



## Traverse Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results

February 23, 2023

*Recently received U.S. FDA accelerated approval of FILSPARI™ (sparsentan), the first and only non-immunosuppressive therapy for the reduction of proteinuria in IgA nephropathy (IgAN)*

*European Medicines Agency (EMA) review decision for potential conditional approval of sparsentan in IgAN anticipated in second half of 2023*

*Pivotal DUPLEX Study of sparsentan in focal segmental glomerulosclerosis (FSGS) on track to report topline data from confirmatory two-year endpoints in second quarter of 2023*

*Net product sales of \$52 million for the fourth quarter of 2022; \$201 million for the full year 2022*

SAN DIEGO, Feb. 23, 2023 (GLOBE NEWSWIRE) -- Traverse Therapeutics, Inc. (NASDAQ: TVTX) today reported its fourth quarter and full year 2022 financial results and provided a corporate update.

- On February 17, 2023, the U.S. Food and Drug Administration (FDA) granted accelerated approval to FILSPARI™ (sparsentan) to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$  g/g
- Commercial availability of FILSPARI expected the week of February 27, 2023
- Review decision by the EMA on the potential approval of the Conditional Marketing Authorization (CMA) application for sparsentan for the treatment of IgAN in Europe expected in second half 2023
- Topline data from the two-year confirmatory endpoints in the ongoing Phase 3 DUPLEX Study of sparsentan in FSGS expected in the second quarter of 2023
- Topline data from the two-year confirmatory endpoints in the ongoing Phase 3 PROTECT Study of sparsentan in IgAN expected in the fourth quarter of 2023
- Total revenue for the fourth quarter of 2022 was \$55.9 million, consisting of \$52.3 million in net product sales and \$3.5 million in licensing and collaboration revenue
- Total revenue for the full year 2022 was \$212.0 million, consisting of \$200.5 million in net product sales and \$11.5 million in licensing and collaboration revenue
- Cash, cash equivalents and marketable securities, as of December 31, 2022, totaled \$450.2 million

"2022 was a foundational year for Traverse. We demonstrated clinical expertise with the advancement of our development programs, reached new patients with our approved products, and prepared our organization for a new phase of growth to deliver new medicines to rare disease patients," said Eric Dube, Ph.D., chief executive officer of Traverse Therapeutics. "Most importantly, our accomplishments in 2022 led to the recent accelerated approval of FILSPARI for the reduction of proteinuria in patients with IgAN, the first FDA approval from our development pipeline of therapies targeting rare diseases with limited or no treatment options. Our teams began calling on prescribers on February 20<sup>th</sup> and we are pleased with the early reception to education on FILSPARI's superior proteinuria reduction compared to irbesartan and its well-defined safety profile. In addition to remaining focused on a successful U.S. launch of FILSPARI in 2023, we are continuing to advance our programs with a number of exciting milestones ahead. In the second quarter, we look forward to two-year data from the ongoing DUPLEX Study of sparsentan in FSGS, and later in the year we expect a review decision on the CMA application for sparsentan for the treatment of IgAN in Europe. We also anticipate additional data from our novel pegtibatinase program for HCU and the potential initiation of a Phase 3 program this year. We take great pride in our progress to date and are honored to provide life-changing treatments to patients with rare disease."

### Fourth Quarter and Full Year 2022 Financial Results

Net product sales for the fourth quarter of 2022 were \$52.3 million, compared to \$54.6 million for the same period in 2021. For the full year 2022, net product sales were \$200.5 million, compared to \$210.8 million for the same period in 2021. The difference is largely attributable to a decrease in Thiola sales partially offset by an increase in sales of the Company's bile acid products.

Research and development (R&D) expenses for the fourth quarter of 2022 were \$60.2 million, compared to \$62.2 million for the same period in 2021. For the full year 2022, R&D expenses were \$235.8 million, compared to \$210.3 million for the same period in 2021. The difference is largely attributable to the continued advancement of the Company's sparsentan and pegtibatinase clinical programs, including clinical trial expenses, manufacturing and increased headcount. On a non-GAAP adjusted basis, R&D expenses were \$54.2 million for the fourth quarter of 2022, compared to \$57.7 million for the same period in 2021.

