Seres Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Updates

March 5, 2024

VOWST net sales of $10.4 million for the fourth quarter of 2023 and $19.6 million since launch in June through year-end 2023

Significant adoption of VOWST since launch in June 2023 through year-end 2023 with 2,833 patient enrollment forms received and 2,015 new patient starts

SER-155 Phase 1b placebo-controlled Cohort 2 clinical data anticipated in third quarter of 2024

Conference call at 8:30 a.m. ET today

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 5, 2024-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, today reported fourth quarter and full year 2023 financial results and provided business updates.

“2023 was an historic year for Seres as we launched our first-in-class oral microbiome therapeutic, VOWST, for recurrent CDI into commercialization with our collaborators at Nestlé Health Science,” said Eric Shaff, President and Chief Executive Officer of Seres. “We are proud of the impact VOWST is having on patients and, as we enter 2024, our top priority remains continuing to deliver VOWST to patients and advancing the potential of microbiome therapeutics. VOWST is indicated to prevent the recurrence of *Clostridioides difficile* infection (CDI) in adults following antibacterial treatment for recurrent CDI. We are also excited about obtaining clinical results from the Phase 1b study with SER-155 and the potential to prevent enteric infections and resulting blood stream infections and GvHD in allo-HSCT patients. These complications are far too frequent, potentially fatal, and costly to the healthcare system.”

“Our 2023 results since the launch of VOWST in June, exceeded our expectations across multiple dimensions,” said Terri Young, Ph.D., Chief Commercial and Strategy Officer at Seres. “We saw quarterly acceleration in demand in terms of new patient starts and prescription enrollment forms as well as progress on the reimbursement front. In close collaboration with our colleagues at Nestlé Health Science, we will continue our focus on HCP education, customer experience, payer coverage and hospital outflow.”

“In December, we were excited to announce the Fast Track Designation for SER-155 based on preclinical and cohort 1 data, with the cohort 2 data readout anticipated in the third quarter of 2024,” said Mr. Shaff. “We believe positive data from this readout would further validate the promise of this novel therapeutic modality in addressing difficult to tackle infections, including in immunocompromised patients such as those with chronic liver disease, cancer neutropenia, solid organ transplant, and AMR infections more broadly in settings of high-risk such as intensive care units. These additional opportunities have the potential to extend the value of SER-155 or our pre-clinical stage assets significantly and establish a new standard of care in protecting immunocompromised patients from life-threatening infections.”

VOWST Commercial Performance (Previously announced on January 9, 2024)

Broad demand for VOWST has been observed across rCDI patients and healthcare providers since product launch in June 2023:

- Fourth quarter net sales were approximately $10.4 million and reflected a gross-to-net reduction of 11%. Total 2023 net sales since launch in June were approximately $19.6 million and reflected a gross-to-net reduction of 13%.
- Fourth quarter completed prescription enrollment forms received for VOWST were 1,322; of those 1,082 resulted in new patient starts by year-end 2023.
- From launch through year-end 2023, there were 2,833 completed prescription enrollment forms received for VOWST, of those 2,015 resulted in new patient starts by year-end 2023.
- In 2023, prescription enrollment forms were submitted by approximately 1,330 unique healthcare providers (HCPs) since launch, with approximately 65% from gastroenterology and the remainder from other specialties; approximately 340 HCPs have prescribed VOWST to more than one patient.
- VOWST demand has been observed across the recurrent CDI patient pool, including first recurrence, which is the largest recurrent CDI patient segment.

2023 and Recent Highlights

- VOWST received FDA approval in April as the first and only FDA approved oral microbiome therapeutic to prevent

recurrence of CDI in patients 18 or older with rCDI, after treatment with standard of care antibacterials. Please see the full Indication, Limitation of Use, and Important Safety Information below.

- Strong adoption of VOWST since commercial launch in June 2023 with broad utilization, continued quarter over quarter growth, and significant progress achieving patient access.
- Production of VOWST commercial supply enabled a strong commercial launch within weeks of approval; progress in expansion of VOWST manufacturing capacity.
- SER-155 Phase 1b Cohort 1 clinical data showed favorable tolerability, successful drug bacteria engraftment, and a substantial reduction in pathogen domination in the gastrointestinal microbiome as compared to a reference cohort of patients, supporting progression to the placebo-controlled Cohort 2.
- SER-155 was awarded FDA Fast Track Designation.
- Completed strategic restructuring of Company to focus resources and investment on continued VOWST growth, completion of SER-155 Phase 1b study and supporting longer-term business sustainability.
- Named to “TIME 100 Most Influential Companies” list of 100 companies making an extraordinary impact around the world.
- Announced the appointment of Marella Thorell as Executive Vice President and Chief Financial Officer following the retirement of David Arkowitz.

