

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): November 2, 2023

SERES THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37465
(Commission
File Number)

27-4326290
(IRS Employer
Identification No.)

200 Sidney Street - 4th Floor
Cambridge, MA
(Address of principal executive offices)

02139
(Zip Code)

Registrant's telephone number, including area code: (617) 945-9626

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001 per share	MCRB	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On November 2, 2023, Seres Therapeutics, Inc. (the “Company”) announced its financial results for the quarter ended September 30, 2023 and provided operational updates. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the “Current Report”).

The information in this Item 2.02 of this Current Report (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits**

The following Exhibit 99.1 relates to Item 2.02 and shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Seres Therapeutics, Inc. Press Release issued November 2, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SERES THERAPEUTICS, INC.

Date: November 2, 2023

By: /s/ Thomas J. DesRosier

Name: Thomas J. DesRosier

Title: Chief Legal Officer and Executive Vice President



Seres Therapeutics Reports Third Quarter 2023 Financial Results Including VOWST™ Net Sales of \$7.6 Million

Rapid growth of VOWST continues with more than 1,500 patient enrollment forms received since FDA approval

Announces strategic restructuring to focus resources and investment on continued VOWST growth, completion of SER-155 Phase 1b study, and supporting longer-term business sustainability

Reduction of current workforce by 41%; total anticipated 2024 annual cash savings of \$75-\$85 million and cash runway expected into the fourth quarter of 2024

Conference call at 8:00 a.m. ET today

CAMBRIDGE, Mass., Nov. 2, 2023 — Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, today reported financial results for the third quarter ended September 30, 2023, including VOWST net sales of \$7.6 million. Third quarter VOWST commercial results show strong continued progress, driven by a significant increase in new patient starts and exceeding the Company's forecasted expectations across multiple dimensions. VOWST is indicated to prevent the recurrence of *Clostridioides difficile* infection (CDI) in adults following antibacterial treatment for recurrent CDI (rCDI) and is commercialized by Nestlé Health Science in collaboration with Seres.

"With a broad label and compelling clinical profile, the launch of VOWST is off to a great start, exceeding our sales expectations. Performance metrics from this first full quarter of launch support our belief that the product is on track to deeply penetrate the rCDI market and fundamentally transform how this disease is managed," said Eric Shaff, President and Chief Executive Officer at Seres.

The Company also announced that it will pursue a strategic restructuring to focus its business operations to prioritize the commercialization of VOWST and the completion of the SER-155 Phase 1b study, while significantly reducing costs and supporting longer-term business sustainability. The Company expects the restructuring, which includes a reduction in the current workforce of 41%, to result in annual cash savings of approximately \$75-\$85 million in 2024, excluding any one-time charges primarily associated with the workforce reduction.

“Following a thorough review of the Company, we have decided to implement a significant corporate restructuring to substantially reduce expenses and prioritize the commercialization of VOWST. Given the realities of this challenging financial environment for biopharmaceutical companies, we believe that concentrating our resources on VOWST offers an attractive opportunity for targeted revenue growth, while operating in a more capital efficient manner. We will also support our ongoing SER-155 Phase 1b study to an anticipated clinical dataset, expected in the third quarter of 2024. These pending data could extend the highly encouraging early study results that we have already reported. If favorable, these results will provide another potential opportunity to create value for all stakeholders, especially patients.”

Mr. Shaff concluded, “Seres’ talented team has been at the forefront of microbiome therapeutics for over a decade and has been responsible for the construction of an unprecedented microbiome platform and knowledge base. We are deeply appreciative of the dedication and valuable contributions of our colleagues who have tirelessly worked and successfully brought our first important medicine to patients in need.”

VOWST Performance

Broad demand for VOWST has been observed across both recurrent patients and healthcare providers during the first four months of launch (metrics noted below as provided by Nestlé Health Science through September 30, 2023):

- 1,513 completed prescription enrollment forms for VOWST were received, including 1,215 in the third quarter; of those 934 have culminated in new patient starts, including 837 in the third quarter.
- Prescription enrollment forms have been submitted by 698 unique healthcare providers (HCPs) since launch, with approximately 70% from gastroenterology and the remainder from other specialties; 129 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 rCDI patient segment.

Key Elements of the Restructuring

Seres is prioritizing the commercial launch of VOWST and continued production capabilities and capacity to support its growth. The Company has implemented operational efficiencies related to the VOWST manufacturing process, providing cost savings, expanding upon actions begun earlier this year. Seres will support the ongoing SER-155 Phase 1b study through its anticipated clinical dataset in the third quarter of 2024.

Seres is significantly scaling back all non-partnered R&D programs and activities other than the completion of the SER-155 Phase 1b study. The Company maintains extensive proprietary microbiome therapeutic drug development capabilities and know-how that may be used to support future R&D efforts. These include proprietary capabilities related to microbiome biomarker discovery, consortia design, pharmacological validation, and advanced manufacturing techniques. In addition, Seres owns a valuable intellectual property estate related to the discovery, development, and manufacture of microbiome therapeutics.

Workforce Reduction: Seres is reducing its workforce by 41% across the organization, which will result in the elimination of approximately 160 positions.

Expected Cost Savings: The workforce reduction and other cost-saving measures, including significantly scaling back all non-partnered research and development activities and reducing general and administrative expenses, are expected to result in annual cash savings of approximately \$75-\$85 million in 2024, excluding any one-time charges. Seres anticipates incurring a one-time charge of \$5.0-\$5.5 million in the fourth quarter of 2023, primarily related to the workforce reduction.

