738	191,198
Proceeds from the issuance of pre-funded warrants, net of issuance costs	—	—	24,630
Proceeds from exercise of stock options	34,745	4,452	3,240
Proceeds from the issuances under the employee stock purchase plan	2,792	2,332	3,166
Net cash (used in) provided by financing activities - continuing operations	(33,467)	139,422	220,134
Net cash used in financing activities - discontinued operations	—	—	(1,382)
Net cash (used in) provided by financing activities	(33,467)	139,422	218,752
Effect of exchange rate changes on cash	2,291	(913)	1,981
Net increase (decrease) in cash and cash equivalents	34,500	359	(3,512)
Cash and cash equivalents, beginning of year	58,535	58,176	61,688
Cash and cash equivalents, end of year	$ 93,035	$ 58,535	$ 58,176
Supplemental Disclosure of Cash Flow Information:			
Operating cash flows used for operating leases	$ 6,578	$ 6,392	$ 6,315
Cash paid for interest	$ 8,838	$ 8,838	$ 8,838
Non-cash investing and financing activities:			
Accrued royalty in excess of minimum payable to the sellers of Thiola	$ 14,280	$ 15,436	$ 16,206

The accompanying notes are an integral part of these consolidated financial statements.

TRAVERE THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. DESCRIPTION OF BUSINESS

Organization and Description of Business

Travere Therapeutics, Inc. (“we”, “our”, “us”, “Travere” and the “Company”) refers to Travere Therapeutics, Inc., a Delaware corporation, as well as its subsidiaries. Travere is a fully integrated biopharmaceutical company headquartered in San Diego, California focused on identifying, developing and delivering life-changing therapies to people living with rare kidney and metabolic diseases. The Company regularly evaluates and, where appropriate, acts on opportunities to expand its product pipeline and approved products through licenses and acquisitions of products in areas that will serve rare disease patients with serious unmet medical need and that the Company believes offer attractive growth characteristics.

Discontinued Operations - Sale of Bile Acid Product Portfolio

In July 2023, Travere entered into an Asset Purchase Agreement (the “Purchase Agreement”) with Mirum Pharmaceuticals, Inc. ("Mirum Pharmaceuticals" or “Mirum”), pursuant to which Mirum agreed to purchase from Travere substantially all of the assets primarily related to Travere’s business of development, manufacture (including synthesis, formulation, finishing or packaging) and commercialization of Chenodal and Cholbam (also known as Kolbam, and together with Chenodal, the “Products”) (collectively, the "bile acid business"). In August 2023, the Company and Mirum consummated the transactions contemplated by the Purchase Agreement (the “Closing”). In connection with the Closing, Mirum paid Travere an upfront cash payment of $210.0 million. Pursuant to the Purchase Agreement, Travere is eligible to receive up to $235.0 million upon the achievement of certain milestones based on specified amounts of annual net sales (tiered from $125.0 million to $500.0 million) of the Products. The Company has reflected the bile acid business as a discontinued operation in the consolidated financial statements for all periods presented. Mirum achieved the first such milestone based on its annual net sales in 2025, and Travere recognized a milestone payment of $25.0 million for the year ended December 31, 2025 in discontinued operations, as a result of such achievement. See Note 19 for further discussion.

Unless otherwise noted, amounts and disclosures throughout the Notes to the consolidated financial statements relate to the Company's continuing operations.

Approved Products:

FILSPARI® (sparsentan)

In September 2024, the FDA granted full approval of FILSPARI® (sparsentan) to slow kidney function decline in adults with primary Immunoglobulin A nephropathy (IgAN) who are at risk of disease progression. FILSPARI had previously been granted accelerated approval in February 2023 based on the surrogate marker of proteinuria. Full approval was based on positive long-term confirmatory results from the PROTECT Study demonstrating that FILSPARI significantly slowed kidney function decline over two years compared to irbesartan.

FILSPARI is the only oral, once-daily, non-immunosuppressive medication that directly targets glomerular injury in the kidney by blocking two critical pathways of IgAN disease progression (endothelin-1 and angiotensin II).

In September 2021, the Company entered into a license and collaboration agreement (the "CSL Vifor License Agreement") with Vifor (International) Ltd. ("CSL Vifor"). In April 2024, the Company and CSL Vifor announced that the European Commission had granted conditional marketing authorization (“CMA”) for FILSPARI (sparsentan) for the treatment of adults with primary IgAN with a urine protein excretion ≥1.0 g/day (or urine protein-to-creatinine ratio ("UPCR") ≥0.75 g/g), and in April 2025, the Company and CSL Vifor announced that the European Commission had converted the CMA into a standard marketing authorization (“MA”) for FILSPARI for the treatment of adults with primary IgAN with a urine protein excretion ≥1.0 g/day (or UPCR ≥0.75 g/g). The MA was granted for all member states of the European Union, as well as in Iceland, Liechtenstein and Norway. As a result of the standard MA approval, the Company received a regulatory milestone payment of $17.5 million in May 2025 under the terms of the CSL Vifor License Agreement. FILSPARI became commercially available in Europe under the CMA in August 2024, with an initial launch in Germany and Austria. In October 2024, the Company and CSL Vifor announced that Swissmedic had granted temporary marketing authorization for FILSPARI for the treatment of adults with primary IgAN with a urine protein excretion ≥1.0 g/day (or UPCR ≥0.75 g/g). In April 2025, the Medicines and Healthcare products Regulatory Agency ("MHRA") in the UK converted its conditional approval of FILSPARI in IgAN to standard approval. During the third quarter of 2025, the Company recognized a $40.0 million market access milestone from CSL Vifor; payment was received in the fourth quarter of 2025.

In January 2024, the Company entered into an exclusive licensing agreement (the "Chugai License Agreement") with Renalys Pharma, Inc. ("Renalys"), to bring sparsentan for the treatment of IgAN to patients in Japan and other countries in Asia. In December 2024, Renalys announced that sparsentan received Orphan Drug Designation from the Japanese Ministry of Health, Labour and Welfare for the indication of primary IgA

nephropathy in November 2024. In the fourth quarter of 2025, Renalys announced positive topline results from its Phase 3 study of sparsentan in Japanese patients with IgAN. Renalys has also announced that it has reached an agreement with the PMDA regarding development plans for two other Phase 3 clinical trials of sparsentan, one investigating the use of sparsentan in focal segmental glomerulosclerosis (FSGS) and the other in Alport syndrome, in Japan. In the fourth quarter of 2025, Renalys was acquired by and merged into Chugai Pharmaceutical Co., Ltd. (“Chugai”). Through the acquisition, Chugai gained exclusive rights to develop and commercialize sparsentan in Japan, South Korea, and Taiwan. As a minority shareholder in Renalys, Travere received $10.2 million at the closing of the transaction and Travere is also eligible to receive multiple milestones according to the progress of sparsentan regulatory approval, and consideration linked to sparsentan's net sales in the applicable territory. Under the terms of the licensing agreement, Chugai is responsible for development, regulatory matters, and commercialization in the licensed territories. Chugai plans to file for the regulatory approval for sparsentan in Japan in 2026.

Thiola® and Thiola EC® (tiopronin tablets)

Thiola® and Thiola EC® (tiopronin tablets) are approved in the United States for the prevention of cystine (kidney) stone formation in patients with severe homozygous cystinuria.

Clinical-Stage Programs:

Sparsentan for the treatment of FSGS

Sparsentan remains a novel investigational product candidate which has been granted Orphan Drug Designation for the treatment of FSGS in the U.S. and the European Economic Area countries (the “EEA”). In December 2023, the Company announced that it had completed a planned Type C meeting with the FDA to discuss results from the Phase 3 DUPLEX Study of sparsentan in FSGS. The FDA acknowledged the high unmet need for approved therapies as well as the challenges in studying FSGS but indicated that the two-year results from the Phase 3 DUPLEX Study alone were not sufficient to support an sNDA submission. In February 2025, the Company announced that it had completed a Type C meeting with the FDA and in March 2025, the Company announced that it had submitted an sNDA to the FDA seeking traditional approval of FILSPARI for the treatment of FSGS. In May 2025, the Company announced that the FDA accepted the sNDA, assigned a Prescription Drug User Fee Act ("PDUFA") target action date of January 13, 2026, and initially indicated that it planned to hold an advisory committee meeting to discuss the application. In September 2025, following further review of the sNDA, the FDA informed the Company that an advisory committee meeting was no longer needed. In January 2026, the FDA extended the review timeline of the sNDA, and that the new PDUFA target action date is April 13, 2026. The extension followed the recent submission of responses requested by the FDA to further characterize the clinical benefit of FILSPARI. The FDA determined that the additional responses constituted a Major Amendment to the sNDA and extended the action date accordingly. The sNDA remains under review by the FDA with a PDUFA target action date of April 13, 2026.

Pegtibatinase

Pegtibatinase is a novel investigational human enzyme replacement candidate being evaluated for the treatment of classical homocystinuria ("HCU"). Pegtibatinase has been granted Rare Pediatric Disease, Fast Track and Breakthrough Therapy designations by the FDA, as well as orphan drug designation in the United States and European Union. In May 2023, the Company announced positive topline results from cohort 6 in the Phase 1/2 COMPOSE Study. 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. In the beginning of 2024, the first patients were dosed in the HARMONY Study.

In September 2024, the Company announced a voluntary pause of enrollment in the Phase 3 HARMONY Study. The voluntary enrollment pause was enacted following the Company's determination that the desired drug substance profile was not achieved in the initial scale-up process, and it enabled the Company to address necessary process improvements in manufacturing scale-up to support initial commercial scale manufacturing as well as full enrollment in the HARMONY Study. Currently enrolled patients will be able to continue on study medication as scheduled for the duration of the trials in which they are participating. Following further optimization of the manufacturing process in 2025, the Company restarted enrollment activities for the pivotal Phase 3 HARMONY Study in the first quarter of 2026.

The Company acquired pegtibatinase as part of the November 2020 acquisition of Orphan Technologies Limited.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

A summary of the significant accounting policies applied in the preparation of the accompanying consolidated financial statements follows:

Principles of Consolidation

The consolidated financial statements represent the consolidation of the accounts of the Company, its subsidiaries and variable interest entities for which the Company has been determined to be the primary beneficiary, in conformity with accounting principles generally accepted in the United States ("U.S. GAAP"). All intercompany accounts and transactions have been eliminated in consolidation. See Note 5 for further discussion of variable interest entities (“VIE”) that the Company consolidates.

Use of Estimates

In preparing financial statements in conformity with U.S. GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of expenses during the reporting period. Due to inherent uncertainty involved in making estimates, actual results reported in future periods may be affected by changes in these estimates. On an ongoing basis, the Company evaluates its estimates and assumptions. These estimates and assumptions include revenue recognition, forecasting probability-weighted cash flows based upon estimates of forecasted revenues, clinical and regulatory timelines and discount rates, valuing equity securities in share-based payments, estimating expenses of contracted research organizations, estimating reserves for inventory, estimating the useful lives of depreciable and amortizable assets, estimating of valuation allowances and uncertain tax positions, and estimates associated with the assessment of impairment for long-lived assets.

Revenue Recognition

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("ASC 606"), the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only recognizes revenue from contracts when it is probable that the entity will collect substantially all the consideration it is entitled to in exchange for the goods or services it transfers to the customer. See Note 3 and Note 4 for further discussion.

Payments received under collaboration and licensing agreements may include non-refundable fees at the inception of the arrangements, milestone payments for specific achievements and royalties on the sale of products. At the inception of arrangements that include milestone payments, the Company uses judgment to evaluate whether the milestones are probable of being achieved and estimates the amount to include in the transaction price utilizing the most likely amount method. If it is probable that a significant revenue reversal will not occur, the estimated amount is included in the transaction price. Milestone payments that are not within the Company or the licensee’s control, such as regulatory approvals, are considered to be constrained due to a high degree of uncertainty and are not included in the transaction price until such uncertainty is resolved. At the end of each reporting period, the Company re-evaluates the probability of achievement of development milestones and any related constraint and adjusts the estimate of the overall transaction price, if necessary. The Company recognizes aggregate sales-based milestones and royalty payments from product sales of which the license is deemed to be the predominant item to which the royalties relate, at the later of when the related sales occur or when the performance obligation has been satisfied. Revenue from collaboration and licensing agreements may also include sales of inventory, at cost plus a margin, which is recorded in license and collaboration revenue.

The Company utilizes significant judgment to develop estimates of the stand-alone selling price for each distinct performance obligation based upon the relative stand-alone selling price. Variable consideration that relates specifically to the Company’s efforts to satisfy specific performance obligations is allocated entirely to those performance obligations. The stand-alone selling price for license-related performance obligations requires judgment in developing assumptions to project probability-weighted cash flows based upon estimates of forecasted revenues, clinical and regulatory timelines and discount rates. The stand-alone selling price for clinical development performance obligations is based on forecasted expected costs of satisfying a performance obligation plus an appropriate margin.

If the licenses to intellectual property are determined to be distinct from the other performance obligations identified in the arrangement and have stand-alone functionality, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to benefit from the license. For licenses that are not distinct from other promises, the Company applies judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the related revenue recognition accordingly.

The selection of the method to measure progress towards completion requires judgment and is based on the nature of the products or services to be provided. Revenue is recorded proportionally as costs are incurred. The Company generally utilizes the cost-to-cost method of progress because it best measures the transfer of control to the customer which occurs as the Company incurs costs. Under the cost-to-cost measure of progress, the extent of progress towards completion is measured based on the ratio of costs incurred to date to the total estimated costs at completion of the performance obligation. The Company uses judgment to estimate the total costs expected to complete the clinical development performance obligations, which include subcontractor costs, labor, materials, other direct costs and an allocation of indirect costs. The Company evaluates these cost estimates and the progress each reporting period and adjusts the measure of progress, if necessary.

Inventory, Related Reserves and Cost of Goods Sold

Inventory, which is recorded at the lower of cost or net realizable value, includes materials and other direct and indirect costs and is valued using the first-in, first-out method. The Company periodically analyzes its inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value, and writes down such inventory as appropriate. In addition, the Company's products are subject to strict quality control and monitoring which the Company's manufacturers perform throughout their manufacturing process. The Company does not directly manufacture any product. The Company has a single supplier for its product Thiola, and utilizes contract service providers for the manufacture of the active pharmaceutical ingredient for FILSPARI and the manufacture of primary packaging, secondary packaging and serialization for its product FILSPARI.

