Seres Therapeutics Reports First Quarter 2024 Financial Results and Provides Business Updates

May 8, 2024

Continued market adoption of VOWST® with approximately 1,411 patient enrollment forms received, approximately 1,083 new patient starts, and net sales of $10.1 million during Q1 2024, and accelerated net sales in March and April

SER-155 Phase 1b placebo-controlled Cohort 2 clinical readout expected end of Q3 2024

Further microbiome therapeutic candidates have potential to expand product franchise into additional medically vulnerable patient populations

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

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 8, 2024-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, today reported first quarter 2024 financial results and provided business updates.

"With a broad indication and compelling clinical profile to prevent the recurrence of *Clostridioides difficile* infection (CDI) in adults following antibacterial treatment for recurrent CDI (rCDI), VOWST enables healthcare providers to fundamentally transform how they treat this life-threatening disease. Along with our collaborators at Nestlé Health Science, we have continued to make progress with the launch of VOWST. Nestlé continues to refine its launch execution, and we have seen a resulting acceleration of VOWST sales during March and April," said Eric Shaff, President and Chief Executive Officer of Seres.

"Additionally, we completed enrollment of Cohort 2 in our ongoing SER-155 Phase 1b study and look forward to sharing a comprehensive topline dataset during the third quarter. These clinical results could further validate the vast potential of microbiome therapeutics in preventing adverse outcomes linked to gastrointestinal pathogens," continued Mr. Shaff. "Our goal remains to leverage Seres' industry-leading microbiome capabilities to advance the development of SER-155 and other product candidates in additional indications such as chronic liver disease, cancer neutropenia, and solid organ transplants, which could protect millions of medically vulnerable patients from life-threatening infections. In support of this objective, we are evaluating various options to provide the Company with additional capital and to advance our pipeline."

VOWST Commercial Performance

Commercial adoption of VOWST has continued since its June 2023 launch in the U.S., with increasing breadth of utilization across healthcare providers. Metrics are noted below as provided by Nestlé Health Science:

- First quarter 2024 net sales were approximately $10.1 million and reflected a gross-to-net reduction of approximately 15%.
- An acceleration of net sales occurred with March net sales of approximately $4.6 million, the highest monthly net sales figure since product launch, and similar results in April.
- In the first quarter of 2024, approximately 1,411 completed prescription enrollment forms were received for VOWST and there were approximately 1,083 new patient starts.
- From launch through March 31, 2024, approximately 4,239 completed prescription enrollment forms were received for VOWST; of which approximately 3,096 resulted in new patient starts.
- From launch through March 31, 2024, prescription enrollment forms were submitted by approximately 1,939 unique healthcare providers (HCPs) (including approximately 609 added in the first quarter); with approximately 65% from gastroenterology and the remainder from other specialties; approximately 604 HCPs have prescribed VOWST to more than one patient.
- VOWST demand has been observed across the recurrent CDI patient pool, including first recurrence, the largest CDI patient segment.

Additional Program and Corporate Highlights

- In April, the Company announced the completion of enrollment of Cohort 2 of the SER-155 Phase 1b study. Initial Cohort 2 study data, anticipated late in the third quarter, will include safety, drug pharmacology, and efficacy measures through day 100 following Allogeneic Hematopoietic Stem Cell Transplantation (Allo HSCT), a period in which many patients experience infections. The Company previously announced SER-155 Phase 1b Cohort 1 clinical data that showed favorable tolerability, successful drug bacteria engraftment, and a substantial reduction in pathogen domination in the gastrointestinal (GI) microbiome compared to a reference cohort of patients. SER-155 has been awarded FDA Fast Track Designation.
- Favorable SER-155 clinical results could support its continued development and provide broader validation of the promise of microbiome therapeutics in preventing poor outcomes associated with pathogens in the GI tract. Seres intends to evaluate SER-155 and other microbiome therapeutic candidates in other medically vulnerable patient populations, including

chronic liver disease, cancer neutropenia, and solid organ transplants.
- Production of VOWST commercial supply remains strong, and the Company has continued to make progress in expanding manufacturing capacity.
- In February, Seres announced Marella Thorell's appointment as Executive Vice President and Chief Financial Officer following David Arkowitz's retirement.

