
**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): March 6, 2019

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))
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Item 2.02. Results of Operations and Financial Condition.

On March 6, 2019, Seres Therapeutics, Inc. (the “Company”) announced its financial results for the year and quarter ended December 31, 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 March 6, 2019

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: March 6, 2019

By: /s/ Thomas J. DesRosier

Name: Thomas J. DesRosier

Title: Chief Legal Officer and Executive Vice President



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

- Initiated SER-287 Phase 2b study in mild-to-moderate ulcerative colitis -

- Initiated SER-401 Phase 1b study in metastatic melanoma -

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

CAMBRIDGE, Mass., March 6, 2019 — Seres Therapeutics, Inc. (Nasdaq: MCRB) today reported fourth quarter and full year 2018 financial results and provided an operational update.

“This has been a highly eventful period where we advanced our microbiome clinical programs and implemented a more focused R&D strategy. During the last several months, we initiated two clinical studies and implemented corporate changes to concentrate resources on the highest priority programs,” said Eric Shaff, President and Chief Executive Officer of Seres Therapeutics. “Seres is working to expeditiously progress our ongoing clinical studies to data read outs while also advancing our next generation, rationally-designed, fermented microbiome drug discovery capabilities centered on SER-301 for ulcerative colitis. We expect to complete SER-287 Phase 2b study enrollment by mid-2020 and obtain SER-401 Phase 1b study results in 2020. We continue to evaluate design options around our SER-109 Phase 3 study in order to expedite trial results.”

Seres also announced today the initiation of a SER-401 Phase 1b study in patients with metastatic melanoma. SER-401 is an oral microbiome therapeutic candidate sourced from healthy individuals identified to have a microbiome bacterial signature similar to that observed in immunotherapy responders. The Phase 1b study, conducted in collaboration with The University of Texas MD Anderson Cancer Center and the Parker Institute for Cancer Immunotherapy, will evaluate the potential for SER-401 to augment response to anti-PD-1 checkpoint inhibitor therapy. The study is designed to enroll 30 patients, who will receive the FDA-approved anti-PD-1 inhibitor nivolumab and will be randomized 2:1 to receive either SER-401 or placebo. The study will evaluate safety, impact on the gastrointestinal microbiome and various clinical and immunological outcome measures.

Recent Highlights and Events

- **SER-109 Phase 3 study progress:** Seres continues to recruit patients into the SER-109 Phase 3 study for recurrent *C. difficile* infection. The widespread use of fecal microbiota transplantation, an unapproved and uncontrolled practice, has impacted the enrollment rate of this placebo-controlled clinical trial. Seres is evaluating modification of the study design to expedite clinical results.

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- **Corporate changes to focus on highest priority programs and appointment of chief scientific officer (January 2019):** The Company has concentrated resources on completing the SER-287 Phase 2b study in mild-to-moderate ulcerative colitis, the SER-109 Phase 3 study for recurrent *C. difficile* infection and the SER-401 Phase 1b study in metastatic melanoma. In addition, Seres will continue to advance its next generation, rationally-designed, fermented drug discovery capabilities, with a focus on SER-301 for ulcerative colitis. Seres made changes to its executive team and reduced its full-time workforce by approximately 30%. Matthew Henn, Ph.D., previously Executive Vice President and Head of Discovery and Microbiome R&D, was appointed Chief Scientific Officer.
 - **Chief executive officer appointed (January 2019):** Seres announced the appointment of Eric D. Shaff as President and Chief Executive Officer. Mr. Shaff, who was Chief Operating and Financial Officer, succeeded Roger J. Pomerantz, M.D., who continues as Chair of Seres' Board of Directors.
 - **SER-287 Phase 2b study initiated in ulcerative colitis (January 2019):** Seres announced the start of a Phase 2b trial, ECO-RESET, evaluating SER-287 in patients with active mild-to-moderate ulcerative colitis. Seres received \$40 million in milestone payments associated with this study start from Nestlé Health Science. The Company obtained feedback from the FDA indicating that results from this study, in conjunction with data from a second pivotal study, could enable a Biologics License Application. The Company expects to complete trial enrollment by mid-2020.
 - **Chief medical officer appointed (October 2018):** 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.