Inventory, net of reserves, consisted of the following at December 31, 2025 and 2024 (*in thousands*):

	December 31, 2025	December 31, 2024
Raw materials	$ 24,169	$ 30,552
Work in process	2,348	7,625
Finished goods	9,638	3,679
Total inventory	$ 36,155	$ 41,856
Classified as:		
Inventory	$ 5,875	$ 6,200
Long-term inventory	30,280	35,656
Total inventory	$ 36,155	$ 41,856

The balance classified as long-term inventory consists of raw materials, work in process and finished goods for both Thiola and FILSPARI as of December 31, 2025. The Company maintains levels of these inventories beyond a one-year production plan to limit exposure to potential supply disruption.

Cost of goods sold includes the cost of inventory sold, third party manufacturing and supply chain costs, product shipping and handling costs, and provisions for excess and obsolete inventory. Cost of goods sold also includes the cost of goods sold under the Company's license and collaboration agreements, which currently consists of the sale of active pharmaceutical ingredients to the Company's collaboration partners, at cost or at cost plus a margin.

The following table summarizes cost of goods sold for the years ended December 31, 2025, 2024 and 2023 (*in thousands*):

	Year Ended December 31,		
	2025	2024	2023
Cost of goods sold - product sales	$ 5,813	$ 7,446	$ 8,406
Cost of goods sold - license and collaboration	4,526	298	3,044
Total cost of goods sold	$ 10,339	$ 7,744	$ 11,450

Capitalization of Inventory Costs

Prior to the regulatory approval of the Company's drug candidates, the Company incurs expenses for the manufacture of drug product supplies to support clinical development that could potentially be available to support the commercial launch of those drugs. The Company capitalizes inventory costs associated with its products after regulatory approval, when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Until the date at which regulatory approval has been received, costs related to the production of inventory are recorded as research and development expenses as incurred. Any eventual sale of previously expensed ("zero-cost") inventories may impact future margins, for any periods in which those inventories are sold.

Prior to the February 2023 FDA accelerated approval of FILSPARI (sparsentan), the Company expensed the production of active pharmaceutical ingredients purchased to support the commercial launch of FILSPARI, in research and development expenses. For the year ended December 31, 2025, sales of FILSPARI primarily consisted of zero-cost inventories. As of December 31, 2025 the zero-cost inventory remaining was immaterial. The Company began capitalizing inventory costs associated with FILSPARI following the February 2023 accelerated approval.

For the year ended December 31, 2023, the Company's evaluation of excess inventory and obsolescence considered certain minimum purchase obligations, which in combination with lower forecasted sales of FILSPARI resulted in a $3.2 million charge to cost of goods sold. The charge to cost of goods of sold included a $2.1 million write-down of inventory balances and $1.1 million accrued for firm purchase commitments.

Research and Development Expenses

Research and development includes expenses related to sparsentan, pegtibatinase, and the Company's other pipeline programs. The Company expenses all research and development costs as they are incurred. The Company's research and development costs are composed of salaries and bonuses, benefits, share-based compensation, license fees, milestones under license agreements, costs paid to third-party contractors to perform research, conduct clinical trials, costs to develop drug materials and delivery devices, costs to manufacture drug product supplies to support clinical development, and associated overhead expenses and facilities costs. The Company charges direct internal and external program costs to the respective development programs. The Company also incurs indirect costs that are not allocated to specific programs because such costs benefit multiple development programs and allow us to increase our pharmaceutical development capabilities. These consist of internal shared resources related to the development and maintenance of systems and processes applicable to all of our programs.

Nonrefundable advance payments for goods and services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered.

Clinical Trial Expenses

The Company records expenses in connection with its clinical trials under contracts with contract research organizations ("CROs") that support conducting and managing clinical trials, as well as contract manufacturing organizations ("CMOs") for the manufacture of drug product supplies to support clinical development. The financial terms and activities of these agreements vary from contract to contract and may result in uneven expense levels. Generally, these agreements set forth activities that drive the recording of expenses such as start-up, initiation activities, enrollment, treatment of patients, or the completion of other clinical trial activities, and in the case of CMOs, costs associated with the production of drug product supplied and the procurement of raw materials to be consumed in the manufacturing process.

Expenses related to clinical trials are accrued based on our estimates of the progress of services performed, including actual level of patient enrollment, completion of patient studies and progress of the clinical trials or the delivery of goods. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the amounts we are obligated to pay under our clinical trial agreements are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), the Company adjusts its estimates accordingly on a prospective basis. Revisions to the Company's contractual payment obligations are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

The Company currently has four Phase 3 clinical trials in process that are in varying stages of activity, with ongoing non-clinical support trials. As such, clinical trial expenses will vary depending on all the factors set forth above and may fluctuate significantly from quarter to quarter and year to year.

Advertising Expenses

Advertising costs are expensed as incurred. The Company incurred $14.7 million, $7.8 million and zero in advertising costs during the years ended December 31, 2025, 2024 and 2023, respectively.

Share-Based Compensation

The Company recognizes all employee share-based compensation as a cost within research and development expenses and selling, general, and administrative expenses. Equity-classified awards principally related to stock options, restricted stock units (“RSUs”) and performance stock units ("PSUs"), are measured at the grant date fair value of the award. The Company determines grant date fair value of stock option awards using the Black-Scholes option-pricing model. The fair value of RSUs and PSUs are determined using the closing price of the Company’s common stock on the grant date. For service based vesting grants, expense is recognized over the requisite service period. For PSUs, expense is recognized over the implicit service period, once vesting is probable. No expense is recognized for PSUs if it is not probable the vesting criteria will be satisfied. Forfeitures are accounted for as they occur.

	Expiration Term	Vesting Term
Stock Options	10 years	3 to 4 years
Restricted Stock Units	----	1 to 4 years

Earnings (Loss) Per Share

The Company calculates basic earnings per share by dividing net income/(loss) by the weighted average number of shares outstanding during the period. Pre-funded warrants issued and sold by the Company to purchase shares of its common stock are included in the calculation of basic net loss per common share if the exercise price of the pre-funded warrant represents little consideration and is non-substantive in relation to the price paid for the warrant, and if the warrants are immediately exercisable with no further vesting conditions or contingencies associated with them.

The Company's diluted earnings/(loss) per share computation includes the effect, if any, of shares that would be issuable upon the exercise of outstanding stock options, convertible debt and RSUs using the treasury stock method. The treasury stock method reduces the number of shares issuable by the shares assumed to be purchased by the Company from the resulting proceeds at the average market price during the year, when such amounts are dilutive to the earnings/(loss) per share calculation. As the Company has reported net losses for all periods presented, all potentially dilutive securities are antidilutive and, accordingly, basic net loss per share equals diluted net loss per share. In accordance with ASC 260, *Earnings per Share*, if a company had a discontinued operation, the company uses income from continuing operations, adjusted for preferred dividend and similar adjustments, as its control number to determine whether potential common shares are dilutive.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. Due to the short-term maturity of such investments, the carrying amounts are a reasonable estimate of fair value.

Concentration of Credit Risk

The Company maintains its cash and cash equivalents at insured financial institutions, the balances of which may, at times, exceed federally insured limits. Generally, these deposits may be redeemed upon demand, and the Company believes there is minimal risk of losses on such balances.

The Company monitors its investments with counterparties with the objective of minimizing concentrations of credit risk. The Company's investment policy is to invest only in institutions that meet high credit quality standards and established limits on the amount and time to maturity of investments with any individual counterparty. The policy also requires that investments are only entered into with corporate and financial institutions that meet high quality standards.

Marketable Debt Securities

The Company classified marketable debt securities held as “available-for-sale” and carries them at fair value. The Company classifies these investments as current assets, even if the maturity when acquired by the Company is greater than one year due to the ability to liquidate within the next 12 months. The amortized cost of marketable debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion, as well as interest and dividends, is included in interest income. Unrealized gains and losses on marketable debt securities are recorded as a separate component of stockholders’ equity as accumulated other comprehensive loss, unless an impairment is determined to be the result of credit-related factors or the Company intends to sell the security or it is more likely than not that the Company will be required to sell the security before recovery. Unrealized losses that are determined to be credit-related are recorded as an allowance against the amortized cost basis. Realized gains or losses on debt security transactions and declines in value that are determined to be the result of credit losses, if any, are reported in other income or expense in the Consolidated Statements of Operations and Comprehensive Loss. The cost of securities sold is based on the specific identification method. Marketable debt securities are maintained at one financial institution and are governed by the Company’s investment policy. See Note 6 for further discussion.

Accounts Receivables, Net

Trade accounts receivable are recorded net of reserves for prompt pay discounts and expected credit losses. Estimates for allowances for credit losses are determined based on existing contractual obligations, historical payment patterns and individual customer circumstances. The allowance for credit losses was zero at both December 31, 2025 and 2024, respectively. For the years ended December 31, 2025, 2024 and 2023, provision for credit losses was immaterial. The Company's evaluation of credit losses for the current period included an assessment of our aged trade receivables balances and their underlying credit risk characteristics. Our evaluation of past events, current conditions, and reasonable and supportable forecasts about the future resulted in an expectation of immaterial credit losses. As of December 31, 2025 the Company's accounts receivable balance includes a $25.0 million milestone payment from Mirum. See Note 19 for further discussion.

Supplier Concentration Risk

The Company has no manufacturing capabilities and relies on third party manufacturers who are sole source suppliers for manufacturing of its products. The Company intends to rely on third-party manufacturers for the long-term commercial supply of Thiola and FILSPARI and for its development stage product candidates, including sparsentan for the treatment of FSGS and pegtibatinase. The Company expects the manufacturers of each product or product candidate to, at least initially and potentially for a significant period of time, be single source suppliers to the Company.

Property and Equipment, net

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed using the straight-line method over the related estimated useful lives as presented in the table below. Significant additions and improvements are capitalized, while repairs and maintenance are charged to expense as incurred. Property and equipment purchased for specific research and development projects with no alternative use is expensed as incurred.

The major classifications of property and equipment, including their respective expected useful lives, consist of the following:

Computers and equipment	3 years
Furniture and fixtures	7 years
Leasehold improvements	Shorter of length of lease or life of the asset

Leases

The Company determines whether a contract is, or contains, a lease at inception. The Company classifies each of its leases as operating or financing considering factors such as the length of the lease term, the present value of the lease payments, the nature of the asset being leased, and the potential for ownership of the asset to transfer during the lease term. Leases with terms greater than one year are recognized on the Consolidated Balance Sheets as Right-of-use assets and Lease liabilities and are measured at the present value of the fixed payments due over the expected lease term minus the present value of any incentives, rebates or abatement expected to be received from the lessor. Options to extend a lease are typically excluded from the expected lease term as the exercise of the option is typically not reasonably certain. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the appropriate incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis an amount equal to the lease payments over a similar term and in a similar economic environment.

In addition to rent, the leases may require the Company to pay additional amounts for taxes, insurance, maintenance, and other expenses, which are generally referred to as non-lease components. The Company has elected to not separate lease and non-lease components. Only the fixed costs for lease components and their associated non-lease components are accounted for as a single lease component and recognized as part of the Right-of-use assets and Lease liabilities. The Company records expense to recognize fixed lease payments, including payment escalation, on a straight-line basis over the expected lease term. Costs determined to be variable and not based on an index or rate are not included in the measurement of the lease liability and are expensed as incurred.

The Company has made an accounting policy election to not recognize short-term leases, or leases that have a lease term of 12 months or less at commencement date, within its Consolidated Balance Sheets and to recognize those lease payments in the Consolidated Statements of Operations and Comprehensive Loss on a straight-line basis over the lease term.

The Company recognizes income from sublet office space on a straight-line basis over the term of the sublease, recorded in other income in the Consolidated Statements of Operations and Comprehensive Loss.

Intangible Assets, Net

The Company's intangible assets consist of licenses and purchased technology. Intangible assets with definite lives are amortized on a straight-line basis over their estimated useful lives and are reviewed periodically for impairment.

Intangible Assets with Cost Accumulation Model

In 2014, the Company entered into a license agreement with Mission Pharmacal ("Mission") in which the Company obtained the exclusive right to license the trademark of Thiola ("Mission License Agreement"). The acquisition of the Thiola license qualified as an asset acquisition under the principles of ASC 805, Business Combinations ("ASC 805") in effect at the time of acquisition. The license agreement requires the Company to make royalty payments based on net sales of Thiola. The liability for royalties in excess of the annual contractual minimum is recognized in the period in which the royalties become probable and estimable, which is typically in the period corresponding with the respective sales. The Company records an offsetting increase to the cost basis of the intangible asset under the cost accumulation model ("Thiola Intangible"). The additional cost basis is subsequently amortized over the remaining estimated useful life of the license agreement.

In the second quarter of 2023, the Company reduced the estimated useful life of the Thiola Intangible to better reflect the pattern of projected future cash flows, resulting in incremental expense of $3.7 million recorded in selling, general, and administrative. The change in estimated useful life was accounted for as a change in accounting estimate and the remaining carrying amounts of the Thiola Intangible are being amortized prospectively over the new useful life.

Consistent with all prior periods since Thiola was acquired, the Company has not accrued any liability for future royalties in excess of the annual contractual minimum at December 31, 2025 as such royalties are not yet probable and estimable.

In 2012, the Company entered into an agreement with Ligand Pharmaceuticals, Inc. (“Ligand”) for a worldwide sublicense to develop, manufacture and commercialize sparsentan (the “Ligand License Agreement”). The acquisition of the Ligand License Agreement qualified as an asset acquisition under the principles of ASC 805 in effect at the time of acquisition. The license agreement requires the Company to make royalty payments based on net sales of FILSPARI (sparsentan) and milestone payments. The liabilities for royalties and milestone payments are recognized in the period in which they become probable and estimable, which is typically in the period corresponding with the respective sales or achievement of the milestone. The Company records an offsetting increase to the cost basis of the intangible asset under the cost accumulation model following the approval of FILSPARI. The additional cost basis is subsequently amortized over the remaining estimated useful life.