Selling, general and administrative (SG&A) expenses for the fourth quarter of 2022 were \$62.9 million, compared to \$42.1 million for the same period in 2021. For the full year 2022, SG&A expenses were \$220.2 million, compared to \$149.9 million for the same period in 2021. The difference is largely attributable to commercial launch preparations for FILSPARI, including additional field-based headcount. On a non-GAAP adjusted basis, SG&A expenses were \$50.2 million for the fourth quarter of 2022, compared to \$30.9 million for the same period in 2021.

Total other income, net, for the fourth quarter of 2022 was \$1.1 million, compared to total other expense, net, of \$4.4 million for the same period in 2021. The difference is largely attributable to increased interest income and lower interest expense during the period.

Net loss for the fourth quarter of 2022 was \$65.8 million, or \$1.03 per basic share, compared to a net loss of \$51.6 million, or \$0.84 per basic share for the same period in 2021. For the full year 2022, net loss was \$278.5 million, compared to \$180.1 million for the same period in 2021. On a non-GAAP adjusted basis, net loss for the fourth quarter of 2022 was \$49.1 million, or \$0.76 per basic share, compared to a net loss of \$37.6 million, or \$0.61 per basic share for the same period in 2021.

As of December 31, 2022, the Company had cash, cash equivalents and marketable securities of \$450.2 million.

## Program Updates

### *FILSPARI™ (sparsentan) – IgAN*

- On February 17, 2023, the U.S. FDA granted accelerated approval to FILSPARI to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$  g/g. The approval of FILSPARI is based on clinically meaningful and statistically significant improvements in proteinuria compared to irbesartan, an active comparator, in the pivotal and ongoing Phase 3 PROTECT Study, the largest head-to-head interventional study to date in IgAN.
- FILSPARI is expected to be commercially available beginning the week of February 27, 2023. The Company has launched Travere TotalCare™ to provide a comprehensive patient support program to enable a smooth experience for patients, their caregivers and healthcare providers. This program provides services, assistance and resources that will help patients understand IgAN, manage the insurance process, fill their prescriptions and initiate treatment.
- In the second half of 2023, the Company together with its collaborator CSL Vifor, anticipates a review decision by the EMA on the potential approval of the CMA application for sparsentan for the treatment of IgAN in Europe. If approved, sparsentan would receive CMA in all member states of the European Union, as well as in Iceland, Liechtenstein and Norway.
- In the fourth quarter of 2023, the Company expects to report topline results from the two-year confirmatory endpoints in the ongoing Phase 3 PROTECT Study, which are designed to support traditional approval of sparsentan in IgAN.
- Beginning in 2023, the Company plans to expand data generation through a sub study in the open-label extension of the ongoing PROTECT Study, as well as an open-label clinical study to investigate the safety and efficacy of sparsentan in combination with sodium glucose cotransporter-2 inhibitors (SGLT2i) for the treatment of IgAN.

### *Sparsentan - FSGS*

- In February 2021, the Company announced that the ongoing pivotal Phase 3 DUPLEX Study of sparsentan in FSGS achieved its pre-specified interim FSGS partial remission of proteinuria endpoint (FPRE) with statistical significance. FPRE is a clinically meaningful endpoint defined as urine protein-to-creatinine ratio (UP/C)  $\leq 1.5$  g/g and a  $>40$  percent reduction in UP/C from baseline. After 36 weeks of treatment, 42.0 percent of patients receiving sparsentan achieved FPRE, compared to 26.0 percent of irbesartan-treated patients ( $p=0.0094$ ). Preliminary results at the time of the interim assessment suggested that sparsentan had been generally well-tolerated and showed a comparable safety profile to irbesartan. The DUPLEX Study is fully enrolled and scheduled to continue as planned on a blinded basis to assess the confirmatory eGFR endpoint after 108 weeks of treatment.
- In the second quarter of 2023, the Company expects to report topline results from the two-year confirmatory endpoints in the ongoing Phase 3 DUPLEX Study of sparsentan in FSGS. Pending data supportive of approval, the Company anticipates submitting a supplemental New Drug Application (sNDA) for traditional approval for FSGS in the second half of 2023.
- Pending completion of the DUPLEX Study of sparsentan in FSGS and data supportive of approval, a subsequent variation to the CMA of sparsentan for the treatment of FSGS in Europe is targeted for submission by the end of 2023.

