
**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 8, 2018

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
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)

Indicate by check mark whether the registrant is an emerging growth company as defined in 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. ☒

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 (see General Instructions A.2. below):

- ☐ 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))
-
-

Item 2.02. Results of Operations and Financial Condition.

On November 8, 2018, Seres Therapeutics, Inc. (the “Company”) announced its financial results for the quarter ended September 30, 2018 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 information in this Item 2.02 of this Form 8-K (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 provided by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibit

The following exhibit relates to Item 2.02, which shall be deemed to be furnished, and not filed:

Exhibit

<u>No.</u>	<u>Description</u>
99.1	Press Release issued on November 8, 2018

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 8, 2018

By: /s/ Thomas J. DesRosier

Name: Thomas J. DesRosier

Title: Chief Legal Officer and Executive Vice President



Seres Therapeutics Reports Third Quarter Financial Results and Provides Operational Updates

- Kevin Horgan, M.D. an accomplished drug developer and immunology expert, hired as Chief Medical Officer -
- Planning for two new microbiome clinical studies in ulcerative colitis and metastatic melanoma; Company expects to receive \$40M in payments from Nestlé Health Science with SER-287 Phase 2b study start -
- Conference call at 8:30 a.m. ET today -

CAMBRIDGE, Mass., November 8, 2018 — Seres Therapeutics, Inc. (NASDAQ:MCRB) today reported third quarter 2018 financial results and provided an operational update.

“Based on a growing body of promising clinical data and preclinical data from our laboratories and others, Seres has increased its strategic focus toward immunology and immuno-oncology, and we are very pleased to have hired Kevin Horgan, M.D., an expert in these key areas, as our new Chief Medical Officer. Kevin has led the development and approval of numerous important drugs, and he has an ideal background to drive the Company’s clinical programs forward,” said Roger J. Pomerantz, M.D., President, CEO and Chairman of Seres. “Seres has also been working to expedite data read outs from the ongoing SER-109 clinical study for recurrent *C. difficile* infection, and the soon-to-be initiated SER-287 Phase 2b study for ulcerative colitis. In addition, Seres and our collaborators at MD Anderson Cancer Center and the Parker Institute for Cancer Immunotherapy have taken significant steps to advance our SER-401 immuno-oncology program toward the clinic.”

Recent Highlights and Events

- **SER-109 ECOSPOR III Phase 3 Study:** Enrollment for ECOSPOR III remains ongoing with approximately 100 clinical sites open across the U.S. and Canada. Study enrollment has been impacted by the widespread availability of unapproved fecal microbiota transplantation. The Company is considering alternatives, including study design modification, to expedite the availability of clinical results. Based on ECOSPOR III screening to date, 38% of subjects screened have had a negative *C. difficile* toxin test, despite having a positive *C. difficile* PCR test. In agreement with recent clinical guidelines, these subjects were deemed to not have an active *C. difficile* infection and were not eligible for study inclusion. These data provide additional support for our important requirement of a positive toxin test implemented in ECOSPOR III, and suggest that *C. difficile* clinical studies relying on PCR-based testing alone may include a significant proportion of subjects without active disease.

-
- **New data supporting SER-109 activity presented at ID Week 2018 conference:** SER-109 data from the completed Phase 2 study provided insights into the potential mechanism of action of microbiome therapeutics for *C. difficile* infection. Presented results showed that SER-109 administration led to changes in the metabolic products created by the microbiome, including higher concentrations of secondary bile acids thought to be inhibitory to *C. difficile* growth.
 - **SER-287 development activity:** The Company has made operational progress towards initiating a SER-287 Phase 2b clinical study in patients with active mild-to-moderate ulcerative colitis (UC). To expedite the time and resources required to obtain top-line results from this study, the Company has modified the previously planned four-arm placebo-controlled study design into a smaller, three-arm study in approximately 200 patients that will include two different doses of SER-287, both following pretreatment with oral vancomycin, and a placebo arm. Seres has designed this study as a potentially pivotal trial, and the Company is awaiting feedback from the FDA on this final study design.