Variable Interest Entity

The Company reviews each investment and collaboration agreement to determine if it has a variable interest in the entity. In assessing whether the Company has a variable interest in the entity as a whole, the Company considers and makes judgments regarding the purpose and design of the entity, the value of the licensed assets to the entity, the value of the entity’s total assets and the significant activities of the entity. If the Company has a variable interest in the entity as a whole, the Company assesses whether or not the Company is a primary beneficiary of that VIE, based on a number of factors, including: (i) which party has the power to direct the activities that most significantly affect the VIE’s economic performance, (ii) the parties’ contractual rights and responsibilities pursuant to the collaboration agreement, and (iii) which party has the obligation to absorb losses of or the right to receive benefits from the VIE that could be significant to the VIE. If the Company determines that it is the primary beneficiary of a VIE at the onset of the collaboration, the collaboration is treated as a business combination and the Company consolidates the financial statements of the VIE into the Company’s consolidated financial statements. On a quarterly basis, the Company evaluates whether it continues to be the primary beneficiary of the consolidated VIE. If the Company determines that it is no longer the primary beneficiary of a consolidated VIE, it deconsolidates the VIE in the period in which the determination is made.

Assets and liabilities recorded as a result of consolidating the financial results of the VIE into the Company’s Consolidated Balance Sheets do not represent additional assets that could be used to satisfy claims against the Company’s general assets or liabilities for which creditors have recourse to the Company’s general assets.

Equity Securities

The Company applies the equity method of accounting for investments when it has significant influence, but no controlling interest in the investee. Judgment regarding the level of influence over each equity method investment includes key factors such as ownership interest, representation on the board of directors, participation in joint steering committees and material intercompany transactions. Upon investment, the Company evaluates any basis difference between the carrying value and fair value of the Company's proportionate share of the investee's net assets. Basis differences relating to in-process research and development (IPR&D) are expensed when the investee is not considered a business as defined in ASC 805, *Business Combinations,* due to substantially all of the estimated fair value of the gross assets being concentrated in a group of similar IPR&D assets with no alternative future use. For the year ended December 31, 2025, the Company did not record any basis adjustments. For the year ended December 31, 2024, the Company recognized $3.4 million in other income (expense), net for these basis adjustments and reduced the equity method investment's carrying value to zero, as the Company's proportionate share of the basis difference exceeded the carrying value. See Note 5 for further discussion. Investments accounted for using the equity method are be reported on a lag of up to three months if the financial statements of the investee are not available in sufficient time for the Company to apply the equity method as of the current reporting date.

Goodwill

Goodwill represents the excess of purchase price over fair value of net assets acquired in a business combination and is not amortized. Goodwill is subject to impairment testing at least annually or when a triggering event occurs that could indicate a potential impairment. The Company has one segment and one reporting unit and as such reviews goodwill for impairment at the consolidated level.

Impairment of Long-Lived Assets

The Company's long-lived assets are primarily comprised of intangible assets, right-of-use assets, and property and equipment. The Company evaluates its finite-lived intangible assets, right-of-use assets, and property and equipment for impairment whenever events or changes in circumstances indicate the carrying value of an asset or group of assets may not be recoverable. If these circumstances exist, recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset group to future undiscounted net cash flows expected to

be generated by the use and eventual disposition of the asset group. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets.

In addition, indefinite-lived intangible assets are reviewed for impairment annually and whenever events or changes in circumstances indicate that it is more likely than not that the asset is impaired by comparing the fair value to the carrying value of the asset. To determine the fair value of the asset, the Company used the multi-period excess earnings method of the income approach. The more significant assumptions inherent in the application of this method include: the amount and timing of projected future cash flows (including revenue, cost of sales, research and development costs, and sales and marketing expenses), and the discount rate selected to measure the risks inherent in the future cash flows. See Note 8 for further discussion of certain long-lived assets measured at fair value on a nonrecurring basis when there are indicators of impairment.

Income Taxes

The Company follows ASC 740, *Income Taxes* ("ASC 740"), which requires recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are based on the differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to the extent management concludes it is more likely than not that the asset will not be realized.

The standard addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the tax authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position should be measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate settlement. ASC 740 also provides guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. The Company's policy is to record estimated interest and penalty related to the underpayment of income taxes or unrecognized tax benefits as a component of its income tax provision.

Foreign Currency Translation

Functional and presentation currency

Items included in the financial statements of each entity comprising the Company are measured using the currency of the primary economic environment in which the entity operates (the functional currency).

Transactions and balances

Foreign currency transactions in each entity comprising the Company are remeasured into the functional currency of the entity using the exchange rates prevailing at the respective transaction dates. Foreign exchange gains and losses resulting from the settlement of such transactions and from the remeasurement at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized within Other income (expense), net in the Consolidated Statements of Operations and Comprehensive Loss.

An aggregate loss of $0.3 million, $0.7 million and a gain of $0.5 million arising from foreign exchange transactions is included in other income (expense), net for the years ended December 31, 2025, 2024 and 2023, respectively.

The results and financial position of the Company that have a functional currency different from the U.S. dollar are translated as follows:

a. assets and liabilities presented are translated at the closing exchange rate as of December 31, 2025 and 2024;

b. income and expenses for the statements of operations and comprehensive loss are translated at average exchange rates that are relevant for the respective periods for which the income and expenses occurred; and

c. significant transactions use the exchange rate on the date of the transaction.

All resulting exchange differences arising from such translations are recognized directly in comprehensive income and presented as a separate component of equity.

The following table summarizes the foreign currency translation adjustment included in accumulated other comprehensive loss for the year ended December 31, 2025, 2024 and 2023 (*in thousands*):

	Foreign Currency Translation Adjustments included in Accumulated Other Comprehensive Loss		
	2025	2024	2023
Balance at January 1,	$ (34)	$ (1,456)	$ 415
Foreign currency translation adjustments	(945)	1,422	(1,871)
Balance at December 31,	$ (979)	$ (34)	$ (1,456)

Reclassifications

Certain reclassifications have been made to the prior year financial statements in order to conform to the current year's presentation. These reclassifications did not have an impact on total assets or total liabilities and stockholders' equity in the Consolidated Balance Sheets or net loss in the Consolidated Statements of Operations and Comprehensive Loss.

Patents

The Company expenses external costs, such as filing fees and associated attorney fees, incurred to obtain issued patents and patent applications pending. The Company also expenses costs associated with maintaining and defending patents subsequent to their issuance in the period incurred.

Legal Contingencies

The Company may, from time to time, be involved in various claims and legal actions that arise in the ordinary course of business. The Company accrues for legal contingencies when it is determined probable that a liability has been incurred and the amount of the loss can be reasonably estimated. See Note 11 for further discussion.

Discontinued Operations

Discontinued operations is presented when there is a disposal of a component or a group of components that in the Company's judgment represents a strategic shift that will have a major effect on the Company's operations and financial results. Results of operations directly related to discontinued operations are aggregated into a single line item in the Consolidated Statements of Operations and Comprehensive Loss for all periods presented. See Note 19 for further discussion.

Restructuring

Restructuring charges consist primarily of employee severance, one-time termination benefits related to the reduction of its workforce, and other costs. Liabilities for costs associated with a restructuring activity are recognized when the liability is incurred and are measured at fair value. One-time termination benefits are expensed at the date the entity notifies the employee, unless the employee must provide future service, in which case the benefits are expensed ratably over the service period. Termination benefits are calculated based on regional benefit practices and local statutory requirements.

In December 2023, the Company initiated a restructuring plan that resulted in a reduction of its workforce, primarily impacting non-field-based employees. Restructuring costs were primarily comprised of one-time termination benefits, including severance, continuation of health insurance coverage, and other benefits for a specified period of time. The Company recognized $2.4 million during the year ended December 31, 2024, including $1.2 million related to the impairment of operating lease right-of-use assets and related leasehold improvements, as well as disposal costs associated with the sublease of office space. As of December 31, 2024, the Company had recognized total costs of $13.8 million in connection with the restructuring and no such expenses were incurred for the year ended December 31, 2025.

The following table summarizes the cash payments and accruals, included in accrued expenses of the Consolidated Balance Sheets, related to the restructuring for the year ended December 31, 2024 (*in thousands*):

	2024
Liability balance at January 1,	$ 11,421
Restructuring expenses	2,438
Non-cash impairment and disposal charges	(856)
Payments	(12,929)
Foreign currency impact	(74)
Liability balance at December 31,	$ —

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued Accounting Standards Update ("ASU") No. 2023-09, Improvements to Income Tax Disclosures. This ASU does not change accounting for income taxes but requires new disclosures focusing on two areas, the effective rate reconciliation and taxes paid. The Company adopted the standard and applied the disclosure requirements on a prospective basis as required for the year ended December 31, 2025.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its consolidated financial position or results of operations upon adoption.

In September 2025, the FASB issued ASU No. 2025-06—Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software. This ASU removed the language around project stages that was used to assess when costs could be capitalized for an internal-use software. The update also requires internal-use software to be disclosed under the ASC 360 Property, Plant, and Equipment guidance. The guidance is effective for annual periods beginning after December 15, 2027. The Company is currently assessing the impact of this standard on the Company's accounting policies and the financial statements.

In July 2025, the FASB issued ASU No. 2025-05—Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets. This ASU added a practical expedient that assumes that current conditions as of the balance sheet date do not change for the remaining life of the asset when estimating expected credit losses for current accounts receivable and current contract assets. The guidance is effective for annual periods beginning after December 15, 2025. The Company is currently evaluating the impact of the adoption of this standard on the accounting for credit losses.

In November 2024, the FASB issued ASU No. 2024-04, Debt with Conversion and Other Options (Subtopic 470-20): Induced Conversions of Convertible Debts Instruments. This ASU clarifies the requirements for determining whether to account for certain early settlements of convertible debt instruments as induced conversions or extinguishments. The guidance is effective for fiscal years beginning after December 15, 2025, with early adoption permitted for entities that have adopted ASU 2020-06. The Company is currently evaluating the impact of the adoption of this standard on the accounting for the Company's convertible notes.

In November 2024, the FASB issued ASU No. 2024-03, Income Statement - Reporting Comprehensive Income - Expense Recognition Disclosures. This ASU will require entities to provide enhanced disclosures related to certain expense categories included in income statement captions. The ASU aims to increase transparency and provide investors with more detailed information about the nature of expenses reported on the face of the income statement. The new standard does not change the requirements for the presentation of expenses on the face of the income statement. Under this ASU, entities are required to disaggregate, in a tabular format, expense captions presented on the face of the income statement — excluding earnings or losses from equity method investments — if they include any of the following expense categories: purchases of inventory, employee compensation, depreciation, intangible asset amortization, and depreciation or depletion. For any remaining items within each relevant expense caption, entities must provide a qualitative description of the nature of those expenses. The new ASU is effective, as clarified by ASU No. 2025-01, for annual reporting periods beginning after December 15, 2026 and interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of this standard on the related disclosures.

NOTE 3. REVENUE RECOGNITION

Product Sales, Net

Product sales consist of FILSPARI and tiopronin products (Thiola and Thiola EC). The Company sells its products to specialty pharmacies and through direct-to-patient distributors worldwide, with the United States representing over 98% of the Company's net product sales.

The Company sells FILSPARI to two direct-to-patient specialty pharmacies in the United States. The Company sells its tiopronin products to patients and pharmacies, with distribution facilitated through a single direct-to-patient distributor. Revenues from product sales are recognized in satisfaction of a single performance obligation when the customer obtains control of the Company's product. For FILSPARI, sales are recognized upon delivery of the product to the specialty pharmacies. The Company receives payments from its FILSPARI sales based on terms that are generally 30 days from shipment of the product to the specialty pharmacy. For the Company's tiopronin products, product sales are recognized upon delivery to the patient. The Company receives payments from sales of its tiopronin products, primarily through third party payers, based on terms that generally are within 30 days of delivery of product to the patient. Contracts do not contain significant financing components based on the typical period of time between performance of services and collection of consideration.

Deductions from Revenue

Revenues from product sales are recorded at the net sales price, which includes provisions resulting from discounts, rebates and co-pay assistance that are offered to customers, payers and other indirect customers relating to the Company's sales of its products. These provisions are based on the estimates of the amounts earned or to be claimed on the related sales. These amounts are treated as variable consideration, estimated and recognized as a reduction of the transaction price at the time of the sale, using the most likely amount method, and are classified as a reduction of accounts receivable (if the amount is payable to a customer) or as a current liability (if the amount is payable to a party other than a customer). The Company includes these estimated amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized for such transactions will not occur. Where appropriate, these reserves take into consideration the Company's historical experience, current contractual and statutory requirements and specific known market events and trends. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract. If actual results in the future vary from the Company's provisions, the Company will adjust the estimate, which would affect net product revenue and earnings in the period such variances become known. For the years ended December 31, 2025, 2024 and 2023, adjustments to net product revenue related to performance obligations satisfied in previous periods were $1.1 million, $0.5 million, and $0.4 million, respectively.

Government Rebates: The Company calculates the rebates that it will be obligated to provide to government programs and deducts these estimated amounts from its gross product sales at the time the revenues are recognized. Allowances for government rebates and discounts are established based on an estimated allocation of payers and the government-mandated discounts applicable to government-funded programs. Rebate discounts are included in accrued expenses in the accompanying Consolidated Balance Sheets.

Commercial Rebates: The Company calculates the rebates it incurs according to any contracts with certain commercial payers and deducts these amounts from its gross product sales at the time the revenues are recognized. Allowances for commercial rebates are established based on actual payer information, which is reasonably estimated at the time of delivery for applicable products. Rebate discounts are included in accrued expenses in the accompanying Consolidated Balance Sheets.

Prompt Pay Discounts: The Company offers discounts to certain customers for prompt payments. The Company accrues for the calculated prompt pay discount based on the gross amount of each invoice for those customers at the time of sale.

Other Fees: The Company pays service fees to certain customers based on a contractually fixed percentage of the wholesale acquisition cost and fees for data. Other fees are recorded as an offset to revenue based on contractual terms at the time revenue from the sale is recognized.

Product Returns: Consistent with industry practice, the Company offers its customers a limited right to return product purchased directly from the Company, which is principally based upon the product's expiration date. Historically, returns have been immaterial.

Co-pay Assistance: The Company offers a co-pay assistance program, which is intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the estimated cost per claim associated with product that has been recognized as revenue.