### *Pegtibatinase (TVT-058) – HCU*

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

- In the fourth quarter of 2022, enrollment completed in the sixth and final cohort of the ongoing Phase 1/2 COMPOSE Study. The Company anticipates reporting additional data from COMPOSE in mid-2023.
- In parallel with completing the final cohort in the COMPOSE Study, the Company is preparing for the potential initiation of

a pivotal Phase 3 clinical trial of pegtibatnase in patients with HCU in the second half of 2023.

#### **CDCA – CTX**

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

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

#### **Conference Call Information**

Travere Therapeutics will host a conference call and webcast today, Thursday, February 23, 2023, at 4:30 p.m. ET to discuss company updates as well as fourth quarter and full year 2022 financial results. To participate in the conference call, dial +1 (888) 204-4368 (U.S.) or +1 (323) 794-2551 (International), confirmation code 6044043. The webcast can be accessed on the Investor page of Travere's website at [ir.travere.com/events-presentations](http://ir.travere.com/events-presentations). Following the live webcast, an archived version of the call will be available for 30 days on the Company's website.

#### **Use of Non-GAAP Financial Measures**

To supplement Travere's financial results and guidance presented in accordance with U.S. generally accepted accounting principles (GAAP), the Company uses certain non-GAAP adjusted financial measures in this press release and the accompanying tables. The Company believes that these non-GAAP financial measures are helpful in understanding its past financial performance and potential future results. They are not meant to be considered in isolation or as a substitute for comparable GAAP measures and should be read in conjunction with the consolidated financial statements prepared in accordance with GAAP. Travere's management regularly uses these supplemental non-GAAP financial measures internally to understand, manage and evaluate its business and make operating decisions. In addition, Travere believes that the use of these non-GAAP measures enhances the ability of investors to compare its results from period to period and allows for greater transparency with respect to key financial metrics the Company uses in making operating decisions.

Investors should note that these non-GAAP financial measures are not prepared under any comprehensive set of accounting rules or principles and do not reflect all of the amounts associated with the Company's results of operations as determined in accordance with GAAP. Investors should also note that these non-GAAP financial measures have no standardized meaning prescribed by GAAP and, therefore, have limits in their usefulness to investors. In addition, from time to time in the future the Company may exclude other items, or cease to exclude items that it has historically excluded, for purposes of its non-GAAP financial measures; because of the non-standardized definitions, the non-GAAP financial measures as used by the Company in this press release and the accompanying tables may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by the Company's competitors and other companies.

As used in this press release, (i) the historical non-GAAP net loss measures exclude from GAAP net loss, as applicable, stock-based compensation expense, amortization and depreciation expense, revaluation of business combination related contingent consideration and income tax; (ii) the historical non-GAAP SG&A expense measures exclude from GAAP SG&A expenses, as applicable, stock-based compensation expense, and amortization and depreciation expense; (iii) the historical non-GAAP R&D expense measures exclude from GAAP R&D expenses, as applicable, stock-based compensation expense, and amortization and depreciation expense.

#### **About Travere Therapeutics**

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

#### **About FILSPARI (sparsentan)**

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

#### **FILSPARI (sparsentan) U.S. Indication**

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

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

#### **FILSPARI (sparsentan) Important Safety Information**

##### **BOXED WARNING: HEPATOTOXICITY AND EMBRYO-FETAL TOXICITY**

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

##### ***Hepatotoxicity***

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

of FILSPARI-treated patients, including cases confirmed with rechallenge.