Anticipated 2024 Milestones

- Increase VOWST utilization into rCDI market:
    - Expansion of the number of HCPs prescribing VOWST as a result of new efforts scaled by Nestlé Health Science in Q4 2023 such as strengthened promotional campaigns and expanded reach of digital promotion.
    - Increase VOWST utilization earlier in the treatment paradigm including in patients experiencing their first recurrence.
    - Maintenance of strong patient access and expansion of payer coverage for VOWST across Commercial and Medicare Part D plans.
    - Increase penetration of the hospital outflow patient segment.
- SER-155 Phase 1b placebo-controlled Cohort 2 data readout anticipated in third quarter of 2024.

Financial Results

Seres reported a net loss of $113.7 million for the full year of 2023, as compared to a net loss of $250.2 million for the prior year. Seres reported a net loss of $41.2 million for the fourth quarter of 2023, as compared to a net loss of $68.8 million for the same period in 2022.

Net sales of VOWST for the fourth quarter and full year 2023, were $10.4 million and $19.6 million, respectively based on 673 and 1,284 units of VOWST sold. Following the first commercial sale of VOWST, Seres shares equally with Nestlé, its collaborator, in the VOWST commercial profits and losses. Seres’ share of the VOWST net loss for the fourth quarter and full year 2023 was $10.3 million and $18.9 million, respectively, which was included in the Company’s operating results within Collaboration (profit) loss sharing—related party.

Research and development expenses for the fourth quarter of 2023 were $26.8 million, compared with $46.2 million for the same period in 2022. The research and development expenses were primarily related to Seres’ VOWST clinical development program and manufacturing costs, as well as personnel costs. The year-over-year decrease in R&D expenses is primarily driven by VOWST commercial manufacturing costs no longer being recognized in the Seres P&L following the product approval in April 2023, but instead capitalized and recognized on the Company’s balance sheet.

General and administrative expenses for the fourth quarter of 2023 were $17.2 million, compared with $22.4 million for the same period in 2022. General and administrative expenses were primarily related to personnel expenses, professional fees, including VOWST commercial readiness and pre-launch expenses incurred prior to the launch of VOWST in June 2023, and facility costs.

In November 2023, Seres announced a significant corporate restructuring to substantially reduce expenses and prioritize the commercialization of VOWST. The restructuring, which is expected to achieve approximately $75 million to $85 million in annual cash saving in 2024, was substantially implemented around year-end 2023. As a result, research and development and general and administrative expenses for the fourth quarter of 2023 were minimally impacted by the restructuring. In addition, included within research and development and general and administrative expenses for the fourth quarter of 2023 were $5.6 million of one-time charges related to the restructuring.

Cash Runway

As of December 31, 2023, Seres had $128.0 million in cash, cash equivalents and marketable securities as compared with $181.3 million at the end of 2022. Seres anticipates that this year-end cash balance, in conjunction with the planned savings from the restructuring announced in November 2023 and, assuming continued quarter-over-quarter revenue growth of VOWST, the expected receipt of the $45 million Tranche B under its existing senior secured debt facility (the Term Loan Facility) with Oaktree Capital Management, L.P. (Oaktree), will support its operations into the fourth quarter of 2024.

Conference Call Information

Seres' management will host a conference call today, March 5, 2023, at 8:30 a.m. ET. The conference call may be accessed by calling 1-800-715-9871 (international callers dial 1-646-307-1963) and reference the conference ID number 4030622. To join the live webcast, please visit the "Investors and News" section of the Seres website at www.serestherapeutics.com. A webcast replay will be available on the Seres website beginning approximately two hours after the event and will be archived for at least 21 days.

INDICATION AND IMPORTANT SAFETY INFORMATION FOR VOWST

INDICATION

VOWST (fecal microbiota spores, live-brpk) is indicated to prevent the recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI.

Limitation of Use: VOWST is not indicated for treatment of CDI.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Transmissible infectious agents: Because VOWST is manufactured from human fecal matter, it may carry a risk of transmitting infectious agents. Report any infection that is suspected to have been transmitted by VOWST to Aimmune Therapeutics, Inc. at 1-833-246-2566.

Potential presence of food allergens: VOWST may contain food allergens. The potential to cause adverse reactions due to food allergens is unknown.

ADVERSE REACTIONS

The most common adverse reactions (reported in ≥5% of participants) were abdominal distension (31.1%), fatigue (22.2%), constipation (14.4%), chills (11.1%), and diarrhea (10.0%).

To report SUSPECTED ADVERSE REACTIONS, contact Aimmune Therapeutics at 1-833-AIM-2KNO (1-833-246-2566), or the FDA at 1-800-FDA-1088, or visit www.fda.gov/MedWatch.

DRUG INTERACTIONS

Do not administer antibacterials concurrently with VOWST.