The following table summarizes net product sales for the year ended December 31, 2025, 2024 and 2023 (*in thousands*):

	Year Ended December 31,		
	2025	2024	2023
FILSPARI	$ 322,005	$ 132,222	$ 29,208
Tiopronin products	88,455	94,485	98,329
Total net product sales	$ 410,460	$ 226,707	$ 127,537

NOTE 4. COLLABORATION AND LICENSE AGREEMENTS

License Agreement with CSL Vifor

In September 2021, the Company entered into the CSL Vifor License Agreement, pursuant to which the Company granted an exclusive license to CSL Vifor for the commercialization of FILSPARI in Europe, Australia and New Zealand. In June 2025, the CSL Vifor License Agreement was amended in order to expand the license to cover additional countries ("CSL Vifor Licensed Territories") and to provide that the license rights to each additional country will revert to the Company if CSL Vifor does not take certain specified actions within specified timelines with respect to such country. CSL Vifor also has first right of negotiation to expand the licensed territories into Canada and/or Mexico.

Under the terms of the CSL Vifor License Agreement, the Company received an upfront payment of $55.0 million and will be eligible for up to $135.0 million in aggregate regulatory and market access related milestone payments and up to $655.0 million in aggregate sales-based milestone payments for a total potential value of up to $845.0 million. The Company is also entitled to receive tiered double-digit royalties of up to 40 percent of annual net sales of FILSPARI in the CSL Vifor Licensed Territories.

Under the License Agreement, CSL Vifor is responsible for all commercialization activities in the CSL Vifor Licensed Territories. The Company remains responsible for the worldwide clinical development of sparsentan through regulatory approval as defined. Development costs for any post regulatory approval development activities, subject to approval by both parties, will be borne by the Company and CSL Vifor as defined, respectively. The CSL Vifor License Agreement will remain in effect, unless terminated earlier, until the expiration of all royalty terms for FILSPARI in the CSL Vifor Licensed Territories. Each party has the right to terminate the CSL Vifor License Agreement for the other party's uncured material breach, insolvency or if the time required for performance under the CSL Vifor License Agreement by the other party is extended due to a force majeure event that continues for six months or more.

The Company assessed the CSL Vifor License Agreement and determined that it meets both criteria to be considered a collaborative agreement within the Scope of ASC 808, *Collaborative Arrangements* of active participation by both parties and exposures to significant risks and rewards dependent on the commercial success of the activities. Both parties participate on joint steering and other committees overseeing the collaboration activities. Also, both parties are exposed to significant risks and rewards based on the economic outcomes of regulatory approvals and commercialization of sparsentan.

The Company determined the initial transaction price under the CSL Vifor License Agreement totaled $55.0 million, consisting of the fixed non-refundable upfront payment. The variable regulatory and access related milestones were considered variable consideration and excluded from the transaction price given the substantial uncertainty at inception related to their achievement, based on the most likely amount method. Sales-based milestone payments and royalties on net sales were excluded from the transaction price and are recognized at the later of when the related sales occur or when the performance obligation to which the sales-based milestone or royalty has been allocated have been satisfied. The Company re-evaluates the transaction price for each reporting period and as uncertainties are resolved.

The Company concluded that CSL Vifor represented a customer and applied relevant guidance from ASC 606 to evaluate the accounting under the CSL Vifor License Agreement. In accordance with this guidance, the Company concluded at inception that the promise to grant the license is distinct from the promise to provide clinical development services resulting in two performance obligations. As a result, the Company allocated $12.0 million of the transaction price, based on the performance obligations' relative standalone selling prices, to the license, which was recognized in full in 2021. The remaining $43.0 million of the transaction price was allocated to the clinical development activities and recorded as deferred revenue, which was recognized over the development period based upon the ratio of costs incurred to date to the total estimated costs through June 30, 2025.

For the year ended December 31, 2025, the Company achieved a market access milestone in the UK and European Union of $40.0 million and a regulatory milestone as a result of the European Commission granting standard MA approval of $17.5 million that were added to the transaction price under the most likely amount method and recognized in full.

For the years ended December 31, 2025, 2024 and 2023, royalties on net sales, recorded when the related sales occur, were $5.9 million, $0.6 million and zero, respectively.

For the years ended December 31, 2025, 2024 and 2023, the Company recognized $71.0 million, $6.5 million and $17.7 million, respectively, in license and collaboration revenue associated with the CSL Vifor License Agreement.

Deferred revenue related to the clinical development activities as of December 31, 2025 and 2024 was zero and $2.8 million, respectively, classified as current in the Consolidated Balance Sheets.

The following table sets forth a summary of changes in deferred revenue for the years ended December 31, 2025, 2024 and 2023 *(in thousands)*:

	Deferred Revenue		
	2025	2024	2023
Balance at January 1,	$ 2,815	$ 8,931	$ 22,907
License and collaboration revenue	(2,872)	(5,847)	(14,363)
Foreign currency impact	57	(269)	387
Balance at December 31,	$ —	$ 2,815	$ 8,931

Licensing Agreement with Chugai

In January 2024, the Chugai License Agreement came into effect, pursuant to which, the Company granted an exclusive license to Renalys (which has since been merged with and into Chugai) for the development and commercialization of sparsentan in Japan and other specified Asian countries ("Chugai Licensed Territories"). In October 2025, the Chugai License Agreement was amended to remove certain specified countries from the Chugai Licensed Territories. Under the terms of the Chugai License Agreement, the Company received a non-refundable upfront payment and will be eligible to receive up to $120.0 million in aggregate regulatory, development and sales-based milestones. The Company is also entitled to receive tiered double-digit to mid-20 percent royalties of annual net sales of sparsentan in the Chugai Licensed Territories. In addition, the Company received an option to purchase shares of common stock of Renalys (“Option Agreement”), which it exercised in January 2024. The Company also had the option to purchase all equity securities of Renalys at any time prior to the top-line results of the Phase 3 trial in Japan (“Buyout Right”).

Under the Chugai License Agreement, Chugai is responsible for all development and commercialization activities in the Chugai Licensed Territories. The Company will retain all rights to sparsentan in the United States and rest of world outside of the CSL Vifor Licensed Territories and Chugai Licensed Territories, provided that CSL Vifor has a right of negotiation to expand the licensed territories into Canada and/or Mexico. The Chugai License Agreement will remain in effect, unless terminated earlier, until the expiration of all royalty terms for sparsentan in the Chugai Licensed Territories. Each party has the right to terminate the Chugai License Agreement for the other party’s uncured material breach or insolvency, or if the time required for performance under the Chugai License Agreement by the other party is extended due to a force majeure event that continues for nine months or more. Chugai may terminate the Chugai License Agreement for any reason upon prior written notice to the Company. The Company may terminate the Chugai License Agreement if Chugai abandons development in Japan or South Korea prior to first commercial sales of sparsentan in either Japan or South Korea.

The Company assessed the Chugai License Agreement and determined that it meets both criteria to be considered a collaborative agreement within the Scope of ASC 808, Collaborative Arrangements of active participation by both parties and exposures to significant risks and rewards dependent on the commercial success of the activities. Both parties participate on a joint steering committee overseeing the development and commercial activities. Also, both parties are exposed to significant risks and rewards based on the economic outcomes of regulatory approvals and commercialization of sparsentan.

The Company determined the transaction price under the Chugai License Agreement totaled $8.3 million, consisting of the fixed non-refundable upfront payment, milestone payment and estimated fair value of the Option Agreement. The variable development-related milestones were excluded from the transaction price given the substantial uncertainty related to their achievement under the most likely amount method. Sales-based milestone payments and royalties on net sales were excluded from the initial transaction price and will be recognized at the later of when the related sales occur or when the performance obligation to which the sales-based milestone or royalty has been allocated has been satisfied.

The Company concluded that Chugai represents a customer and applied relevant guidance from ASC 606 to evaluate the accounting under the Chugai License Agreement. In accordance with this guidance, the Company concluded that the promise to grant the license is distinct, resulting in one performance obligation as the license has stand-alone functionally at contract inception. The Buyout Right precluded transferring control of the

license to Renalys under ASC 606 and the Company's option to repurchase the common stock at a price greater than the original license premium results in accounting for the Chugai License Agreement as a financing arrangement. The transaction price was recorded in other current liabilities as a result of the Buyout Right as of December 31, 2024. During the year ended December 31, 2025, the Buyout Right was relinquished and the Company recognized the Renalys deferred revenue amount of $9.3 million in license and collaboration revenue.

See Note 5 for further discussion of VIEs.

NOTE 5. VARIABLE INTEREST ENTITIES

Stock Purchase and Collaboration Agreement with PharmaKrysto

In March 2022, the Company entered into a Collaboration Agreement with PharmaKrysto Limited ("PharmaKrysto"), a privately held pre-clinical stage company and concurrently entered into a Stock Purchase Agreement (together, the "Agreements") whereby the Company acquired 5% of the outstanding common shares of PharmaKrysto. The Agreements granted the Company an option to purchase the remaining outstanding shares of PharmaKrysto for $5.0 million upon the occurrence of a subsequent pre-clinical milestone, which expired on March 8, 2025. As the option was not exercised by the Company prior to expiration, the rights granted to the Company under the Agreements ceased, and the previously purchased common shares were transferred back to PharmaKrysto for immaterial consideration. The Company deconsolidated PharmaKrysto as of March 8, 2025, resulting in an immaterial amount recognized in the Consolidated Statements of Operations and Comprehensive Loss for the year ended December 31, 2025. The consolidated assets and liabilities as of December 31, 2024 were immaterial. The results of operations were not significant for the years ended December 31, 2025, 2024 and 2023.

Licensing Agreement with Chugai

In January 2024, the Chugai License Agreement between the Company and Renalys (which has since been acquired by and merged into Chugai) came into effect and the Company exercised its option to purchase shares of common stock of Renalys. The Company determined that Renalys was a VIE as they could require additional funding to support development and commercial activities. The Company had variable interests in Renalys, including an equity interest, Buyout Right and performance-related payments under the Chugai License Agreement that absorb variability from the performance of Renalys.

In order to determine the primary beneficiary of Renalys, the Company evaluated its variable interest to identify if the Company had the power to direct the activities that most significantly impact the economic performance. Based upon the capital structure, governing documents and overall business operations, the Company determined that it was not the primary beneficiary as it did not have the power to direct the activities that most significantly impact the economic performance of Renalys and did not have an obligation to absorb losses.

The carrying amount of the liabilities related to the Company's variable interests was zero and $8.9 million as of December 31, 2025 and 2024, respectively, included in other current liabilities in the Company's Consolidated Balance Sheets. During the year ended December 31, 2025, the Buyout Right was relinquished and the Company recognized the deferred revenue balance of $9.3 million in license and collaboration revenue. In the fourth quarter of 2025, Renalys was acquired by and merged into Chugai. The Company sold its equity interest in Renalys to Chugai as part of the acquisition and recognized a gain of $10.2 million in other income (expense), net.

NOTE 6. MARKETABLE DEBT SECURITIES

The Company's marketable debt securities as of December 31, 2025 and 2024 were composed of available-for-sale commercial paper, corporate debt securities, securities of government-sponsored entities and municipal bonds. The primary objective of the Company's investment portfolio is to preserve capital and liquidity while enhancing overall returns. The Company's investment policy limits interest-bearing security investments to certain types of instruments issued by institutions with primarily investment grade credit ratings and places restrictions on maturities and concentration by asset class and issuer.

Marketable debt securities consisted of the following (*in thousands*):

	As of December 31,	
	2025	2024
Marketable debt securities:		
Commercial paper	$ 62,988	$ 73,325
Corporate debt securities	151,777	203,816
Securities of government-sponsored entities	9,993	35,025
Municipal bonds	5,003	—
Total available-for-sale marketable debt securities	$ 229,761	$ 312,166

In addition to funding operations, the decrease in the marketable debt securities balance as of December 31, 2025 is due to the repayment of convertible notes in September 2025. See Note 7 for further discussion.

The following is a summary of short-term marketable debt securities classified as available-for-sale as of December 31, 2025 (*in thousands*):

	Remaining Contractual Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Estimated Fair Value
Marketable debt securities:					
Commercial paper	Less than 1	$ 62,974	$ 20	$ (6)	$ 62,988
Corporate debt securities	Less than 1	77,414	12	(33)	77,393
Municipal bonds	Less than 1	5,000	3	—	5,003
Total maturity less than 1 year		145,388	35	(39)	145,384
Corporate debt securities	1 to 2	74,389	69	(74)	74,384
Securities of government-sponsored entities	1 to 2	10,000	—	(7)	9,993
Total maturity 1 to 2 years		84,389	69	(81)	84,377
Total available-for-sale marketable debt securities		$ 229,777	$ 104	$ (120)	$ 229,761

The following is a summary of short-term marketable debt securities classified as available-for-sale as of December 31, 2024 (*in thousands*):

	Remaining Contractual Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Estimated Fair Value
Marketable debt securities:					
Commercial paper	Less than 1	$ 73,410	$ 1	$ (86)	$ 73,325
Corporate debt securities	Less than 1	203,395	483	(62)	203,816
Securities of government-sponsored entities	Less than 1	34,993	33	(1)	35,025
Total available-for-sale marketable debt securities		$ 311,798	$ 517	$ (149)	$ 312,166

During 2025 and 2024, realized gains and losses on marketable debt securities were immaterial. As of December 31, 2025 and December 31, 2024, the accrued interest receivable related to the Company's marketable debt securities was $1.3 million and $2.3 million, respectively, and was recorded in prepaid expenses and other current assets on the Consolidated Balance Sheets.

The Company reviews the available-for-sale marketable debt securities for declines in fair value below the cost basis each quarter. For any security whose fair value is below its amortized cost basis, the Company first evaluates whether it intends to sell the impaired security, or will otherwise be more likely than not required to sell the security before recovery. If either are true, the amortized cost basis of the security is written down to its fair value at the reporting date. If neither circumstance holds true, the Company assesses whether any portion of the unrealized loss is a result of a credit loss. Any amount deemed to be attributable to credit loss is recognized in the income statement, with the amount of the loss limited to the difference between fair value and amortized cost and recorded as an allowance for credit losses. The portion of the unrealized loss related to factors other than credit losses is recognized in other comprehensive loss.

