

**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 5, 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)

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))

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 Global Select Market

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.

Item 2.02. Results of Operations and Financial Condition.

On November 5, 2019, Seres Therapeutics, Inc. (the “Company”) announced its financial results for the quarter ended September 30, 2019 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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on November 5, 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: November 5, 2019

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 Business Update

– Two late-stage microbiome clinical study readouts in ulcerative colitis and *C. difficile* infection anticipated in 2020 –

– Debt facility secured, providing up to \$50 million in additional capital; Corporate resources are expected to support operations into Q2 2021 –

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

CAMBRIDGE, Mass., Nov. 5, 2019 — Seres Therapeutics, Inc. (Nasdaq: MCRB) today reported financial results for the three months ended September 30, 2019 and provided a business update.

“Seres continues to advance our microbiome programs, and the Company is well resourced to reach important corporate milestones in 2020, including two late-stage clinical readouts: SER-287 Phase 2b study in mild-to-moderate ulcerative colitis and SER-109 Phase 3 study in recurrent *C. difficile* infection,” said Eric D. Shaff, President and Chief Executive Officer at Seres. “We are very pleased that our SER-109 ECOSPOR III study is now approaching target enrollment. SER-109 could provide patients with a meaningful new treatment option and also provide definitive clinical validation for our microbiome therapeutic approach. We are eagerly looking forward to top-line results from both of these important programs.”

Program Updates and Corporate Highlights

- **SER-287 Phase 2b ECO-RESET study in ulcerative colitis:** SER-287 is an orally-administered, biologically-derived, live microbiome therapeutic candidate designed to modulate the gastrointestinal microbiome of individuals with ulcerative colitis. Seres continues to enroll the SER-287 Phase 2b ECO-RESET induction study in patients with active mild-to-moderate ulcerative colitis. The SER-287 Phase 2b ECO-RESET study is expected to enroll approximately 201 patients. Based on U.S. Food and Drug Administration feedback, Seres expects that with positive Phase 2b study results, the study could serve as one of two pivotal trials to enable a SER-287 Biologics License Application submission. Seres expects Phase 2b ECO-RESET study top-line results in the second half of 2020.
- **SER-109 Phase 3 ECOSPOR III study in recurrent *C. difficile* infection:** SER-109 is an orally-administered, biologically-derived, live microbiome therapeutic candidate designed to restore the depleted, or dysbiotic, gastrointestinal microbiome of patients with recurrent *C. difficile* infection. The Company continues to enroll the ECOSPOR III trial, which is

evaluating efficacy and safety in 188 patients with recurrent *C. difficile* infection. All patients enrolled in ECOSPOR III are required to test positive for *C. difficile* cytotoxin to ensure enrollment of only patients with an active *C. difficile* infection. As of October 31, ECOSPOR III was more than 85% enrolled, and top-line study results are expected in mid-2020.

- **SER-301 preclinical candidate for ulcerative colitis:** The Company has nominated the lead candidate for SER-301, a rationally-designed, live microbiome therapeutic for ulcerative colitis. Next-generation, rationally-designed microbiome therapeutics may provide important benefits that include the optimization of pharmacological properties for target diseases and streamlined manufacturing. The consortia of bacteria in SER-301 are designed to modify the microbiome and microbe-associated metabolites in the gastrointestinal tract to modulate ulcerative colitis-relevant anti-inflammatory and immune pathways and to improve epithelial barrier integrity. SER-301 incorporates species associated with clinical efficacy in prior Seres human studies. Further, bacterial species selected for inclusion in SER-301 have been confirmed to engraft across human subjects. The consortia has demonstrated the capacity to modulate disease-relevant cellular mechanisms in human cell-based screening assays and *in vivo* models. Seres is entitled to a \$10 million milestone payment associated with the SER-301 Phase 1 clinical study from its ongoing collaboration with Nestlé Health Science. Seres expects to initiate clinical development in early 2020.
- **SER-401 Phase 1b in metastatic melanoma:** SER-401 is an orally-administered, biologically-derived, live microbiome therapeutic candidate comprising bacteria that reflect the bacterial signature in the gastrointestinal microbiome associated with response to checkpoint inhibitor immunotherapy. The ongoing Phase 1b study, supported by the Parker Institute for Cancer Immunotherapy and The University of Texas MD Anderson Cancer Center, will evaluate the potential for SER-401 to improve clinical response to nivolumab, an approved anti-PD-1 checkpoint inhibitor therapy, and will evaluate tumor biopsies and various biomarkers. Seres expects to obtain SER-401 Phase 1b preliminary study results in the second half of 2020.
- **New debt financing:** Seres entered into a debt financing agreement with Hercules Capital in October 2019 that provides the Company with up to \$50 million in additional capital. The Company received a first tranche of approximately \$25 million following the agreement closing. Two subsequent tranches of \$12.5 million each would become available to the Company upon the achievement of certain milestones.

Financial Results

Seres reported a net loss of \$16.4 million for the third quarter of 2019, as compared to a net loss of \$21.9 million for the same period in 2018. 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 \$7.0 million in recognized revenue associated primarily with the Company's collaborations with Nestlé Health Science and AstraZeneca.

Research and development expenses for the third quarter of 2019 were \$18.3 million, as compared to \$23.7 million for the same period in 2018. The research and development expense was primarily related to Seres' late stage SER-109 and SER-287 clinical development programs.