Based on modification to the Nestlé Health Science collaboration agreement, Seres now expects to receive \$40 million in milestone payments from Nestlé Health Science following initiation of the SER-287 Phase 2b study. Because the SER-287 Phase 2b study could serve as a pivotal trial, the parties agreed that at initiation of the SER-287 Phase 2b study Seres would receive \$40 million in contractual payments corresponding to both the Phase 2 milestone and a payment of the Phase 3 milestone.

- **SER-401 immuno-oncology development activity:** In collaboration with the Parker Institute for Cancer Immunotherapy and MD Anderson Cancer Center, Seres is continuing activities to prepare the evaluation of the potential for SER-401 to augment checkpoint inhibitor response in patients with metastatic melanoma.
- **New Chief Medical Officer:** Seres appointed Kevin Horgan, M.D., as Executive Vice President and Chief Medical Officer. Dr. Horgan will lead Seres' clinical development, clinical operations, regulatory affairs, and medical affairs functions, and report directly to Dr. Pomerantz. He succeeds Seres' outgoing Chief Medical Officer, Michele Trucksis, Ph.D., M.D., who will continue to provide clinical consulting services to the Company. Over a three-decade academic and industry career, Dr. Horgan has contributed to the development and approval of multiple therapeutics across immunology and oncology indications. Most recently, Dr. Horgan was Vice President of Clinical Development at AstraZeneca where he led the development of combination immuno-oncology programs. Dr. Horgan earned his medical degree from University College Cork in Ireland and did his medical residency at The Johns Hopkins Hospital in Baltimore, Maryland.

Financial Results

Seres reported a net loss of \$21.9 million for the third quarter of 2018, as compared to a net loss of \$6.9 million for the same period in 2017. The third quarter net loss was driven primarily by clinical and development expenses, personnel expenses, and ongoing development of the Company's microbiome therapeutics platform. The third quarter net loss figure was inclusive of \$9.1 million in recognized revenue primarily associated with the Company's collaboration with Nestlé Health Science.

Research and development expenses for the third quarter were \$23.7 million, as compared to \$22.2 million for the same period in 2017. The research and development expenses were primarily related to Seres' microbiome therapeutics platform, the clinical development of SER-109, SER-262 and SER-287, as well as the Company's SER-301, SER-155 and immuno-oncology preclinical programs.

General and administrative expenses for the third quarter were \$7.6 million, as compared to \$8.1 million for the same period in the prior year. General and administrative expenses were primarily due to headcount, professional fees, and facility costs.

The decrease in cash, cash equivalents and investments balance during the quarter was \$23.2 million. Seres ended the third quarter with approximately \$72.9 million in cash, cash equivalents and investments. Current resources, that do not include \$40 million of milestone payments that the Company expects to receive following the initiation of the SER-287 Phase 2b study, are expected to fund the Company into the second quarter of 2019.

Conference Call Information

Seres' management will host a conference call today, November 8, 2018, at 8:30 a.m. ET. To access the conference call, please dial 844-277-9450 (domestic) or 336-525-7139 (international) and reference the conference ID number 9877087. Accompanying slides will be made available on the Seres website prior to the call. To join the live webcast, please visit the "Investors and Media" 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.

About Seres Therapeutics

Seres Therapeutics, Inc. (Nasdaq:MCRB) is a leading microbiome therapeutics platform company developing a novel class of biological drugs that are designed to treat disease by restoring the function of a dysbiotic microbiome, where the state of bacterial diversity and function is imbalanced. Seres' lead program, SER-109, has obtained Breakthrough Therapy and Orphan Drug designations from the U.S. Food and Drug Administration and is in Phase 3 development for multiply recurrent *C. difficile* infection. SER-287 has successfully completed a Phase 1b study in patients with mild-to-moderate ulcerative colitis. Seres is developing SER-262, the first ever synthetic microbiome therapeutic candidate, in a Phase 1b study in patients with primary *C. difficile* infection. Seres is also advancing SER-401 to augment the efficacy of immuno-oncology treatment. For more information, please visit www.serestherapeutics.com. Follow us on Twitter [@SeresTx](https://twitter.com/SeresTx).