The following is a summary of available-for-sale marketable debt securities in an unrealized loss position with no credit losses aggregated by investment category and length of time those individual securities have been in a continuous unrealized loss position reported as of December 31, 2025 (*in thousands*):

Description of Securities	Less Than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Commercial paper	$ 12,317	$ 6	$ —	$ —	$ 12,317	$ 6
Corporate debt securities	118,443	107	—	—	118,443	107
Securities of government-sponsored entities	9,993	7	—	—	9,993	7
Total	$ 140,753	$ 120	$ —	$ —	$ 140,753	$ 120

The following is a summary of available-for-sale marketable debt securities in an unrealized loss position with no credit losses aggregated by investment category and length of time those individual securities have been in a continuous unrealized loss position reported as of December 31, 2024 (*in thousands*):

Description of Securities	Less Than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Commercial paper	$ 68,446	$ 86	$ —	$ —	$ 68,446	$ 86
Corporate debt securities	40,112	56	9,969	6	50,081	62
Securities of government-sponsored entities	—	—	4,975	1	4,975	1
Total	$ 108,558	$ 142	$ 14,944	$ 7	$ 123,502	$ 149

As of December 31, 2025 and December 31, 2024, the amortized cost of the available-for-sale marketable debt securities in an unrealized loss position was $140.9 million and $123.7 million, respectively.

As of December 31, 2025 and December 31, 2024, the Company does not intend to sell these investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost basis. The decrease in unrealized losses for the year ended December 31, 2025 was primarily due to fluctuations in short-term interest rates. The Company does not believe the unrealized losses incurred during the period are due to credit-related factors. The credit ratings of the securities held remain of the highest quality. Moreover, the Company continues to receive payments of interest and principal as they become due, and our expectation is that those payments will continue to be received timely. Factors unknown to us at this time may cause actual results to differ and require adjustments to the Company's estimates and assumptions in the future.

NOTE 7. CONVERTIBLE DEBT

The composition of the Company's convertible senior notes are as follows (*in thousands*):

	December 31, 2025	December 31, 2024
2.25% convertible senior notes due 2029	$ 316,250	$ 316,250
2.50% convertible senior notes due 2025	—	68,904
Unamortized debt issuance costs - 2.25% convertible senior notes due 2029	(4,526)	(5,940)
Unamortized debt issuance costs - 2.50% convertible senior notes due 2025	—	(226)
Total convertible senior notes, net of unamortized debt discount and debt issuance costs	$ 311,724	$ 378,988
Classified as:		
Convertible debt, current portion	$ —	$ 68,678
Convertible debt, less current portion	311,724	310,310
Total convertible debt	$ 311,724	$ 378,988

Convertible Senior Notes Due 2029

On March 11, 2022, the Company completed a registered underwritten public offering of $316.3 million aggregate principal amount of 2.25% Convertible Senior Notes due 2029 ("2029 Notes"), which includes $41.3 million aggregate principal amount of 2029 Notes sold pursuant to the full

exercise of the underwriters' option to purchase additional 2029 Notes. The Company issued the 2029 Notes under an indenture, dated as of September 10, 2018, as supplemented by the second supplemental indenture, dated as of March 11, 2022 (collectively, the "2029 Indenture"). The 2029 Notes will mature on March 1, 2029, unless earlier repurchased, redeemed, or converted. The 2029 Notes are senior unsecured obligations of the Company and bear interest at an annual rate of 2.25%, payable semi-annually in arrears on March 1 and September 1 of each year, beginning on September 1, 2022.

The Company received net proceeds from the issuance of the 2029 Notes of $306.4 million, after deducting commissions and offering expenses of $9.9 million. At December 31, 2025 and December 31, 2024 accrued interest on the 2029 Notes of $2.4 million is included in accrued expenses in the accompanying Consolidated Balance Sheets. The 2029 Notes comprise the Company's senior, unsecured obligations and are (i) equal in right of payment with the Company's existing and future senior, unsecured indebtedness; (ii) senior in right of payment to the Company's existing and future indebtedness that is expressly subordinated to the 2029 Notes; (iii) effectively subordinated to the Company's existing and future secured indebtedness, to the extent of the value of the collateral securing that indebtedness; and (iv) structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables.

Holders may convert their 2029 Notes at their option only in the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on June 30, 2022 (and only during such calendar quarter), if the last reported sale price per share of the Company's common stock for each of at least 20 trading days, whether or not consecutive, during the period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter exceeds 130% of the conversion price on the applicable trading day; (2) during the five consecutive business days immediately after any 10 consecutive trading day period (such 10 consecutive trading day period, the "measurement period") if the trading price per $1,000 principal amount of 2029 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price per share of the Company's common stock on such trading day and the conversion rate on such trading day; (3) upon the occurrence of certain corporate events or distributions of the Company's common stock; (4) if the Company calls the 2029 Notes for redemption; and (5) at any time from, and including, December 1, 2028 until the close of business on the scheduled trading day immediately before the maturity date. The Company will settle conversions by paying or delivering, as applicable, cash, shares of the Company's common stock, or a combination of cash and shares of the Company's common stock, at the Company's election, based on the applicable conversion rate. The initial conversion rate for the 2029 Notes is 31.3740 shares of the Company's common stock per $1,000 principal amount of 2029 Notes, which represents an initial conversion price of approximately $31.87 per share. If a "make-whole fundamental change" (as defined in the 2029 Indenture) occurs, then the Company will, in certain circumstances, increase the conversion rate for a specified period of time.

The 2029 Notes will be redeemable, in whole or in part at the Company's option at any time, and from time to time, on or after March 2, 2026 and, in the case of any partial redemption, on or before the 40th scheduled trading day before the maturity date, at a cash redemption price equal to the principal amount of the 2029 Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date but only if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price on (1) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends the related redemption notice; and (2) the trading day immediately before the date the Company sends such notice. However, the Company may not redeem less than all of the outstanding 2029 Notes unless at least $100.0 million aggregate principal amount of 2029 Notes are outstanding and not called for redemption as of the time the Company sends the related redemption notice. In addition, calling any 2029 Note for redemption will constitute a make-whole fundamental change with respect to that 2029 Note, in which case the conversion rate applicable to the conversion of that 2029 Note will be increased in certain circumstances if it is converted after it is called for redemption. If a fundamental change (as defined in the 2029 Indenture) occurs, then, except as described in the 2029 Indenture, holders may require the Company to repurchase their 2029 Notes at a cash repurchase price equal to the principal amount of the 2029 Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. In the event of conversion, holders would forgo all future interest payments, any unpaid accrued interest and the possibility of further stock price appreciation. Upon the receipt of conversion requests, the settlement of the 2029 Notes will be paid pursuant to the terms of the 2029 Indenture. In the event that all of the 2029 Notes are converted, the Company would be required to repay the principal amount and any conversion premium in any combination of cash and shares of its common stock at the Company's option. In addition, calling the 2029 Notes for redemption will constitute a "make-whole fundamental change."

The Company incurred approximately $9.9 million of debt issuance costs relating to the issuance of the 2029 Notes, which were recorded as a reduction to the 2029 Notes on the Consolidated Balance Sheets. The debt issuance costs are being amortized and recognized as additional interest expense over the expected life of the 2029 Notes using the effective interest method. The Company determined the expected life of the debt is equal to the seven-year term of the 2029 Notes. The effective interest rate on the 2029 Notes is 2.74%.

The 2029 Notes are accounted for in accordance with ASC 470-20, *Debt with conversion and Other Options* ("ASC 470-20") and ASC 815-40, *Contracts in Entity's Own Equity* ("ASC 815-40"). Under ASC 815-40, to qualify for equity classification (or nonbifurcation, if embedded) the instrument (or embedded feature) must be both (1) indexed to the issuer's stock and (2) meet the requirements of equity classification guidance. Based upon the Company's analysis, it was determined that the 2029 Notes do not contain embedded features requiring recognition as derivatives and bifurcation, and therefore are measured at amortized cost and recorded as liabilities on the Consolidated Balance Sheets.

The 2029 Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the issuance of other indebtedness or the issuance or repurchase of securities by the Company. There were no events of default for the 2029 Notes at December 31, 2025.

The 2029 Notes are classified as long-term convertible debt on the Company's Consolidated Balance Sheets at December 31, 2025 and December 31, 2024.

Convertible Senior Notes Due 2025

On September 10, 2018, the Company completed a registered underwritten public offering of $276.0 million aggregate principal amount of 2.50% Convertible Senior Notes due 2025 ("2025 Notes"), and entered into a base indenture and supplemental indenture agreement (collectively, the "2025 Indenture") with respect to the 2025 Notes.

The net proceeds from the issuance of the 2025 Notes were approximately $267.2 million, after deducting commissions and the offering expenses of $8.8 million payable by the Company. On March 11, 2022, the Company completed its repurchase of $207.1 million aggregate principal amount of 2025 Notes for cash, including accrued and unpaid interest, for a total of $213.8 million. After giving effect to the repurchase the total remaining principal amount outstanding under the 2025 Notes was $68.9 million. On September 15, 2025, the 2025 Notes matured and the Company repaid the remaining principal amount outstanding of $68.9 million plus accrued interest.

Interest Expense

The following table sets forth total interest expense recognized related to the 2025 and 2029 Notes (*in thousands*):

	Year Ended December 31,		
	2025	**2024**	**2023**
Contractual interest expense	$ 8,336	$ 8,838	$ 8,838
Amortization of debt issuance costs	1,640	1,725	1,718
Total interest expense for the 2025 and 2029 Notes	$ 9,976	$ 10,563	$ 10,556

Total interest expense recognized for the years ended December 31, 2025, 2024 and 2023 was $10.7 million, $11.2 million and $11.3 million, respectively.

NOTE 8. FAIR VALUE MEASUREMENTS

The Company utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

Level 1 – Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2 – Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly; and

Level 3 – Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The valuation techniques used to measure the fair value of the Company’s debt securities and all other financial instruments, all of which have counterparties with high credit ratings, were valued based on quoted market prices or model driven valuations using significant inputs derived from or corroborated by observable market data. Based on the fair value hierarchy, the Company classified marketable debt securities within Level 2.

Financial instruments with carrying values approximating fair value include cash and cash equivalents, accounts receivable, and accounts payable, due to their short-term nature. As of December 31, 2025 and 2024, the fair value of the Company's 2.25% Convertible Senior Notes due 2029, which were issued in 2022, was $448.3 million and $302.1 million, respectively. As of December 31, 2024, the fair value of the Company's 2.50% Convertible Senior Notes due 2025, now repaid, was $68.2 million. The fair values were estimated utilizing market quotations and are considered Level 2.

The following table presents the Company's assets, measured and recognized at fair value on a recurring basis, classified under the appropriate level of the fair value hierarchy as of December 31, 2025 *(in thousands):*

	As of December 31, 2025	Fair Value Hierarchy at December 31, 2025		
	Total carrying and estimated fair value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash and Cash Equivalents	$ 93,035	$ 93,035	$ —	$ —
Marketable debt securities, available-for-sale	229,761	—	229,761	—
Total	$ 322,796	$ 93,035	$ 229,761	$ —

The following table presents the Company's assets, measured and recognized at fair value on a recurring basis, classified under the appropriate level of the fair value hierarchy as of December 31, 2024 *(in thousands):*

	As of December 31, 2024	Fair Value Hierarchy at December 31, 2024		
	Total carrying and estimated fair value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash and Cash Equivalents	$ 58,535	$ 51,060	$ 7,475	$ —
Marketable debt securities, available-for-sale	312,166	—	312,166	—
Total	$ 370,701	$ 51,060	$ 319,641	$ —

Assets Measured at Fair Value on a Nonrecurring Basis

The Company's long-lived assets are measured at fair value on a nonrecurring basis when there are indicators of impairment and a loss is recognized. During the year ended December 31, 2025, there were no impairments to long-lived assets. During the year ended December 31, 2024, the Company recorded impairment charges of $1.2 million on right-of-use assets, property and equipment, and other capitalized assets as the fair value of the asset group was less than their carrying value. The fair value of the asset group was determined under the income approach based on projected future cash flows from the operating sublease discounted by a risk adjusted rate of 6.9%. The Company classified the fair value of the asset group as Level 3. See Note 18 for further discussion.

NOTE 9. INTANGIBLE ASSETS

Amortizable Intangible Assets

Ligand License Agreement

In 2012, the Company entered into the Ligand License Agreement with Ligand for a worldwide sublicense to develop, manufacture and commercialize sparsentan. As consideration for the license, the Company is required to make substantial payments upon the achievement of certain milestones, totaling up to $114.1 million. Through December 31, 2025, the Company has capitalized $47.2 million for contractual milestones achieved under the Ligand License Agreement. Pursuant to the Ligand License Agreement, the Company is obligated to pay to Ligand (and Bristol-Myers Squibb Company ("BMS")) an escalating royalty between 15% and 17% of net sales of sparsentan, with payments due quarterly. The Company began incurring costs associated with such royalties following the February 2023 approval of FILSPARI (sparsentan). For the years ended December 31, 2025 and 2024, the Company capitalized $54.3 million and $20.3 million, respectively, to intangible assets for royalties owed on net sales of FILSPARI. The cost of the milestone payments and royalty payments are being amortized to selling, general and administration on a straight-line basis through April 30, 2033.

Mission License Agreement

In 2014, the Company entered into the Mission License Agreement in which the Company obtained an exclusive, royalty-bearing license to market, sell and commercialize Thiola (tiopronin) in the United States and Canada, and a non-exclusive license to use know-how relating to Thiola to the extent necessary to market Thiola. The initial term of the license was 10 years and was subsequently amended through 2029. The Company paid

Mission an up-front license fee of $3.0 million and during the term of the agreement will pay the greater of $2.1 million, representing the guaranteed minimum royalty, or 20% of the Company's net sales of Thiola during each calendar year.

The present value of guaranteed minimum royalties payable using a discount rate ranging from approximately 7% to 11% based on the Company's then borrowing rate is $6.6 million and $8.2 million as of December 31, 2025 and 2024, respectively. As of December 31, 2025, the guaranteed minimum royalty current and long-term liability was approximately $2.1 million and $4.5 million, respectively, and $2.1 million and $6.1 million, respectively, as of December 31, 2024, recorded in other current and non-current liabilities, respectively, in the Consolidated Balance Sheets.

The Company has capitalized $185.3 million related to the Thiola intangible asset which consists of the up-front license fee, professional fees, present value of the guaranteed minimum royalties and any additional payment obligations through December 31, 2025 in excess of minimum royalties. In 2025 the Company recorded $14.3 million to the intangible asset related to royalties in excess of the minimum. Consistent with all prior periods since Thiola was acquired, the Company has not accrued any liability for future royalties in excess of the annual contractual minimum at December 31, 2025, as such royalties are not yet probable and estimable. The cost of the milestone payments and royalty payments are being amortized to selling, general and administration on a straight-line basis through March 31, 2026.