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

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

#### ***Embryo-Fetal Toxicity***

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

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

#### **Warnings and Precautions**

- **Hepatotoxicity:**

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

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

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

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

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

- **FILSPARI REMS:** FILSPARI is available only through a restricted program under a REMS called the FILSPARI REMS.

Important requirements include:

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

Further information is available at [www.filsparirems.com](http://www.filsparirems.com) or 1-833-513-1325.

Please see Full Prescribing Information for FILSPARI [here](#).

#### **Forward-Looking Statements**

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. Without limiting the foregoing, these statements are often identified by the words "on-track", "positioned", "look forward to", "may", "might", "believes", "anticipates", "plans", "expects", "intends," "potential" or similar expressions. In addition, expressions of our strategies, intentions or plans are also forward-looking statements. Such forward-looking statements include, but are not limited to, references to: the timing of commercial availability of FILSPARI; expectations regarding the EMA's review decision on and potential approval of sparsentan for IgAN during the second half of 2023 or at all; the success and timing of the Company's U.S. launch of FILSPARI in 2023; the Company's continued development of its product candidates; the completion of the DUPLEX Study and targeted submission thereafter of a subsequent variation to the CMA of sparsentan for the treatment of FSGS in Europe; expectations regarding the future conduct of the ongoing PROTECT and DUPLEX Studies and timing for the topline eGFR endpoint analyses; the Company's plans to expand data generation through a sub study in the open-label extension of the PROTECT Study and an open-label clinical study to investigate the safety and efficacy of sparsentan in combination with SGLT2is for the treatment of IgAN; the Company's submission of an sNDA for traditional approval of sparsentan for FSGS in the second half of 2023; expectations regarding the future conduct of and timing for reporting additional data from the COMPOSE Study; the Company's potential initiation of a pivotal Phase 3 trial of pegtibatinase in patients with HCU in the second half of 2023; expectations regarding completion of the RESTORE Study and subsequent submission of an NDA for a CTX indication; references to the efficacy, safety and tolerability profile of sparsentan based on the preliminary data from the DUPLEX and PROTECT Studies' interim analyses; and the potential for pegtibatinase to become the first disease modifying therapy for people living with HCU. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of

them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties associated with the regulatory review and approval process, including the traditional and Subpart H accelerated approval pathways in the United States and the CMA pathway in the European Union, as well as risks and uncertainties associated with the Company's business and finances in general, success of its commercial products and risks and uncertainties associated with the Company's preclinical and clinical stage pipeline. Specifically, the Company faces risks associated with market acceptance of its commercial products including efficacy, safety, price, reimbursement and benefit over competing therapies, as well as risks associated with the successful development and execution of commercial strategies for such products, including FILSPARI. The risks and uncertainties the Company faces with respect to its preclinical and clinical stage pipeline include risk that the Company's clinical candidates will not be found to be safe or effective and that current or anticipated future clinical trials will not proceed as planned. Specifically, the Company faces the risk that the Phase 3 PROTECT Study of sparsentan in IgAN will not demonstrate that sparsentan is safe or effective or serve as the basis for further approval of sparsentan as planned; the risk that the Phase 3 DUPLEX Study of sparsentan in FSGS will not demonstrate that sparsentan is safe or effective or serve as a basis for traditional approval of sparsentan as planned; the risk that sparsentan will not be approved further for efficacy, safety, regulatory or other reasons; the RESTORE Study in CTX will not demonstrate that Chenodal is safe or effective for CTX or otherwise support an NDA for a CTX indication; and for each of the Company's programs, risk associated with enrollment of clinical trials for rare diseases and risk that ongoing or planned clinical trials may not succeed or may be delayed or abandoned for safety, regulatory, program assessment or other reasons. There is no guarantee that the DUPLEX Study will support an application for traditional review or that sparsentan will be approved for FSGS or in additional territories. There is also no guarantee that the results from the ongoing clinical study of pegtibatinase will be positive, or that the Company will be able to align with regulators on the design of, or ultimately proceed with, a pivotal program for pegtibatinase for HCU. The Company faces risk that it will be unable to raise additional funding that may be required to complete development of any or all of its product candidates, including as a result of macroeconomic conditions; risk relating to the Company's dependence on contractors for clinical drug supply and commercial manufacturing; uncertainties relating to patent protection and exclusivity periods and intellectual property rights of third parties; risks associated with regulatory interactions; risks and uncertainties relating to competitive products, including current and potential future generic competition with certain of the Company's products, and technological changes that may limit demand for the Company's products. The Company also faces additional risks associated with global and macroeconomic conditions, including health epidemics and pandemics, including risks related to potential disruptions to clinical trials, commercialization activity, supply chain, and manufacturing operations. You are cautioned not to place undue reliance on these forward-looking statements as there are important factors that could cause actual results to differ materially from those in forward-looking statements, many of which are beyond our control. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Investors are referred to the full discussion of risks and uncertainties, including under the heading "Risk Factors", as included in the Company's most recent Form 10-K, Form 10-Q and other filings with the Securities and Exchange Commission.