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 our development plans, the ability of ECOSPOR III to support SER-109 approval, the promise and potential impact of any of our microbiome therapeutics or clinical trial data, timing of and plans to initiate clinical studies of SER-287 and SER-401, the timing and results of any clinical studies, and the sufficiency of cash to fund operations.

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 unproven approach to therapeutic intervention; the lengthy, expensive, and uncertain process of clinical drug development; 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; our lack of experience in manufacturing, selling, marketing, and distributing our product candidates; failure to compete successfully against other drug companies; protection of our proprietary technology and the confidentiality of our trade secrets; potential lawsuits for, or claims of, infringement of third-party intellectual property or challenges to the ownership of our intellectual property; our patents being found invalid or unenforceable; our ability to retain key personnel and to manage our growth; the potential volatility of our common stock; and our management and principal stockholders have the ability to control or significantly influence our business. 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, or SEC, on August 2, 2018 and our other reports filed with the SEC, including the Quarterly Report we intend to file later today, 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 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 55,713	\$ 36,088
Investments	17,177	113,895
Prepaid expenses and other current assets	6,556	5,095
Total current assets	79,446	155,078
Property and equipment, net	28,083	32,931
Restricted cash	1,513	1,513
Total assets	<u>\$ 109,042</u>	<u>\$ 189,522</u>
Liabilities and Stockholders' Equity/(Deficit)		
Current liabilities:		
Accounts payable	\$ 6,475	\$ 7,033
Accrued expenses and other current liabilities	14,634	12,513
Deferred revenue - related party	17,901	12,079
Total current liabilities	39,010	31,625
Lease incentive obligation, net of current portion	7,685	8,989
Deferred rent	2,229	2,233
Deferred revenue, net of current portion-related party	89,554	84,847
Other long-term liabilities	1,129	1,129
Total liabilities	<u>139,607</u>	<u>128,823</u>
Commitments and contingencies		
Stockholders' equity/(deficit):		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at September 30, 2018 and December 31, 2017; no shares issued and outstanding at September 30, 2018 and December 31, 2017	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized at September 30, 2018 and December 31, 2017; 40,844,455 and 40,571,015 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	41	40
Additional paid-in capital	337,486	324,376
Accumulated other comprehensive loss	(9)	(146)
Accumulated deficit	(368,083)	(263,571)
Total stockholders' equity/(deficit)	(30,565)	60,699
Total liabilities and stockholders' equity	<u>\$ 109,042</u>	<u>\$ 189,522</u>

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,	
	2018	2017	2018	2017
Revenue:				
Collaboration revenue - related party	\$ 8,684	\$ 23,015	\$ 16,721	\$ 29,044
Grant revenue	371	—	917	—
Total revenue	9,055	23,015	17,638	29,044
Operating expenses:				
Research and development expenses	23,675	22,210	71,188	65,413
General and administrative expenses	7,591	8,119	25,063	25,251
Total operating expenses	31,266	30,329	96,251	90,664
Loss from operations	(22,211)	(7,314)	(78,613)	(61,620)
Other income (expense):				
Interest income (expense), net	262	379	958	1,193
Total other income (expense), net	262	379	958	1,193
Net loss	\$ (21,949)	\$ (6,935)	\$ (77,655)	\$ (60,427)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.54)	\$ (0.17)	\$ (1.91)	\$ (1.49)
Weighted average common shares outstanding, basic and diluted	40,806,413	40,494,049	40,699,422	40,419,522
Other comprehensive income:				
Unrealized gain on investments, net of tax of \$0	\$ 20	\$ 77	\$ 137	\$ 50
Total other comprehensive income	20	77	137	50
Comprehensive loss	\$ (21,929)	\$ (6,858)	\$ (77,518)	\$ (60,377)

IR or PR Contact:

Carlo Tanzi, Ph.D., Seres Therapeutics, 617-203-3467
Vice President, Investor Relations and Corporate Communications
ctanzi@serestherapeutics.com

###