Amortizable intangible assets as of December 31, 2025 (*in thousands*):

	Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Ligand license	11	$ 108,163	$ (13,645)	$ 94,518
Mission license	12	185,304	(166,707)	18,597
Total amortizable intangible assets		$ 293,467	$ (180,352)	$ 113,115

Amortizable intangible assets as of December 31, 2024 (*in thousands*):

	Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Ligand license	11	$ 53,268	$ (5,769)	$ 47,499
Mission license	12	171,025	(115,303)	55,722
Total amortizable intangible assets		$ 224,293	$ (121,072)	$ 103,221

The following table summarizes amortization expense for the year ended December 31, 2025, 2024 and 2023 (*in thousands*):

	2025	2024	2023
Selling, general and administrative	$ 59,210	$ 41,739	$ 29,021
Research and development	—	—	7,261
Total amortization expense	$ 59,210	$ 41,739	$ 36,282

As of December 31, 2025, amortization expense for the next five years and thereafter is expected to be as follows (*in thousands*):

2026	$ 31,479
2027	12,888
2028	12,922
2029	12,888
2030	12,888
Thereafter	30,050
Total	$ 113,115

There were no impairments related to finite-lived intangible assets in the years ended December 31, 2025, 2024 and 2023.

NOTE 10. ACCRUED EXPENSES

Accrued expenses consist of the following at December 31, 2025 and 2024 (*in thousands*):

	2025	2024
Compensation related costs	$ 41,515	$ 35,166
Sales discounts, rebates, and allowances	30,595	10,585
Accrued royalties	22,703	12,309
Research and development	16,027	16,090
Selling, general and administrative	9,818	6,154
Miscellaneous accrued expenses	5,377	5,724
Total accrued expenses	$ 126,035	$ 86,028

NOTE 11. COMMITMENTS AND CONTINGENCIES

Commitments

Certain of the Company's contractual arrangements with contract manufacturing organizations ("CMOs") require binding forecasts or commitments to purchase minimum amounts for the manufacture of drug product supply, which may be material to the Company's financial statements.

Contingencies

In November 2020, the Company completed the acquisition of Orphan Technologies Limited (“Orphan”), including Orphan’s rare metabolic disorder drug pegtibatinase. The Company acquired Orphan by purchasing all of the outstanding shares. Under the stock purchase agreement, the Company has also agreed to make contingent cash payments up to an aggregate of $427.0 million based on the achievement of certain development, regulatory and commercialization events as set forth in the Agreement, as well as additional tiered mid-single digit royalty payments based upon future net sales of any pegtibatinase products in the U.S. and Europe, subject to certain reductions as set forth in the Agreement, and a contingent payment in the event a pediatric rare disease voucher for any pegtibatinase product is granted.

In accordance with ASC 450, *Contingencies*, contingent cash payments will be accrued for when it is probable that a liability has been incurred and the amount can be reasonably estimated. In March 2024, the Company recognized $65.2 million in IPR&D expense upon the achievement of a development milestone, which was paid during the second quarter of 2024 and recorded within investing activities in the Consolidated Statements of Cash Flows. As of December 31, 2025, no contingent cash payments have been accrued.

Legal Proceedings

From time to time in the normal course of business, the Company is subject to various legal matters such as threatened or pending claims or litigation. Although the results of claims and litigation cannot be predicted with certainty, the Company does not believe it is a party to any claim or litigation in which the outcome, if determined adversely to it, would individually or in the aggregate be reasonably expected to have a material adverse effect on its results of operations or financial condition.

NOTE 12. STOCKHOLDERS’ EQUITY

Common Stock

The Company is currently authorized to issue up to 200,000,000 shares of $0.0001 par value common stock. All issued shares of common stock are entitled to vote on a 1 share/1 vote basis.

Preferred Stock

The Company is currently authorized to issue up to 20,000,000 shares of $0.0001 par value preferred stock, of which 1,000 shares are designated Class "A" Preferred shares. Class A Preferred Shares are not entitled to interest, have certain liquidation preferences, special voting rights and other provisions. No preferred stock has been issued to date.

2018 Equity Incentive Plan

The Company's 2018 Equity Incentive Plan (the "2018 Plan") is the successor to and continuation of the Company's 2015 Equity Incentive Plan (the "2015 Plan") and the Company's 2014 Equity Incentive Plan (the "2014 Plan", and together with the 2015 Plan, the "Prior Plans"). Unallocated shares under the Prior Plans are no longer available for issuance under the Prior Plans, and have instead been added to the shares available for issuance under the 2018 Plan. The 2018 Plan, as amended, and including the unallocated shares of the Prior Plans, provides for a total of 22,384,114 shares to be issued, plus the Prior Plans' returning shares, if any, which become available for grant under the 2018 Plan from time to time. Options issued under the 2018 Plan will generally expire ten years from the date of grant and vest over a four-year period. As of December 31, 2025, there were 7,135,921 shares reserved for future issuance under the 2018 Plan.

2017 Employee Stock Purchase Plan

The 2017 Employee Stock Purchase Plan ("2017 ESPP") originated with 380,000 shares of common stock available for issuance. Beginning on January 1, 2018, and ending on (and including) January 1, 2026, the number of shares of common stock available for issuance under the 2017 ESPP may increase by an amount equal to the lesser of (i) one percent (1%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year or (ii) 300,000 shares of common stock.

Substantially all employees are eligible to participate in the 2017 ESPP and, through payroll deductions, can purchase shares on established dates semi-annually. The purchase price per share sold pursuant to the 2017 ESPP will be the lower of (i) 85% of the fair market value of common stock on the first day of the offering period or (ii) 85% of the fair market value on the purchase date. Each offering period will span up to six months. Purchases may be up to 15% of qualified compensation, with an annual limit of $25,000. The 2017 ESPP is intended to qualify as an “employee stock purchase plan” under Section 423 of the Internal Revenue Code.

As of December 31, 2025, there were 2,780,000 shares authorized and 1,089,373 shares reserved for future issuance under the 2017 ESPP.

Stock Options

The fair values of stock option grants during the years ended December 31, 2025, 2024 and 2023 were calculated on the date of grant using the Black-Scholes option pricing model. Compensation expense is recognized over the period of service, generally the vesting period. The following weighted average assumptions were used in the Black-Scholes options pricing model to estimate the fair value of stock options for the specified reporting periods:

	Year Ended December 31,		
	2025	**2024**	**2023**
Risk free rate	4.4 %	3.9 %	3.9 %
Expected volatility	62 %	59 %	50 %
Expected life (in years)	6.4	6.4	6.4
Expected dividend yield	—	—	—

The risk-free interest rate was based on rates established by the Federal Reserve. The Company’s expected volatility was based on analysis of the Company’s historical volatility. The expected life of the Company’s options was determined using the Company's historical exercise activity. The dividend yield is based upon the fact that the Company has not historically paid dividends and does not expect to pay dividends in the foreseeable future.

The following table summarizes our stock option activity and related information for the year ended December 31, 2025:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	9,283,331	$ 20.13	5.51	$ 16,408
Granted	1,484,200	$ 20.65		
Exercised	(1,869,242)	$ 18.63		$ 23,247
Forfeited and expired	(656,860)	$ 28.29		
Outstanding at December 31, 2025	8,241,429	$ 19.91	5.89	$ 150,796
Vested and expected to vest at December 31, 2025	8,241,429	$ 19.91	5.89	$ 150,796
Exercisable at December 31, 2025	5,813,961	$ 20.83	4.77	$ 101,064

The aggregate intrinsic value of stock options exercised in the years ended December 31, 2025, 2024 and 2023 was $23.2 million, $2.0 million, and $1.4 million, respectively.

The weighted average grant date fair value of options granted was $12.86, $5.10, and $11.66 during the years ended December 31, 2025, 2024 and 2023, respectively. The aggregate intrinsic value for outstanding options is calculated as the difference between the exercise price of the underlying awards and the closing price of the Company’s common stock of $38.21, $17.42 and $8.99 as of December 31, 2025, 2024 and 2023, respectively. Unrecognized compensation cost associated with unvested stock options amounts to $20.7 million as of December 31, 2025, which will be expensed over a weighted average remaining vesting period of 2.4 years.

In connection with the retirement of the Company's former Chief Financial Officer, the Board of Directors approved a modification to extend the deadline to exercise each stock option held to the earlier of three months following the last vesting date or the original expiration date of the option, and to continue vesting on the original schedule of any underlying unvested stock options and restricted stock units. The modification resulted in incremental compensation cost of $2.6 million for the year ended December 31, 2023.

Restricted Stock Units

As of December 31, 2025, there was approximately $58.5 million of unrecognized compensation cost related to restricted stock units ("RSUs") granted. This amount is expected to be recognized over a weighted average period of 2.5 years.

The following table summarizes our restricted stock unit activity for the year ended December 31, 2025:

	Number of RSUs	Weighted Average Grant Date Fair Value
Unvested December 31, 2024	3,517,263	$ 15.41
Granted	2,662,490	$ 20.68
Vested	(1,314,671)	$ 16.72
Forfeited/cancelled	(297,715)	$ 16.69
Unvested December 31, 2025	4,567,367	$ 18.02

The fair value of restricted stock units vested for the years ended December 31, 2025, 2024 and 2023 was $22.0 million, $22.8 million, and $18.7 million, respectively. The weighted average grant date fair value for stock awards granted during the years ended December 31, 2025, 2024 and 2023 was $20.68, $9.07 and $21.20, respectively.

Performance-based Stock Units

Performance-based stock units ("PSUs") are subject to vest only if certain specified criteria are achieved. A target number of shares is established for each award; however, the actual number of shares that are issued when an award vests may range from zero to 200% of the target amount depending upon the level of achievement of the applicable performance metric. As of December 31, 2025, there was approximately $0.1 million of unrecognized compensation cost related to PSUs granted and deemed probable of vesting. This amount is expected to be recognized over a weighted average period of 0.4 years.

The following table summarizes our performance-based stock unit activity for the year ended December 31, 2025:

	Number of PSUs	Weighted Average Grant Date Fair Value
Unvested December 31, 2024	216,208	$ 18.34
Granted	88,000	$ 20.46
Vested	(70,604)	$ 27.54
Forfeited/cancelled	—	—
Unvested December 31, 2025	233,604	$ 16.35

The fair value of PSUs vested for the years ended December 31, 2025, 2024 and 2023 was $1.9 million, $1.5 million, and $0.3 million, respectively. The weighted average grant date fair value for performance-based stock awards granted during the years ended December 31, 2025, 2024 and 2023 was $20.46, $8.93 and $22.40, respectively.

Share Based Compensation

Total non-cash stock-based compensation expense consisted of the following for the years ended December 31, 2025, 2024 and 2023 (*in thousands*):

	Year Ended December 31,		
	2025	2024	2023
Selling, general and administrative expenses	$ 28,187	$ 22,735	$ 27,111
Research and development expenses	16,681	14,178	17,135
Total stock-based compensation expense	$ 44,868	$ 36,913	$ 44,246

NOTE 13. NET LOSS PER COMMON SHARE

Basic and diluted net income (loss) per common share is calculated by dividing net loss applicable to common stockholders by the weighted-average number of common shares outstanding during the period. In accordance with *ASC 260, Earnings per Share*, if a company had a discontinued operation, the company uses income from continuing operations, adjusted for preferred dividend and similar adjustments, as its control number to determine whether potential common shares are dilutive.

As discussed in Note 15, as part of its February 2023 underwritten public offering, the Company issued and sold pre-funded warrants to purchase 1.25 million shares of its common stock at a price to the public of $20.9999 per pre-funded warrant. The pre-funded warrants were immediately exercisable upon issuance, and were exercised in the third quarter of 2024, resulting in the issuance of 1.25 million shares of the Company's common stock. Due to the nominal exercise price of the pre-funded warrants and the lack of any contingencies to exercise, the shares underlying the pre-funded warrants have been included in the calculation of basic net loss per common share since the date the warrants were issued.

The Company’s potentially dilutive shares, which include outstanding stock options, restricted stock units, performance-based stock units, and shares issuable upon conversion of the 2025 Notes and 2029 Notes, are considered to be common stock equivalents and are not included in the calculation of diluted net loss per share because their effect is anti-dilutive.

Basic and diluted net loss per share is calculated as follows *(net loss amounts are stated in thousands)*:

	For the year ended December 31,								
	2025			2024			2023		
	Shares	Net (loss) income	EPS	Shares	Net loss	EPS	Shares	Net (loss) income	EPS
Continuing operations	89,211,813	$ (50,261)	$ (0.57)	78,888,861	$ (320,630)	$ (4.07)	74,267,418	$ (376,333)	$ (5.07)
Discontinued operations	89,211,813	24,715	0.28	78,888,861	(915)	(0.01)	74,267,418	264,934	3.57
Basic and diluted loss per share	89,211,813	$ (25,546)	$ (0.29)	78,888,861	$ (321,545)	$ (4.08)	74,267,418	$ (111,399)	$ (1.50)

For the years ended December 31, 2025, 2024 and 2023, the following weighted-average number of common stock equivalents were excluded because they were anti-dilutive:

	For the year ended December 31,		
	2025	2024	2023
Convertible debt	11,172,474	11,697,953	11,697,952
Options	9,665,404	10,447,541	10,555,550
Restricted stock units and performance-based stock units	4,437,355	3,780,441	3,417,245
Total anti-dilutive shares	25,275,233	25,925,935	25,670,747

NOTE 14. INCOME TAXES

For financial reporting purposes, net loss from continuing operations before income taxes includes the following components (*in thousands*):

	Year Ended December 31,		
	2025	2024	2023
United States	$ (2,713)	$ (152,356)	$ (293,283)
Foreign	(46,560)	(168,154)	(82,827)
Total	$ (49,273)	$ (320,510)	$ (376,110)

The components of the provision for income taxes, in the Consolidated Statements of Operations are as follows (*in thousands*):

	Year Ended December 31,		
	2025	2024	2023
Current			
Federal	$ —	$ —	$ —
State	988	120	223
Foreign	—	—	—
Total current	988	120	223
Deferred			
Federal	—	—	—
State	—	—	—
Total deferred	—	—	—
Total tax provision	$ 988	$ 120	$ 223

In July 2025 the One Big Beautiful Bill Act was signed into law, which enacts significant changes to U.S. tax and related laws. The legislation did not have a material impact on the Company's income tax expense for the year ended December 31, 2025, nor did it materially change the Company's effective income tax rate for 2025.