**TRAVERE THERAPEUTICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
*(in thousands, except share amounts)*

	<u>December 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 61,688	\$ 165,753
Marketable debt securities, at fair value	388,557	387,129
Accounts receivable, net	16,646	15,914
Inventory, net	6,922	7,313
Prepaid expenses and other current assets	12,624	6,718
Total current assets	486,437	582,827
Property and equipment, net	9,049	11,106
Operating lease right of use assets	21,000	23,196
Intangible assets, net	145,038	148,435
Other assets	11,061	11,069
Total assets	<u>\$ 672,585</u>	<u>\$ 776,633</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 17,290	\$ 15,144
Accrued expenses	95,742	75,180
Deferred revenue, current portion	11,976	16,268
Business combination-related contingent consideration, current portion	7,000	7,400
Operating lease liabilities, current portion	4,433	3,908
Other current liabilities	5,722	6,188
Total current liabilities	142,163	124,088
Convertible debt	375,545	226,581
Deferred revenue, less current portion	10,931	20,379
Business combination-related contingent consideration, less current portion	64,200	59,700
Operating lease liabilities, less current portion	27,510	31,497
Other non-current liabilities	9,385	12,276

Total liabilities		629,734	474,521
<b>Stockholders' Equity:</b>			
Preferred stock \$0.0001 par value; 20,000,000 shares authorized; no shares issued and outstanding as of December 31, 2022 and 2021		—	—
Common stock \$0.0001 par value; 200,000,000 and 200,000,000 shares authorized; 64,290,570 and 62,491,498 issued and outstanding as of December 31, 2022 and 2021, respectively		6	6
Additional paid-in capital		1,059,975	1,068,634
Accumulated deficit		(1,014,223)	(765,966)
Accumulated other comprehensive loss		(2,907)	(562)
Total stockholders' equity		<u>42,851</u>	<u>302,112</u>
Total liabilities and stockholders' equity		<u>\$ 672,585</u>	<u>\$ 776,633</u>

**Note: Certain adjustments / reclassifications have been made to prior periods to conform to current year presentation.**

**TRAVERE THERAPEUTICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENT OF OPERATIONS**  
*(in thousands, except share and per share data)*