General and administrative expenses for the third quarter of 2019 were \$5.9 million, as compared to \$7.6 million for the same period in 2018. General and administrative expenses were primarily due to headcount, professional fees and facility costs.

Seres ended the third quarter with approximately \$83.8 million in cash, cash equivalents and investments. This amount does not include the \$25 million in debt capital obtained in October 2019.

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 second quarter of 2021.

Conference Call Information

Seres' management will host a conference call today, Nov. 5, 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 3577505. 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' SER-287 program has obtained Fast Track and Orphan Drug designation from the U.S. Food and Drug Administration and is being evaluated in a Phase 2b study in patients with active mild-to-moderate ulcerative colitis. Seres' SER-109 program has obtained Breakthrough Therapy and Orphan Drug designations from the FDA and is in Phase 3 development for recurrent *C. difficile* infection. Seres is also developing SER-401 in a Phase 1b study in patients with metastatic melanoma. SER-301, a next-generation, rationally-designed, live microbiome therapeutic candidate is in preclinical development for ulcerative colitis. 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 timing, results and initiation of our clinical studies, the potential for any of the Company's studies to serve as a pivotal trial to enable a BLA submission, the receipt of future milestone payments, the potential impact of any of Seres' development candidates, the sufficiency of the Company's cash resources to fund operating expenses and capital expenditure requirements, the availability of additional cash resources and other statements that are not historical facts.

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; the success of our leadership transition; our ability to retain key personnel and to manage our growth; 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 Annual Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on August 6, 2019 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)

	<u>September 30,</u> 2019	<u>December 31,</u> 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 49,296	\$ 85,820
Investments	34,492	—
Prepaid expenses and other current assets	4,073	6,845
Accounts receivable	1,717	—
Total current assets	89,578	92,665
Property and equipment, net	21,160	26,294
Operating lease assets	11,899	—
Restricted investments	1,400	1,400
Restricted cash	114	113
Total assets	\$ 124,151	\$ 120,472
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 4,455	\$ 6,415
Accrued expenses and other current liabilities	10,522	15,207
Operating lease liabilities	4,335	—
Deferred revenue - related party	21,135	20,419
Deferred revenue	1,790	—
Total current liabilities	42,237	42,041
Operating lease liabilities, net of current portion	16,844	—
Lease incentive obligation, net of current portion	—	6,776
Deferred rent	—	2,216
Deferred revenue, net of current portion - related party	94,215	116,840
Deferred revenue, net of current portion	2,410	—
Other long-term liabilities	664	644
Total liabilities	156,370	168,517
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at September 30, 2019 and December 31, 2018; no shares issued and outstanding at September 30, 2019 and December 31, 2018	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized at September 30, 2019 and December 31, 2018; 69,993,952 and 40,936,735 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	70	41
Additional paid-in capital	408,575	341,284
Accumulated other comprehensive loss	7	—
Accumulated deficit	(440,871)	(389,370)
Total stockholders' deficit	(32,219)	(48,045)
Total liabilities and stockholders' deficit	\$ 124,151	\$ 120,472

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,	
	2019	2018	2019	2018
Revenue:				
Collaboration revenue—related party	\$ 4,840	\$ 8,684	\$ 21,909	\$ 16,721
Grant revenue	85	371	791	917
Collaboration revenue	2,106	—	4,183	—
Total revenue	<u>7,031</u>	<u>9,055</u>	<u>26,883</u>	<u>17,638</u>
Operating expenses:				
Research and development expenses	18,317	23,675	59,109	71,188
General and administrative expenses	5,897	7,591	18,966	25,063
Restructuring expenses	—	—	1,492	—
Total operating expenses	<u>24,214</u>	<u>31,266</u>	<u>79,567</u>	<u>96,251</u>
Loss from operations	<u>(17,183)</u>	<u>(22,211)</u>	<u>(52,684)</u>	<u>(78,613)</u>
Other income (expense):				
Interest income (expense), net	335	262	744	958
Other income	439	—	439	—
Total other income (expense), net	<u>774</u>	<u>262</u>	<u>1,183</u>	<u>958</u>
Net loss	<u>\$ (16,409)</u>	<u>\$ (21,949)</u>	<u>\$ (51,501)</u>	<u>\$ (77,655)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.23)</u>	<u>\$ (0.54)</u>	<u>\$ (0.99)</u>	<u>\$ (1.91)</u>
Weighted average common shares outstanding, basic and diluted	<u>69,944,068</u>	<u>40,806,413</u>	<u>52,143,492</u>	<u>40,699,422</u>
Net loss	<u>(16,409)</u>	<u>(21,949)</u>	<u>(51,501)</u>	<u>(77,655)</u>
Other comprehensive income:				
Unrealized gain on investments, net of tax of \$0	\$ 7	\$ 20	\$ 7	\$ 137
Total other comprehensive income	<u>7</u>	<u>20</u>	<u>7</u>	<u>137</u>
Comprehensive loss	<u>\$ (16,402)</u>	<u>\$ (21,929)</u>	<u>\$ (51,494)</u>	<u>\$ (77,518)</u>

Seres Therapeutics Contact

Carlo Tanzi, Ph.D.
Investor Relations
ctanzi@serestherapeutics.com

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