



## Traverse Therapeutics Reports Second Quarter 2022 Financial Results

August 4, 2022

SAN DIEGO, Aug. 04, 2022 (GLOBE NEWSWIRE) -- Traverse Therapeutics, Inc. (NASDAQ: TVTX) today reported its second quarter 2022 financial results and provided a corporate update.

- New Drug Application (NDA) for accelerated approval of sparsentan in IgA nephropathy (IgAN) accepted by the U.S. Food and Drug Administration (FDA) and granted Priority Review; Prescription Drug User Fee Act (PDUFA) target action date set for November 17, 2022
- Total revenue for the second quarter 2022 was \$54.2 million, consisting of \$51.0 million in net product sales and \$3.2 million in licensing and collaboration revenue
- Cash, cash equivalents and marketable securities, as of June 30, 2022, totaled \$553.2 million

"In the second quarter, the FDA accepted for review our NDA for sparsentan for the treatment of IgA nephropathy and granted priority review; this positions us for the first potential approval of sparsentan in November and keeps us on course to achieve our goal of making sparsentan a new treatment standard for rare kidney disorders" said Eric Dube, Ph.D., president and chief executive officer of Traverse Therapeutics. "Our organization is making great progress in building upon our existing commercial capabilities to prepare for a potential launch that will provide broad access to sparsentan, if approved. In addition, we continue to advance our pipeline with the vision of strengthening our leadership position in the rare disease community. The DUPLEX Study of sparsentan in FSGS continues to progress and we look forward to reporting two-year results in the first half of next year. We are also very pleased to receive Breakthrough Therapy Designation for our pegtibatase program in HCU. We look forward to continuing to work with regulators this year to align on the design of a pivotal program that can enable pegtibatase to potentially become the first disease modifying therapy for the HCU community."

### Quarter Ended June 30, 2022

Net product sales for the second quarter of 2022 were \$51.0 million, compared to \$54.6 million for the same period in 2021. For the six months ended June 30, 2022, net product sales were \$97.4 million, compared to \$102.0 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 for the Company's bile acid products.

Research and development (R&D) expenses for the second quarter of 2022 were \$59.7 million, compared to \$51.8 million for the same period in 2021. For the six months ended June 30, 2022, R&D expenses were \$116.3 million, compared to \$99.8 million for the same period in 2021. The difference is largely attributable to increased headcount and medical affairs activities to support the continued advancement of the sparsentan and pegtibatase programs. On a non-GAAP adjusted basis, R&D expenses were \$54.4 million for the second quarter of 2022, compared to \$48.7 million for the same period in 2021.

Selling, general and administrative (SG&A) expenses for the second quarter of 2022 were \$53.0 million, compared to \$35.0 million for the same period in 2021. For the six months ended June 30, 2022, SG&A expenses were \$99.8 million, compared to \$71.7 million for the same period in 2021. The difference is largely attributable to increased headcount as a result of the Company's operational growth, and commercial launch preparations. On a non-GAAP adjusted basis, SG&A expenses were \$37.5 million for the second quarter of 2022, compared to \$24.0 million for the same period in 2021.

Total other expense, net, for the second quarter of 2022 was \$1.5 million, compared to \$3.6 million for the same period in 2021. The difference is largely attributable to lower interest expense during the period.

Net loss for the second quarter of 2022 was \$67.0 million, or \$1.05 per basic share, compared to a net loss of \$39.0 million, or \$0.64 per basic share for the same period in 2021. For the six months ended June 30, 2022, net loss was \$143.0 million, compared to \$92.9 million for the same period in 2021. On a non-GAAP adjusted basis, net loss for the second quarter of 2022 was \$41.3 million, or \$0.65 per basic share, compared to a net loss of \$23.3 million, or \$0.39 per basic share for the same period in 2021.

As of June 30, 2022, the Company had cash, cash equivalents and marketable securities of \$553.2 million.