Financial Results

- Seres reported a net loss of $40.1 million for the first quarter of 2024, as compared to a net loss of $71.2 million for the same period in 2023.
- Net sales of VOWST for the first quarter were $10.1 million based on 642 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 first quarter of 2024 was $7.1 million, which was included in the Company's operating results within Collaboration (profit) loss sharing—related party.
- Research and development (R&D) expenses for the first quarter of 2024 were $21.7 million, compared with $44.0 million for the same period in 2023. The research and development expenses were primarily related to investment in our microbiome therapeutics platform and R&D operations, SER-155 clinical costs and 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 being capitalized and recognized on the Company's balance sheet, and lower personnel and other costs as a result of the restructuring plan announced in November 2023.
- General and administrative (G&A) expenses for the first quarter of 2024 were $15.5 million, compared with $22.5 million for the same period in 2023. General and administrative expenses were primarily related to personnel expenses, professional fees, and facilities. The year-over-year decrease in G&A expenses is primarily driven by a reduction in professional fees and lower personnel costs as a result of the restructuring plan.

Cash Runway

As of March 31, 2024, Seres had $111.2 million in cash and cash equivalents as compared with $128.0 million at the end of 2023. Based on Seres' current cash and various operating plans, the Company anticipates it has sufficient resources to support operations through obtaining the SER-155 Cohort 2 data and into the fourth quarter of 2024.

The Company's operating plans include drawing down the $45 million Tranche B under the Company's existing senior secured debt facility with Oaktree Capital Management, L.P. if the net sales and other conditions are met, as well as alternate plans if such conditions are not met. Operating plans may include selling shares under the Company's at the market (ATM) equity offering, implementing additional cost reduction initiatives, and other measures.

Conference Call Information

Seres' management will host a conference call today, May 8, 2024, 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 referencing the conference ID number 5686561. 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 (rCDI).

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 statements about the potential for VOWST; the timing and results of our clinical studies; future product candidates and development plans; our ability to generate additional capital; operating plans and 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 history of operating losses; the restrictions in our debt agreement; the ability of our restructuring plan to deliver cash savings; our novel approach to therapeutic intervention; our reliance on third parties to conduct our clinical trials and manufacture our product candidates; 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC), on March 5, 2024, 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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands, except share and per share data)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 111,184	$ 127,965
Collaboration receivable - related party	7,418	8,674
Inventories	41,973	29,647
Prepaid expenses and other current assets	4,606	9,124
Total current assets	165,181	175,410
Property and equipment, net	19,115	22,457
Operating lease assets	105,669	109,793
Restricted cash	8,430	8,185
Restricted investments	1,401	1,401
Other non-current assets (1)	41,466	41,354
Total assets	$ 341,262	$ 358,600
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 5,219	$ 3,641
Accrued expenses and other current liabilities (2)	76,317	80,611
Operating lease liabilities	8,833	6,677
Deferred income - related party	8,109	7,730
Total current liabilities	98,478	98,659
Long term portion of note payable, net of discount	102,009	101,544
Operating lease liabilities, net of current portion	103,341	105,715
Deferred revenue - related party	95,364	95,364
Warrant liabilities	130	546
Other long-term liabilities	1,678	1,628
Total liabilities	401,000	403,456

Commitments and contingencies (Note 15)		
Stockholders' deficit:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2024 and December 31, 2023; no shares issued and outstanding at March 31, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value; 240,000,000 shares authorized at March 31, 2024 and December 31, 2023, respectively; 151,442,034 and 135,041,467 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	151	135
Additional paid-in capital	958,479	933,244
Accumulated other comprehensive loss	—	—
Accumulated deficit	(1,018,368)	(978,235)
Total stockholders' deficit	(59,738)	(44,856)
Total liabilities and stockholders' deficit	$ 341,262	$ 358,600

[1] Includes $38,877 as of March 31, 2024 and December 31, 2023, of milestones related to the construction of the Company's dedicated manufacturing suite at BacThera AG, or Bacthera

[2] Includes related party amounts of $36,211 and $28,053 at March 31, 2024 and December 31, 2023, respectively

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

	Three Months Ended March 31,	
	2024	**2023**
Revenue:		
Collaboration revenue - related party	$ —	$ (522)
Total revenue	—	(522)
Operating expenses:		
Research and development expenses	21,702	43,969
General and administrative expenses	15,466	22,470
Collaboration (profit) loss sharing - related party	2,418	3,607
Total operating expenses	39,586	70,046
Loss from operations	(39,586)	(70,568)
Other income (expense):		
Interest income	1,648	1,032
Interest expense	(4,663)	(1,948)
Other income	2,468	310
Total other expense, net	(547)	(606)
Net loss	$ (40,133)	$ (71,174)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.27)	$ (0.57)
Weighted average common shares outstanding, basic and diluted	146,101,581	125,862,975
Other comprehensive income (loss):		
Unrealized gain (loss) on investments, net of tax of $0	—	12
Currency translation adjustment	—	2
Total other comprehensive income (loss)	—	14
Comprehensive loss	$ (40,133)	$ (71,160)

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