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
	<i>(unaudited)</i>			
Net product sales:				
Bile acid products	\$ 26,529	\$ 24,363	\$ 102,558	\$ 95,654
Tiopronin products	25,816	30,215	97,970	115,122
Total net product sales	<u>52,345</u>	<u>54,578</u>	<u>200,528</u>	<u>210,776</u>
License and collaboration revenue	3,523	2,671	11,490	16,714
Total revenue	<u>55,868</u>	<u>57,249</u>	<u>212,018</u>	<u>227,490</u>
Operating expenses:				
Cost of goods sold	1,728	1,896	7,592	6,784
Research and development	60,232	62,168	235,780	210,328
Selling, general and administrative	62,920	42,075	220,206	149,883
Change in fair value of contingent consideration	(2,161)	(1,700)	15,006	22,260
Total operating expenses	<u>122,719</u>	<u>104,439</u>	<u>478,584</u>	<u>389,255</u>
Operating loss	<u>(66,851)</u>	<u>(47,190)</u>	<u>(266,566)</u>	<u>(161,765)</u>
Other income (expenses), net:				
Interest income	3,115	236	6,276	1,993
Interest expense	(2,896)	(5,069)	(11,275)	(20,141)
Other income, net	872	454	974	231
Loss on extinguishment of debt	—	—	(7,578)	—
Total other income (expense), net	<u>1,091</u>	<u>(4,379)</u>	<u>(11,603)</u>	<u>(17,917)</u>
Loss before income tax (provision) benefit	<u>(65,760)</u>	<u>(51,569)</u>	<u>(278,169)</u>	<u>(179,682)</u>
Income tax (provision) benefit	<u>(63)</u>	<u>(4)</u>	<u>(313)</u>	<u>(409)</u>
Net loss	<u>\$ (65,823)</u>	<u>\$ (51,573)</u>	<u>\$ (278,482)</u>	<u>\$ (180,091)</u>
Basic and diluted net loss per common share	<u>\$ (1.03)</u>	<u>\$ (0.84)</u>	<u>\$ (4.37)</u>	<u>\$ (3.01)</u>
Basic and diluted weighted average common shares outstanding	64,214,167	61,616,896	63,758,515	59,832,287

**RECONCILIATION OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION**  
*(in thousands, except share and per share data)*  
*(unaudited)*

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
<b>GAAP operating loss</b>	<b>\$ (66,851)</b>	<b>\$ (47,190)</b>	<b>\$ (266,566)</b>	<b>\$ (161,765)</b>
R&D operating expense	(60,232)	(62,168)	(235,780)	(210,328)
Stock compensation	3,613	4,155	13,858	12,632
Amortization & depreciation	2,447	293	6,264	1,481
Subtotal non-GAAP items	6,060	4,448	20,122	14,113
Non-GAAP R&D expense	(54,172)	(57,720)	(215,658)	(196,215)
SG&A operating expense	(62,920)	(42,075)	(220,206)	(149,883)
Stock compensation	5,915	4,421	25,319	18,134
Amortization & depreciation	6,855	6,768	26,816	25,137
Subtotal non-GAAP items	12,770	11,189	52,135	43,271
Non-GAAP SG&A expense	(50,150)	(30,886)	(168,071)	(106,612)
Change in fair value of contingent consideration	(2,161)	(1,700)	15,006	22,260
Subtotal non-GAAP items	16,669	13,937	87,263	79,644
<b>Non-GAAP operating loss</b>	<b>\$ (50,182)</b>	<b>\$ (33,253)</b>	<b>\$ (179,303)</b>	<b>\$ (82,121)</b>
<b>GAAP net loss</b>	<b>\$ (65,823)</b>	<b>\$ (51,573)</b>	<b>\$ (278,482)</b>	<b>\$ (180,091)</b>
Non-GAAP operating loss adjustments	16,669	13,937	87,263	79,644
Income tax provision	63	4	313	409
<b>Non-GAAP net loss</b>	<b>\$ (49,091)</b>	<b>\$ (37,632)</b>	<b>\$ (190,906)</b>	<b>\$ (100,038)</b>
<b>Per share data:</b>				
Basic and diluted net loss per common share	\$ (0.76)	\$ (0.61)	\$ (2.99)	\$ (1.67)
Basic and diluted weighted average common shares outstanding	64,214,167	61,616,896	63,758,515	59,832,287

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