The effective income tax rate for the year ended December 31, 2025 differs from the statutory federal income tax rate as follows (*in thousands, except percentages*):

	2025	
	Amount	Percentage
Statutory rate - federal	$ (10,347)	(21.00)%
State taxes, net of federal benefit*	701	1.42 %
Foreign tax effects		
Switzerland		
Statutory tax rate differences	5,831	11.83 %
Changes in valuation allowances	3,758	7.63 %
Other	207	0.42 %
Other foreign jurisdictions		
Other	(18)	(0.04)%
Tax credits		
Orphan drug credits	(16,224)	(32.93)%
Return to provision adjustments	(2,517)	(5.10)%
Changes in valuation allowances	16,275	33.03 %
Nontaxable or nondeductible items		
Executive compensation	1,710	3.47 %
Share-based awards	1,246	2.53 %
Other	442	0.90 %
Change in unrecognized tax benefits	(1,456)	(2.96)%
Other adjustments		
Return to provision adjustments and other true-ups	1,380	2.80 %
Effective tax rate	$ 988	2.00 %

* State taxes in California, Michigan and New Jersey for 2025 made up the majority (greater than 50%) of the tax effect in this category.

The following is a reconciliation of the statutory federal income tax rate to the Company's effective tax rate expressed as a percentage of loss before income taxes for the years ended December 31, 2024 and 2023:

	2024	2023
Statutory rate - federal	(21.00)%	(21.00)%
State taxes, net of federal benefit	(1.55)%	(3.19)%
Foreign rate differential	2.15 %	1.29 %
IPR&D	4.27 %	— %
Nondeductible executive compensation	0.44 %	1.50 %
Excess tax benefits associated with share-based awards	2.92 %	0.68 %
Other permanent differences	0.23 %	0.37 %
Tax credits	(4.24)%	(1.13)%
Return to provision adjustments and other true-ups	(0.80)%	4.19 %
Other	0.93 %	0.57 %
Change in valuation allowance	16.69 %	16.78 %
Income tax provision	0.04 %	0.06 %

The significant components of the Company's deferred tax assets and liabilities as of December 31, 2025 and 2024 are as follows (*in thousands*):

	2025	2024
Deferred Tax Assets:		
Net operating loss	$ 130,051	$ 113,303
Research and development and other tax credits	112,093	91,760
Intangible assets	56,052	53,919
Capitalized research and development	27,170	47,880
Stock based compensation	13,971	15,680
Other accrued expenses	21,727	14,266
Charitable contributions	5,699	5,797
Operating lease liabilities	4,164	5,421
174A state only difference	2,397	—
Depreciation	602	435
Loan costs	117	153
Total deferred tax assets	374,043	348,614
Deferred Tax Liabilities:		
Operating lease right of use assets	(3,211)	(4,259)
Prepaid assets	(184)	(178)
Total deferred tax liabilities	(3,395)	(4,437)
Net deferred tax assets before valuation allowance	370,648	344,177
Valuation allowance	(370,648)	(344,177)
Total deferred tax assets	$ —	$ —

The Company has established a full valuation allowance against its U.S. federal, state, and foreign deferred tax assets due to the uncertainty surrounding the realization of such assets in future periods. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences become deductible. Management considers the scheduled reversal of deferred liabilities and tax planning strategies in making this assessment and evaluates the recoverability of the deferred tax assets as of each reporting date. At such time as it is determined that it is more likely than not that deferred assets are realizable, the valuation allowance will be reduced accordingly and recorded as a tax benefit.

The Company has recorded a valuation allowance of $370.6 million as of December 31, 2025 to reflect the estimated amount of deferred tax assets that may not be realized. The Company increased its valuation allowance by $26.5 million for the year ended December 31, 2025, compared to a $53.5 million increase for the year ended December 31, 2024.

As of December 31, 2025, the Company had available unused U.S. federal and state net operating loss ("NOL") carryforwards of $232.6 million and $214.0 million, respectively, all of which are fully offset by a valuation allowance. The federal NOL has an indefinite life. The state NOL carryforwards will begin to expire in 2026 unless previously utilized, except for $41.1 million of the state net operating losses that have an indefinite carryforward period. In addition, at December 31, 2025, the Company had federal orphan drug tax credit carryforwards of $122.8 million that begin to expire in 2035 unless utilized, federal research and development tax credit carryforwards of $4.9 million that begin to expire in 2033 unless utilized, state research and development tax credit carryforwards of $1.3 million that begin to expire in 2030 unless utilized and $11.0 million that have an indefinite carryforward period, and California Competes tax credit carryforwards of $0.8 million that begin to expire in 2026. Pursuant to Internal Revenue Code Sections 382 and 383, use of the Company's federal net operating loss and credit carryforwards may be limited upon a cumulative change in ownership of more than 50% within a three-year period. The Company continues to monitor potential historical ownership changes.

As of December 31, 2025, the Company had Irish NOL carryforwards of $15.9 million which are fully offset by a valuation allowance and have an indefinite life. The Company also had Swiss NOL carryforwards of $475.2 million which are fully offset by a valuation allowance and begin to expire in 2026, as well as Federal Act on Tax Reform and AHV Financing cantonal tax benefits of $526.2 million which expire in 2029.

The Company accounts for uncertain tax benefits in accordance with the provisions of ASC 740-10 of the *Accounting for Uncertainty in Income Taxes*. As of December 31, 2025, the Company had $26.0 million in unrecognized tax benefits, which were recorded as a reduction to the deferred tax assets with a corresponding reduction in the Company's valuation allowance of $26.0 million. To the extent unrecognized tax benefits are recognized at a time when a valuation allowance does not exist, the recognition of the $26.0 million tax benefit would reduce the effective tax rate.

A reconciliation of the Company's unrecognized tax benefits for the years 2025, 2024 and 2023 is provided in the following table (*in thousands*):

	2025	2024	2023
Balance as of January 1:	$ 27,404	$ 22,906	$ 11,490
Increase in current period positions	3,343	4,248	4,871
Increase in prior period positions	—	250	7,383
Decrease in prior period positions	(4,716)	—	(838)
Balance as of December 31:	$ 26,031	$ 27,404	$ 22,906

The Company files income tax returns in the U.S. federal jurisdiction, various state and local, and foreign jurisdictions. With few exceptions, the Company's income tax returns are open to examination by federal and state authorities for the years ended December 31, 2013 and forward, due to the carryforward of unutilized tax attributes. The Company's Swiss income tax returns are open to examination for the years ended December 31, 2020 and forward, and the Company's Irish tax returns are open to examination for the years ended December 31, 2021 and forward.

The Company recognizes interest and penalties as a component of income tax expense. The Company did not recognize any interest or penalties for the year ended December 31, 2025, 2024 and 2023.

The cash taxes paid by the Company for the years ended December 31, 2025, 2024 and 2023 were immaterial.

NOTE 15. EQUITY OFFERINGS

Underwritten Public Offering of Common Stock

In November 2024, the Company sold an aggregate of approximately 9.0 million shares of its common stock in an underwritten public offering, at a price to the public of $16.00 per share of common stock. The net proceeds to the Company from the offering, after deducting the underwriting discounts and offering expenses, were approximately $134.7 million.

In February 2023, the Company sold an aggregate of approximately 9.7 million shares of its common stock and pre-funded warrants to purchase 1.25 million shares of its common stock in an underwritten public offering, at a price to the public of $21.00 per share of common stock and $20.9999 per pre-funded warrant. The pre-funded warrants are exercisable immediately, subject to certain beneficial ownership limitations which can be modified by the respective holders with at least 61 days' notice, and are exercisable for one share of the Company's common stock. The exercise price of each pre-funded warrant is $0.0001 per share of common stock. The net proceeds to the Company from the offering, after deducting the underwriting discounts and offering expenses, were approximately $215.8 million. The pre-funded warrants were exercised in the third quarter of 2024, resulting in the issuance of 1.25 million shares of the Company's common stock.

At-the-Market Equity Offering

In October 2024, the Company filed a prospectus supplement to the prospectus included in its registration statement on Form S-3 (File No. 333-281194), pursuant to which the Company may offer and sell, from time to time through Jefferies LLC, as agent ("Jefferies"), up to $100.0 million of common stock pursuant to an Amended and Restated Open Market Sale Agreement ("ATM Agreement") with Jefferies. As of December 31, 2025, the Company has not sold any shares under the ATM Agreement.

NOTE 16. RETIREMENT PLAN

401(k) Savings Plan

The Company has a 401(k) defined contribution savings plan for the benefit of all eligible employees. Employer matching contributions were $2.8 million, $2.4 million, and $2.7 million for the years ended December 31, 2025, 2024 and 2023, respectively.

Switzerland Defined Benefit Plan

The Company maintains a defined benefit pension plan covering employees of its Swiss subsidiary, Travere Therapeutics Switzerland GmbH (the "Swiss Plan"). The Swiss Plan is a government-mandated retirement fund that provides employees with a minimum benefit. Employer and employee contributions are made to the Swiss Plan based on various percentages of participants' salaries and wages that vary according to the participants' age and other factors. As of December 31, 2025, the projected benefit obligations under the Swiss Plan were approximately $1.7 million, and plan assets were approximately $1.0 million. The funded status of the Swiss Plan is included in other long-term liabilities on the Company's Consolidated Balance Sheets.

NOTE 17. PROPERTY AND EQUIPMENT

Property, plant and equipment, net consisted of the following *(in thousands*):

	December 31,	
	2025	2024
Leasehold improvements	$ 8,992	$ 9,370
Furniture and fixtures	2,397	2,446
Computers and equipment	2,731	2,275
	14,120	14,091
Less: Accumulated depreciation	(10,098)	(8,755)
Total property and equipment, net	$ 4,022	$ 5,336

Depreciation expense for the years ended December 31, 2025, 2024 and 2023 was $1.5 million, $1.8 million and $2.2 million, respectively.

NOTE 18. LEASES

As of December 31, 2025, the Company had an operating lease with Kilroy Realty, L.P. (the "Landlord") for office space located in San Diego, California, which was entered into in April 2019 and subsequently amended in May 2020. Coinciding with the Company's ability to direct the use of the office space and utilizing a discount rate equal to the Company's estimated incremental borrowing rate, the Company established right-of-use assets totaling $34.6 million and lease liabilities totaling $34.5 million. The total right-of-use asset and lease liability at measurement were each offset by lease incentives associated with tenant improvement allowances totaling $7.9 million.

The initial term of the office lease ends in August 2028, and the Landlord has granted the Company an option to extend the term of the lease by a period of five years. At lease inception, it was not reasonably certain that the Company will extend the term of the lease and therefore the renewal period has been excluded from the aforementioned right-of-use asset and lease liability measurements. The measurement of the lease term occurs from the February 2021 occupancy date of the office space.

In November 2024, the Company entered into a sublease of its 5th floor premises. The term of the sublease runs from January 2025 through August 2028. The Company’s sublease arrangement has been classified as an operating lease with sublease income recognized on a straight-line basis over the term of the sublease arrangement. To measure the Company’s periodic sublease income, the Company elected to use a practical expedient under ASC 842 to aggregate non-lease components with the related lease components when (i) the timing and pattern of transfer for the non-lease components and the related lease components are the same and (ii) the lease components, if accounted for separately, would be classified as an operating lease.

During the year ended December 31, 2024, the Company identified an indicator of impairment of the 5th floor operating lease right-of-use assets, property and equipment, and other capitalized assets and compared the carrying value of the asset group to an estimate of the future undiscounted cash flows expected to result from the sublease and eventual disposition of the asset group. The sum of the undiscounted cash flows of the asset group was below the carrying value. Consequently, the Company utilized the present value of the estimated future cash flows attributable to the assets to determine the fair value of the asset group. The resulting fair value of the operating lease right-of-use assets, property and equipment, and other capitalized assets resulted in an impairment of $1.2 million recorded in restructuring expense and categorized the aforementioned measurement of fair value as Level 3 within the ASC Topic 820, "Fair Value Measurements" fair value hierarchy. There were no impairments related to right-of-use assets or property and equipment in the years ended December 31, 2025 and 2023.

The following is a schedule of the future minimum rental commitments for the Company's operating leases reconciled to the lease liability and ROU asset as of December 31, 2025 (*in thousands*):

	December 31, 2025
2026	$ 6,775
2027	6,978
2028	4,782
2029 and thereafter	—
Total undiscounted future minimum payments	18,535
Present value discount	(1,526)
Total lease liability	17,009
Unamortized lease incentives	(2,539)
Cash payments in excess of straight-line lease expense	(3,894)
Total ROU asset	$ 10,576

The weighted-average remaining lease term and weighted-average discount rate of the Company's operating leases are as follows:

	December 31,	
	2025	2024
Weighted-average remaining lease term in years	2.7	3.7
Weighted-average discount rate	6.48 %	6.48 %

For the years ended December 31, 2025, 2024 and 2023 the Company recorded $4.4 million, $4.8 million, and $4.9 million, respectively, in expense related to operating leases, including amortized tenant improvement allowances.

NOTE 19. DIVESTITURES

Discontinued Operations

Sale of Bile Acid Product Portfolio

On August 31, 2023, the Company closed the sale of its bile acid business to Mirum Pharmaceuticals pursuant to the terms of the Purchase Agreement dated July 16, 2023 between the Company and Mirum. The assets sold consisted of substantially all of the assets primarily related to the Company's business of development, manufacture (including synthesis, formulation, finishing or packaging) and commercialization of the products, Chenodal and Cholbam (also known as Kolbam). In connection with the Closing, the Company received an upfront cash payment of $210.0 million.

Pursuant to the Purchase Agreement, after the Closing, the Company is eligible to receive up to $235.0 million upon the achievement of certain milestones based on specified amounts of annual net sales (tiered from $125.0 million to $500.0 million) of the Products. The Company will recognize the contingent consideration receivable in earnings when the target annual sales for the milestones are met and the contingency is resolved. Mirum achieved the first such milestone based on its annual net sales in 2025, and Travere recognized a milestone of $25.0 million for the year ended December 31, 2025 in discontinued operations. The $25.0 million is included in accounts receivable as of December 31, 2025.