Financial Results

Seres reported a net loss of \$98.9 million for the full year 2018, as compared to a net loss of \$89.4 million for the prior year. Seres reported a net loss of \$21.3 million for the fourth quarter of 2018, as compared to a net loss of \$29.0 million for the same period in 2017. The fourth quarter net loss was driven primarily by clinical and development expenses, personnel expenses and ongoing development of the Company's microbiome therapeutics platform. The fourth quarter net loss figure was inclusive of \$10.6 million in recognized revenue associated primarily with the Company's collaboration with Nestlé Health Science.

Research and development expenses for the fourth quarter 2018 were \$24.8 million, as compared to \$24.0 million for the same period in 2017. The research and development expense was primarily related to Seres' microbiome therapeutics platform, the clinical development of SER-109 and SER-287, as well as the Company's immuno-oncology efforts.

General and administrative expenses for the fourth quarter were \$7.5 million, as compared to \$8.8 million for the same period in the prior year. General and administrative expenses were primarily due to headcount, professional fees and facility costs.

The increase in the Company's cash, cash equivalents and investments balance during the quarter was \$12.9 million. Seres ended the fourth quarter with approximately \$85.8 million in cash, cash equivalents and investments. The increase in cash in Q4 was inclusive of \$40.0 million in milestones received under the Company's collaboration with Nestlé Health Science. Based on the Company's current operating plan, cash resources are expected to fund operating expenses and capital expenditure requirements, excluding net cash flows from future business development activities or potential incoming milestone payments, into the fourth quarter of this year.

Conference Call Information

Seres' management will host a conference call today, March 6, 2019, 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 6566237. 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' most advanced 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 recurrent *C. difficile* infection. SER-287 is being evaluated in a Phase 2b study in patients with active mild-to-moderate ulcerative colitis. Seres is developing SER-401 in a Phase 1b study in metastatic melanoma to augment the efficacy of anti-PD-1 immunotherapy. 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 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.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 85,820	\$ 36,088
Investments	—	113,895
Prepaid expenses and other current assets	6,845	5,095
Total current assets	92,665	155,078
Property and equipment, net	26,294	32,931
Restricted investments	1,400	1,400
Restricted cash	113	113
Total assets	<u>\$ 120,472</u>	<u>\$ 189,522</u>
Liabilities and Stockholder's Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 6,415	\$ 7,033
Accrued expenses and other current liabilities	15,207	12,513
Deferred revenue - related party	20,419	12,079
Total current liabilities	42,041	31,625
Lease incentive obligation, net of current portion	7,250	8,989
Deferred rent	2,216	2,233
Deferred revenue, net of current portion - related party	116,840	84,847
Other long-term liabilities	170	1,129
Total liabilities	<u>168,517</u>	<u>128,823</u>
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at December 31, 2018 and 2017; no shares issued and outstanding at December 31, 2018 and 2017	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized at December 31, 2018 and 2017; 40,936,735 and 40,571,015 shares issued and outstanding at December 31, 2018 and 2017	41	40
Additional paid-in capital	341,284	324,376
Accumulated other comprehensive income (loss)	—	(146)
Accumulated deficit	(389,370)	(263,571)
Total stockholders' equity (deficit)	<u>(48,045)</u>	<u>60,699</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 120,472</u>	<u>\$ 189,522</u>

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

	Year Ended December 31,		
	2018	2017	2016
Revenue:			
Collaboration revenue - related party	\$ 26,917	\$ 32,100	\$ 21,766
Grant revenue	1,350	—	—
Total revenue	28,267	32,100	21,766
Operating expenses:			
Research and development expenses	\$ 95,955	89,455	81,989
General and administrative expenses	32,596	34,040	32,616
Total operating expenses	128,551	123,495	114,605
Loss from operations	(100,284)	(91,395)	(92,839)
Other income (expense):			
Interest income (expense), net	1,172	1,590	1,260
Other income	170	425	—
Total other income (expense), net	1,342	2,015	1,260
Net loss	\$ (98,942)	(89,380)	(91,579)
Net loss per share attributable to common stockholders, basic and diluted	\$ (2.43)	\$ (2.21)	\$ (2.30)
Weighted average common shares outstanding, basic and diluted	40,743,492	40,449,410	39,846,928
Other comprehensive income (loss):			
Unrealized gain (loss) on investments, net of tax of \$0	146	3	(179)
Total other comprehensive income (loss)	146	3	(179)
Comprehensive loss	\$ (98,796)	\$ (89,377)	\$ (91,758)

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