### Program Updates

#### *Sparsentan - IgAN*

- In August 2021, the Company announced positive topline interim results from the ongoing pivotal Phase 3 PROTECT Study of sparsentan in IgAN. The PROTECT Study met its pre-specified interim primary efficacy endpoint with statistical significance. After 36 weeks of treatment, patients receiving sparsentan achieved a mean reduction in proteinuria from baseline of 49.8 percent, compared to a mean reduction in proteinuria from baseline of 15.1 percent for irbesartan-treated patients ( $p < 0.0001$ ). The Company believes that preliminary eGFR data available at the time of the interim analysis are indicative of a potential clinically meaningful treatment effect after two years of treatment. Preliminary results at the time of the interim assessment suggested that sparsentan had been generally well-tolerated to date in the study and consistent with its overall observed safety profile. The PROTECT Study is fully enrolled and is scheduled to continue as planned on a blinded basis to assess the treatment effect on eGFR slope over 110 weeks in the confirmatory endpoint analysis. Topline

results from the confirmatory endpoint analysis are expected in the second half of 2023.

- In May 2022, the Company announced that the FDA had accepted and granted Priority Review of its NDA under Subpart H for accelerated approval of sparsentan for the treatment of IgAN. The FDA indicated that it is not planning to hold an advisory committee meeting to discuss the application and assigned a PDUFA target action date of November 17, 2022.
- The Company and its partner Vifor Pharma are applying for conditional marketing authorization (CMA) of sparsentan for the treatment of IgAN in Europe. A review decision on a potential approval is expected in the second half of 2023. Pending completion of the DUPLEX Study and data supportive of approval, a subsequent variation of sparsentan for the treatment of FSGS is targeted for submission by the end of 2023.

#### *Sparsentan - FSGS*

- In February 2021, the Company announced that the ongoing pivotal Phase 3 DUPLEX Study of sparsentan in focal segmental glomerulosclerosis (FSGS) achieved its pre-specified interim FSGS partial remission of proteinuria endpoint (FPRE) 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 shown 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. The Company anticipates having topline data from the DUPLEX Study, including full two-year eGFR data, in the first half of 2023 and being in position to submit an NDA for traditional approval in the second half of next year.

#### *Pegtibatinase (TVT-058)*

- In December 2021, the Company reported positive topline results from the ongoing Phase 1/2 COMPOSE Study of pegtibatinase, a novel investigational enzyme replacement therapy with the potential to become the first disease modifying therapy for people living with HCU. In the highest dose cohort to date evaluating 1.5mg/kg of pegtibatinase twice weekly, treatment with pegtibatinase resulted in rapid and sustained reductions in total homocysteine (tHcy) through 12 weeks of treatment, including a 55.1 percent mean relative reduction in tHcy from baseline as well as maintenance of tHcy below a clinically meaningful threshold of 100  $\mu\text{mol}$ . As of the data cut-off, pegtibatinase has been generally well-tolerated. Enrollment activities continue for the sixth cohort in the Phase 1/2 COMPOSE Study to further evaluate formulation refinement and pegtibatinase dosing.
- The FDA recently granted Breakthrough Therapy Designation to the pegtibatinase program for the treatment of HCU. The Breakthrough Therapy Designation is supported by data from the ongoing Phase 1/2 COMPOSE Study of pegtibatinase in patients with HCU, as well as data from the Company's ongoing natural history study. To date, the pegtibatinase program has been granted Breakthrough Therapy, Rare Pediatric Disease and Fast Track designations by the FDA, as well as Orphan Drug designation in the US and Europe.
- The Company is engaging with regulators to establish next steps for the design of a pivotal development program to ultimately support potential approvals of pegtibatinase for the treatment of HCU.

#### **Upcoming Investor Conference Participation**

Company management will present at the 2022 Wedbush PacGrow Healthcare Virtual Conference on Tuesday, August 9, 2022 at 4:05 p.m. ET.

A live webcast will be available at <https://ir.travere.com/events-presentations> and an archived replay will be accessible for up to 30 days.

#### **Conference Call Information**

Travere Therapeutics will host a conference call and webcast today, Thursday, August 4, 2022 at 8:00 a.m. ET to discuss company updates as well as second quarter 2022 financial results. To participate in the conference call, dial +1 (888) 220-8474 (U.S.) or +1 (313) 209-6544 (International), confirmation code 5371785 shortly before 8:00 a.m. ET. The webcast can be accessed at [travere.com](https://travere.com), in the Events and Presentations section of the Investors & Media page, and will be archived for at least 30 days. A replay of the call will be available from 11:00 a.m. ET, August 4, 2022 to 11:00 a.m. ET, August 11, 2022. The replay number is +1 (888) 203-1112 (U.S.) or +1 (719) 457-0820 (International), confirmation code 5371785.