Please see Full Prescribing Information and Patient Information

About Seres Therapeutics

Seres Therapeutics, Inc. (Nasdaq: MCRB) is a commercial-stage company developing novel microbiome therapeutics for serious diseases. Seres' lead program, VOWST™, obtained U.S. FDA approval in April 2023 as the first orally administered microbiome therapeutic to prevent recurrence of *C. difficile* infection (CDI) in adults following antibacterial treatment for recurrent CDI and is being commercialized in collaboration with Nestlé Health Science. Seres is evaluating SER-155 in a Phase 1b study in patients receiving allogeneic hematopoietic stem cell transplantation. For more information, please visit www.serestherapeutics.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including the commercial success and continued growth of VOWST, the timing and results of our clinical studies, access to additional debt tranches and/or achieve sales targets, the sufficiency of cash to fund operations, and other statements which are not historical fact.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: we have incurred significant losses, are not currently profitable and may never become profitable; our need for additional funding; our limited operating history; our novel approach to therapeutic intervention; our reliance on third parties and collaborators to conduct our clinical trials, manufacture our product or product candidates and develop and commercialize our product or product candidates, if approved; the unknown degree and competing factors of market acceptance for VOWST; the competition we will face; our ability to protect our intellectual property; and our ability to retain key personnel and to manage our growth. These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC), on November 2, 2023, and our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

SERES THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 127,965	$ 163,030
Short term investments	—	18,311
Collaboration receivable - related party	8,674	—
Inventories	29,647	—
Prepaid expenses and other current assets	9,124	13,423
Total current assets	175,410	194,764
Property and equipment, net	22,457	22,985
Operating lease assets	109,793	110,984
Restricted cash	8,185	8,185
Restricted investments	1,401	1,401
Other non-current assets (1)	41,354	10,465
Total assets	$ 358,600	$ 348,784
Liabilities and Stockholder's Equity		
Current liabilities:		
Accounts payable	$ 3,641	$ 17,440
Accrued expenses and other current liabilities (2)	80,611	59,840
Operating lease liabilities	6,677	3,601
Short term portion of note payable, net of discount	—	456
Deferred income - related party	7,730	—
Deferred revenue - related party	—	4,259
Total current liabilities	98,659	85,596
Long term portion of note payable, net of discount	101,544	50,591
Operating lease liabilities, net of current portion	105,715	107,942
Deferred revenue, net of current portion - related party	95,364	92,430
Warrant liability	546	—
Other long-term liabilities	1,628	1,442
Total liabilities	403,456	338,001
Commitments and contingencies (Note 16)		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2023 and 2022; no shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, $0.001 par value; 240,000,000 and 200,000,000 shares authorized at December 31, 2023 and 2022, respectively; 135,041,467 and 125,222,273 shares issued and outstanding at December 31, 2023 and 2022, respectively	135	125
Additional paid-in capital	933,244	875,181
Accumulated other comprehensive loss	—	(12)
Accumulated deficit	(978,235)	(864,511)
Total stockholders' (deficit) equity	(44,856)	10,783
Total liabilities and stockholders' equity	$ 358,600	$ 348,784

[1] Includes $38,877 and $8,828 as of December 31, 2023 and December 31, 2022 respectively, of milestones related to the construction of the Company's dedicated manufacturing suite at BacThera AG, or Bacthera.

[2] Includes related party amounts of $28,053 and $34,770 at December 31, 2023 and December 31, 2022, respectively

SERES THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Year Ended December 31, 2023	2022	2021
Revenue:			
Collaboration revenue - related party	$ 126,325	$ 7,128	$ 143,857
Grant revenue	—	—	1,070
Total revenue	126,325	7,128	144,927

Operating expenses:			
Research and development expenses	$ 145,860	$ 172,920	$ 141,891
General and administrative expenses	87,744	79,694	69,261
Collaboration (profit) loss sharing - related party	704	1,004	(1,732)
Total operating expenses	234,308	253,618	209,420
Loss from operations	(107,983)	(246,490)	(64,493)
Other (expense) income:			
Interest income	7,301	3,058	2,870
Interest expense	(13,176)	(6,020)	(2,910)
Other income (expense)	134	(705)	(1,045)
Total other (expense) income, net	(5,741)	(3,667)	(1,085)
Net loss	$ (113,724)	$ (250,157)	$ (65,578)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.89)	$ (2.31)	$ (0.72)
Weighted average common shares outstanding, basic and diluted	128,003,294	108,077,043	91,702,866
Other comprehensive income (loss):			
Unrealized gain (loss) on investments, net of tax of $0	10	49	(12)
Currency translation adjustment	2	(1)	(1)
Total other comprehensive income (loss)	12	48	(13)
Comprehensive loss	$ (113,712)	$ (250,109)	$ (65,591)

View source version on businesswire.com: https://www.businesswire.com/news/home/20240305321973/en/

Investor and Media:
Rob Windsor
Rwindsor@serestherapeutics.com

Source: Seres Therapeutics, Inc.