Cash Runway: The restructuring is expected to yield significant savings for the Company and position it for longer-term business sustainability. Seres anticipates that its cash, cash equivalents and investments balance as of September 30, 2023, of \$169.9 million, in conjunction with the anticipated savings from the restructuring and 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. The Company is eligible for Tranche B under the Term Loan Facility upon the achievement of trailing 6-month VOWST net sales of at least \$35 million, no later than September 30, 2024, and other applicable conditions.

Financial Results

Seres reported a net loss of \$47.9 million for the third quarter of 2023, as compared with a net loss of \$60.0 million for the same period in 2022. Net sales of VOWST for the third quarter of 2023, the first full quarter following launch, were \$7.6 million based on 506 units. Following the first commercial sale of VOWST, Seres shares equally with Nestle, its collaborator, in the VOWST commercial profits and losses. Seres' share of the VOWST net loss for the third quarter of 2023 was \$6.5 million, which was included in the Company's operating results within Collaboration (profit) loss sharing—related party.

Research and development expenses for the third quarter of 2023 were \$28.3 million, compared with \$43.1 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 third quarter of 2023 were \$20.0 million, compared with \$18.4 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.

Seres ended the third quarter of 2023 with \$169.9 million in cash, cash equivalents and investments as compared with \$181.3 million at the end of 2022.

Conference Call Information

Seres' management will host a conference call today, November 2, 2023, at 8:00 a.m. ET. The conference call may be accessed by calling 1-866-777-2509 (international callers dial 1-412-317-5413). 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 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 $\geq 5\%$ 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 continued commercial success of VOWST, the Company's commercial expectations, the timing, extent and potential impact of the strategic restructuring, the sufficiency of cash and/or cost reductions to fund operations, the achievement of future milestones, the receipt of future milestone payments, the ability to draw future debt tranches, the timing and success of the SER-155 Phase 1b study, 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; the impact of the

COVID-19 pandemic; our unproven approach to therapeutic intervention; our reliance on third parties and collaborators to conduct our clinical trials, manufacture our product candidates and develop and commercialize our 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 August 8, 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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands, except share and per share data)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 169,912	\$ 163,030
Short term investments	—	18,311
Collaboration receivable—related party	16,857	—
Inventories	18,525	—
Prepaid expenses and other current assets	9,100	13,423
Total current assets	214,394	194,764
Property and equipment, net	23,566	22,985
Operating lease assets	108,105	110,984
Restricted cash	8,185	8,185
Restricted investments	1,401	1,401
Other non-current assets	12,048	10,465
Total assets	<u>\$ 367,699</u>	<u>\$ 348,784</u>
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	\$ 8,958	\$ 17,440
Accrued expenses and other current liabilities (1)	54,158	59,840
Operating lease liabilities	6,280	3,601
Short term portion of note payable, net of discount	—	456
Deferred income—related party	9,465	—
Deferred revenue—related party	364	4,259
Total current liabilities	79,225	85,596
Long term portion of note payable, net of discount	101,135	50,591
Operating lease liabilities, net of current portion	104,863	107,942
Deferred revenue, net of current portion—related party	95,064	92,430
Warrant liabilities	956	—
Other long-term liabilities	1,579	1,442
Total liabilities	<u>382,822</u>	<u>338,001</u>
Commitments and contingencies (Note 14)		
Stockholders' (deficit) equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at September 30, 2023 and December 31, 2022; no shares issued and outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock, \$0.001 par value; 240,000,000 and 200,000,000 shares authorized at September 30, 2023 and December 31, 2022, respectively; 128,630,689 and 125,222,273 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	129	125
Additional paid-in capital	921,735	875,181
Accumulated other comprehensive loss	—	(12)
Accumulated deficit	(936,987)	(864,511)
Total stockholders' (deficit) equity	<u>(15,123)</u>	<u>10,783</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 367,699</u>	<u>\$ 348,784</u>

⁽¹⁾ Includes related party amounts of \$34,543 and \$34,770 at September 30, 2023 and December 31, 2022, respectively (see Note 16)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue:				
Collaboration revenue—related party	\$ 310	\$ 3,444	\$ 126,261	\$ 6,153
Total revenue	310	3,444	\$ 126,261	6,153
Operating expenses:				
Research and development expenses	28,253	43,116	\$ 119,014	126,700
General and administrative expenses	19,989	18,384	\$ 70,510	57,290
Collaboration (profit) loss sharing—related party	(519)	1,051	\$ 5,194	346
Total operating expenses	47,723	62,551	\$ 194,718	184,336
Loss from operations	(47,413)	(59,107)	\$ (68,457)	(178,183)
Other income (expense):				
Interest income	2,572	865	\$ 5,330	1,644
Interest expense	(4,012)	(1,727)	\$ (9,147)	(4,140)
Other income (expense)	999	(33)	\$ (202)	(682)
Total other expense, net	(441)	(895)	\$ (4,019)	(3,178)
Net loss	\$ (47,854)	\$ (60,002)	\$ (72,476)	\$ (181,361)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.37)	\$ (0.49)	\$ (0.57)	\$ (1.77)
Weighted average common shares outstanding, basic and diluted	128,289,871	122,527,275	\$ 127,297,667	102,380,700
Other comprehensive income (loss):				
Unrealized gain (loss) on investments, net of tax of \$0	—	140	10	(56)
Currency translation adjustment	1	(2)	2	(2)
Total other comprehensive income (loss)	1	138	12	(58)
Comprehensive loss	\$ (47,853)	\$ (59,864)	\$ (72,464)	\$ (181,419)

Investor and Media Contacts:

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