#### **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 income (loss) measures exclude from GAAP net income (loss), as applicable, stock-based compensation expense, amortization and depreciation expense, revaluation of acquisition 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 Travele Therapeutics**

At Travele 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 [travele.com](http://travele.com)

### **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" 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 likelihood of the FDA's potential approval of sparsentan for IgAN by the November 17, 2022 target action date or at all; the expectation around any potential future request by the FDA to hold an advisory committee meeting related to the sparsentan IgAN application; the Company's goal of making sparsentan a new treatment standard for rare kidney disorders, if approved; the Company's expectations for a commercial launch of sparsentan for IgAN with broad access, if approved; expectations regarding the future conduct of the ongoing PROTECT and DUPLEX studies and timing for the topline eGFR endpoint analyses; the ability to submit for traditional approval in FSGS following the completion of the DUPLEX Study and expectations regarding the timing thereof, as well as plans for regulatory submissions of sparsentan in Europe for IgAN and FSGS and the timings thereof; references to the efficacy, safety and tolerability profile of sparsentan based on the preliminary data from the DUPLEX and PROTECT Studies' interim analyses; the Company's belief that preliminary eGFR data available at the time of the interim analysis from the PROTECT Study are indicative of a potential clinically meaningful treatment effect after two years of treatment; the potential for sparsentan to become the first medicine approved for both FSGS and IgAN; the Company's plans for working with regulators this year to align on the design of a pivotal program that can enable pegtibatinase to potentially become the first disease modifying therapy for the HCU; and the expectation that Breakthrough Therapy designation for pegtibatinase for HCU will confer advantages on the program. 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 Subpart H accelerated approval pathway in the United States and the conditional marketing authorization (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. 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 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 accelerated 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; and the risk that sparsentan will not be approved for efficacy, safety, regulatory or other reasons, 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 for safety, regulatory or other reasons. There is no guarantee that the review process for the sparsentan IgAN NDA will remain on track for the FDA's assigned target action date, that the FDA will grant accelerated approval of sparsentan for IgAN within the assigned target action date, or at all, or that the DUPLEX Study will support an application for traditional review or that sparsentan will be approved for FSGS. 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 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; 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 faces additional risks associated with the potential impacts the COVID-19 pandemic may have on its business, including, but not limited to (i) the Company's ability to continue its ongoing development activities and clinical trials, (ii) the timing of such clinical trials and the release of data from those trials, (iii) the Company's and its suppliers' ability to successfully manufacture its commercial products and product candidates, and (iv) the market for and sales of its commercial products. 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.**  
**CONSOLIDATED BALANCE SHEETS**  
*(in thousands, except share amounts)*

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
	(unaudited)	
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 179,759	\$ 165,753
Marketable debt securities, at fair value	373,414	387,129
Accounts receivable, net	16,689	15,914
Inventory, net	7,632	7,313
Prepaid expenses and other current assets	9,283	6,718
<b>Total current assets</b>	<u>586,777</u>	<u>582,827</u>
Property and equipment, net	10,080	11,106
Operating lease right of use assets	21,910	23,196
Intangible assets, net	149,920	148,435
Other assets	10,807	11,069
<b>Total assets</b>	<u>\$ 779,494</u>	<u>\$ 776,633</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 11,848	\$ 15,144
Accrued expenses	82,694	75,180
Deferred revenue, current portion	12,503	16,268
Business combination-related contingent consideration, current portion	7,300	7,400
Operating lease liabilities, current portion	4,123	3,908
Other current liabilities	6,024	6,188
<b>Total current liabilities</b>	<u>124,492</u>	<u>124,088</u>
Convertible debt	374,690	226,581
Deferred revenue, less current portion	16,235	20,379
Business combination-related contingent consideration, less current portion	68,400	59,700
Operating lease liabilities, less current portion	29,359	31,497
Other non-current liabilities	9,605	12,276
<b>Total liabilities</b>	<u>622,781</u>	<u>474,521</u>
<b>Stockholders' Equity:</b>		
Preferred stock \$0.0001 par value; 20,000,000 shares authorized; 0 issued and outstanding as of June 30, 2022 and December 31, 2021	—	—
Common stock \$0.0001 par value; 200,000,000 shares authorized; 63,838,050, and 62,491,498 issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	6	6
Additional paid-in capital	1,036,533	1,068,634
Accumulated deficit	(878,744)	(765,966)
Accumulated other comprehensive loss	(1,082)	(562)
Total stockholders' equity	<u>156,713</u>	<u>302,112</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 779,494</u>	<u>\$ 776,633</u>