The Company's sale of the bile acid business resulted in a gain, net of tax, of $226.0 million, which was recognized in 2023. The net gain consists of net consideration, including the upfront payment and the deduction of investment banker fees owed upon the Closing, plus the derecognition of the carrying value of the net liabilities included in the transaction and the immaterial tax due on the sale.

The Company and Mirum have also entered into a transition services agreement ("TSA") pursuant to which the Company has agreed to perform certain services for a period of time following the Closing, with respect to Mirum's use and operation of the assets purchased in the Purchase Agreement. The TSA is designed to ensure and facilitate an orderly transfer of business operations, and the consideration to be received by the Company primarily consists of cost reimbursement. For the year ended December 31, 2024, the Company recognized $0.5 million, under the TSA, included in continuing operations within other income (expense), net. TSA services provided by the Company were substantially complete as of December 31, 2024.

The Company determined that the divestiture represents a strategic shift that will have a major effect on the Company's operations and financial results, and has therefore reflected the bile acid business as a discontinued operation for all periods presented.

Results of discontinued operations are as follows (*in thousands*):

	Year Ended December 31,		
	2025	2024	2023
Net product sales	$ —	$ (550)	$ 66,164
Operating expenses:			
Cost of goods sold	—	(9)	1,899
Research and development	—	247	6,118
Selling, general and administrative	—	127	19,500
Change in fair value of contingent consideration	—	—	(473)
Total operating expenses	—	365	27,044
Operating (loss) income	—	(915)	39,120
Other income, net:			
Interest expense	—	—	(191)
Gain on disposal of discontinued operations, net of tax	24,715	—	226,005
Total other income, net	24,715	—	225,814
Net income (loss) from discontinued operations	$ 24,715	$ (915)	$ 264,934

NOTE 20. SEGMENT INFORMATION

The Company operates in one business segment focused on identifying, developing and delivering life-changing therapies to people living with rare kidney and metabolic diseases. The determination of a single business segment is consistent with the consolidated financial information regularly provided to the Company's chief operating decision maker ("CODM"), who is the President and Chief Executive Officer. The CODM uses net loss to monitor budget versus actual results in assessing segment performance and the allocation of resources. The Company's CODM also utilizes the Company's long-range plan as a strategic tool to allocate resources according to the Company's strategic objectives. Long-lived assets located outside the U.S. were immaterial as of December 31, 2025 and 2024. The measure of segment assets is reported on the Consolidated Balance Sheets as total assets. The accounting policies of the segment are the same as those described in Note 2, Summary of Significant Accounting Policies.

See Note 3 for further discussion of net product sales and Note 4 for discussion of license and collaboration revenues.

The following table presents reportable segment loss, including significant expenses regularly provided to the CODM, attributable to the Company's reportable segment for the years ended December 31, 2025, 2024 and 2023 (*in thousands*):

	Year Ended December 31,		
	2025	**2024**	**2023**
Revenue	$ 490,728	$ 233,175	$ 145,238
Less:			
Cost of goods sold	10,339	7,744	11,450
Research and development:			
External research and development	107,036	126,303	142,482
Internal personnel costs	80,091	73,843	84,658
Other research and development	18,884	17,350	17,850
Total research and development	206,011	217,496	244,990
Selling, general and administrative	337,202	264,119	265,542
In-process research and development	—	65,205	—
Restructuring	—	2,438	11,394
Total other income, net	13,551	3,317	12,028
Income tax provision on continuing operations	(988)	(120)	(223)
Income (loss) from discontinued operations, net of tax	24,715	(915)	264,934
Net loss	$ (25,546)	$ (321,545)	$ (111,399)

EXHIBIT 10.9

2026 Travere Therapeutics, Inc.
Executive Officer Annual Bonus Plan

Plan Objective

The purpose of the Travere Therapeutics, Inc. Executive Officer Bonus Plan (the "Plan") is to provide incentives to and reward executive officers of Travere Therapeutics, Inc. (the "Company") (each a "Participant," as defined below) to achieve corporate performance goals and to work together to achieve outstanding results in all aspects of the Company's business, thus benefiting themselves, Company shareholders and the people who benefit from the Company's services.

Eligibility

- All regular full-time executive officers of Travere Therapeutics are eligible to receive a bonus under this Plan ("Participant").
- Participants must be employed as a regular full-time employee by the Company prior to October 1 of the bonus plan year.
- Employees hired during the Bonus Plan Year prior to October 1 will be eligible to receive a prorated bonus based on the number of calendar days actively paid by Travere during the Bonus Plan Year.
- In order to be eligible to receive a bonus for a particular Bonus Plan Year (if any is earned), a Participant must be actively employed, and in good standing, as of the date the bonus checks are distributed for that year or as otherwise approved by the Board.
- Temporary executive officers and consultants (regardless of their roles or responsibilities) are not eligible to participate.
- Participation in the "Travere Therapeutics, Inc. Executive Officer Bonus Plan" is approved on an annual basis. Criteria for participation may be subject to change at the commencement of the Bonus Plan Year, and eligibility to participate in any Bonus Plan Year does not guarantee eligibility to participate in any subsequent Bonus Plan Year. Participants whose individual performance is deemed to not be meeting expectations by the Compensation Committee are ineligible.

Definitions

- "Bonus Plan Year" means the twelve-month period beginning on each January 1 and ending on each December 31.
- The "Board" means the Board of Directors of the Company.
- The "Compensation Committee" means the Compensation Committee of the Board, as constituted from time to time.
- The "Base Pay" is a Participant's annual rate of base salary in effect as of December 31 of the applicable Bonus Plan Year. However, bonus awards will be based on a blended rate if an employee has a reduction in work schedule and/or annualized salary during the plan year such

that the bonus calculation will take into account the time worked for both the higher and lower salary.

- The "Company Target Performance Measures" shall be determined at the sole discretion of the Compensation Committee or the Board and shall be set forth in writing, and may include, but shall not be limited to, a combination of financial, research and development and/or operational goals.
- The "Company Modifier" is determined at the sole discretion of the Compensation Committee or the Board and is designed to reflect performance against Company results. For illustration purposes only, if the Company performance significantly exceeds the Company Target Performance Measures, the Company Modifier could exceed 100%, but in no case more than 150%. Similarly, if Company performance fails to meet the Company Target Performance Measures, the Company Modifier could be less than 100%. There is a minimum Corporate Performance required of 40% for any payment under the Plan to be considered. No Participant will have any entitlement to or earn a right to receive a bonus under this Plan until the date on which such bonus is paid. The Board and/or Compensation Committee reserve the right, at any time, regardless of corporate performance to approve or not approve the payment of a Bonus during any Plan Year.
- The "Individual Modifier" is determined by the Participant's relative performance during the Plan year, and will generally fall within 0%-125%, as per the Participant's annual performance rating.
- The "Target Bonus" means the percentage of Base Pay that would be awarded to a Participant upon the achievement of the Company Target Performance Measures at a level of 100%.

Bonus Award Components

Unless otherwise specified, the components of a Bonus Award Payment (described below) are as follows:

- Company Modifier based on achievement of Company Performance Measures
- Target Percentage based on Participant's position (see below)
- Participant's Base Pay for the bonus year
    - Number of credible eligible days of service for the Bonus Plan Year
    - Participant's Individual Performance Modifier
    - Weighting of Company Performance Modifier based on level
- Weighting of Individual Performance Modifier based on level

Position	Target Bonus %	Individual Modifier Weighting	Company Modifier Weighting
Chief Executive Officer	75%	N/A	100%
Other Executive Officers	50%	N/A	100%

Bonus Award Payment Calculation

The Bonus Award Payment, if one is approved, is calculated as follows:

[(Participant's base pay x Bonus Target percentage x individual performance modifier x individual performance weighting) x Plan year tenure]	+	[(Participant's base pay x Bonus target percentage x company performance modifier x company performance weighting) x Plan year tenure]

General

- Bonus awards, if earned, will be paid between January 1 and March 15 of the calendar year after the close of the applicable Bonus Plan Year.
- In the event of a Participant's leave of absence in excess of 60 days during the Bonus Plan Year, the bonus earned for that year will be prorated. The calculation will be based on the total number of calendar days of active employment status.
- Executive officers hired after October 1 will not be eligible for a bonus award under this Plan until the following Bonus Plan Year.
- Executive officers hired during the Bonus Plan Year on or before October 1 will be eligible to receive a prorated bonus based on the number of calendar days actively at work.
- Bonus awards are based on the Participant's target percentage and Base Salary as of December 31 of the Bonus Plan Year.
- Travere Therapeutics reserves the right to modify or terminate the Plan at any time without prior notice.
- The Plan does not modify a Participant's at-will employment status or create a contract of employment for a specific term. Receipt of a bonus award is not guaranteed, and this Plan is not a promise of future or continued employment.
- The Plan does not modify a Participant's Employment Agreement.
- The Company will withhold all required taxes and make any other required deductions from payments made under the Plan. This Plan is intended to provide "short term deferrals", as described in Treasury Regulation 1.409A-1(b)(4) under section 409A of the Code or successor guidance thereto, and is intended not to be a "nonqualified deferred compensation plan", as described in Treasury Regulation 1-409A-1(a)(1) under section 409A of the Code or successor guidance thereto. In the administration and interpretation of the Plan, such intention is to govern.
- It is intended that this Plan be exempt from regulation under the Employee Retirement Income Security Act of 1974, as amended, as a "payroll practice" and a "bonus program", as described in U.S. Department of Labor Regulations 2510.3-1(b) and 2510.3-2(c), respectively.
- Any bonuses paid under the Bonus Plan shall be subject to the provisions of any claw-back policy implemented by the Company, including, without limitation, any claw-back policy adopted to comply with the requirements of the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules, regulations or interpretations thereunder.
- This Plan shall be subject to and construed in accordance with the laws of the State of California without regard to conflicts of laws.
- The Compensation Committee possesses sole discretion and authority to construe and interpret the terms and provisions of the Plan and to resolve any issue arising out of, relating to, or resulting from its administration and operation. Any disagreement or dispute by any person claiming a benefit under the Plan regarding any aspect of the Plan

or its administration must be promptly presented in writing to the Compensation Committee for determination. Payments shall be made under the Plan only if the Compensation Committee determines in its sole discretion that the claimant is entitled to them. Any determinations the Compensation Committee makes in relation to the Plan will be final, conclusive, and binding on all persons, entities and parties claiming any interest under the Plan and will be entitled to the maximum possible deference allowed by law.

- Except as explicitly provided by law, this Plan is provided at the Company's sole discretion, and the Company reserves the power at any time and from time to time, to modify, amend or terminate (in whole or in part) any or all of the provisions of the Plan at any time, prospectively or retroactively, without prior notice or obligation. Any amendment to the Plan shall be adopted by formal action of the Board.
- The Plan will be operated as an unfunded arrangement, and nothing in this document will be construed to require the Company to fund any awards or to establish a trust or purchase an insurance policy or other product for such purpose. The Company may make such arrangements as it desires to provide for the payment of bonuses under the Plan.
- Any payments made pursuant to the Plan shall not be counted as compensation for purposes of any other employee benefit plan, program or agreement sponsored, maintained or contributed to by the Company unless expressly provided for in such employee benefit plan, program, agreement, or arrangement.

EXHIBIT 21.1

TRAVERE THERAPEUTICS, INC.
LIST OF SUBSIDIARIES

No.	Name
1	Travere Therapeutics Pharmaceutical, Inc.
2	Travere Therapeutics Ireland Limited
3	Travere Therapeutics Switzerland GmbH
4	Kyalin Biosciences, Inc.
5	Manchester Pharmaceuticals LLC

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statement (Form S-3 No. 333-281194) of Travere Therapeutics, Inc.,

2. Registration Statements (Form S-8 Nos. 333-288114, 333-280213, 333-273667, 333-266957, 333-258257, 333-240222, 333-232857 and 333-224848) pertaining to Inducement Awards, the Travere Therapeutics, Inc. 2017 Employee Stock Purchase Plan and Travere Therapeutics, Inc. 2018 Equity Incentive Plan, as amended,

3. Registration Statement (Form S-8 No. 333-218582) pertaining to the Travere Therapeutics, Inc. 2015 Equity Incentive Plan and Travere Therapeutics, Inc. 2017 Employee Stock Purchase Plan,

4. Registration Statements (Form S-8 Nos. 333-213599 and 333-206510) pertaining to the Travere Therapeutics, Inc. 2015 Equity Incentive Plan, and

5. Registration Statement (Form S-8 No. 333-200224) pertaining to the Travere Therapeutics, Inc. 2014 Incentive Compensation Plan;

of our reports dated February 19, 2026, with respect to the consolidated financial statements of Travere Therapeutics, Inc. and the effectiveness of internal control over financial reporting of Travere Therapeutics, Inc. included in this Annual Report (Form 10-K) of Travere Therapeutics, Inc. for the year ended December 31, 2025.

/s/ Ernst & Young LLP

San Diego, California
February 19, 2026

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO EXCHANGE ACT RULE 13a-14(a) OR 15d-14(a)

I, Eric Dube, certify that:

1. I have reviewed this Annual Report on Form 10-K of Travere Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 19, 2026

/s/ Eric Dube

Eric Dube
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF

CHIEF FINANCIAL OFFICER

PURSUANT TO EXCHANGE ACT RULE 13a-14(a) OR 15d-14(a)

I, Christopher Cline, certify that:

1. I have reviewed this Annual Report on Form 10-K of Travere Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 19, 2026

/s/ Christopher Cline

Christopher Cline
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF

CHIEF EXECUTIVE OFFICER

PURSUANT TO 18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the accompanying Annual Report on Form 10-K of Travere Therapeutics, Inc. (the "Company"), for the period ended December 31, 2025 (the "Report"), the undersigned officer of the Company hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report, fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 19, 2026

/s/ Eric Dube

Eric Dube
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF

CHIEF FINANCIAL OFFICER

PURSUANT TO 18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the accompanying Annual Report on Form 10-K of Travere Therapeutics, Inc. (the "Company"), for the period ended December 31, 2025 (the "Report"), the undersigned officer of the Company hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report, fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 19, 2026

/s/ Christopher Cline

Christopher Cline

Chief Financial Officer

(Principal Financial Officer)