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

**TRAVERE THERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
*(in thousands, except share and per share data)*  
*(unaudited)*

<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>

(unaudited)

Net product sales:				
Bile acid products	\$ 25,534	\$ 24,974	\$ 50,609	\$ 46,938
Tiopronin products	25,416	29,643	46,784	55,086
Total net product sales	50,950	54,617	97,393	102,024
License and collaboration revenue	3,217	—	5,261	—
Total revenue	54,167	54,617	102,654	102,024
Operating expenses:				
Cost of goods sold	2,051	1,651	4,189	3,296
Research and development	59,681	51,807	116,292	99,753
Selling, general and administrative	52,979	34,965	99,767	71,743
Change in fair value of contingent consideration	4,907	1,509	13,987	10,096
Total operating expenses	119,618	89,932	234,235	184,888
Operating loss	(65,451)	(35,315)	(131,581)	(82,864)
Other income (expenses), net:				
Interest income	782	988	1,060	1,397
Interest expense	(2,972)	(4,852)	(5,487)	(10,173)
Loss on early extinguishment of debt	—	—	(7,578)	—
Other income (expense), net	662	216	688	(877)
Total other expense, net	(1,528)	(3,648)	(11,317)	(9,653)
Loss before income tax provision	(66,979)	(38,963)	(142,898)	(92,517)
Income tax provision	(53)	(49)	(105)	(362)
Net loss	<u>\$ (67,032)</u>	<u>\$ (39,012)</u>	<u>\$ (143,003)</u>	<u>\$ (92,879)</u>
Per share data:				
Basic and diluted net loss per common share	\$ (1.05)	\$ (0.64)	\$ (2.26)	\$ (1.59)
Basic and diluted weighted average common shares outstanding	63,638,385	60,571,259	63,387,009	58,431,770

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
<b>GAAP operating loss</b>	<u>\$ (65,451)</u>	<u>\$ (35,315)</u>	<u>\$ (131,581)</u>	<u>\$ (82,864)</u>
R&D operating expense	(59,681)	(51,807)	(116,292)	(99,753)
Stock compensation	3,684	2,845	6,852	5,847
Amortization & depreciation	1,625	288	1,911	574
Subtotal non-GAAP items	5,309	3,133	8,763	6,421
Non-GAAP R&D expense	(54,372)	(48,674)	(107,529)	(93,332)
SG&A operating expense	(52,979)	(34,965)	(99,767)	(71,743)
Stock compensation	8,953	4,665	13,971	9,357
Amortization & depreciation	6,483	6,330	13,289	12,119
Subtotal non-GAAP items	15,436	10,995	27,260	21,476
Non-GAAP SG&A expense	(37,543)	(23,970)	(72,507)	(50,267)

Change in fair value of contingent consideration	4,907	1,509	13,987	10,096
Subtotal non-GAAP items	<u>25,652</u>	<u>15,637</u>	<u>50,010</u>	<u>37,993</u>
<b>Non-GAAP operating loss</b>	<b>\$ (39,799)</b>	<b>\$ (19,678)</b>	<b>\$ (81,571)</b>	<b>\$ (44,871)</b>
<b>GAAP net income (loss)</b>	<b>\$ (67,032)</b>	<b>\$ (39,012)</b>	<b>\$ (143,003)</b>	<b>\$ (92,879)</b>
Non-GAAP operating loss adjustments	25,652	15,637	50,010	37,993
Income tax provision (benefit)	53	49	105	362
<b>Non-GAAP net loss</b>	<b>\$ (41,327)</b>	<b>\$ (23,326)</b>	<b>\$ (92,888)</b>	<b>\$ (54,524)</b>
<b>Per share data:</b>				
Basic and diluted net loss per common share	<u>\$ (0.65)</u>	<u>\$ (0.39)</u>	<u>\$ (1.47)</u>	<u>\$ (0.93)</u>
Basic and diluted weighted average common shares outstanding	<u>63,638,385</u>	<u>60,571,259</u>	<u>63,387,009</u>	<u>58,431,770</u>

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

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Source: Traverse Therapeutics, Inc.