

**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 2, 2020

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 March 2, 2020, Seres Therapeutics, Inc. (the “Company”) announced its financial results for the quarter and year ended December 31, 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 March 2, 2020

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 2, 2020

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 2019 Financial Results and Corporate Highlights

- Data-rich period ahead including two expected late-stage microbiome clinical readouts: *SER-109* in recurrent *C. difficile* infection in mid-2020 and *SER-287* for ulcerative colitis in H2 2020 –
- Clinical development activities initiated for *SER-301*, a next-generation, rationally designed product candidate for ulcerative colitis –
- Approximately \$100M of new capital raised in 2019; Company well funded for multiple anticipated upcoming clinical study readouts –
- Conference call at 8:30 a.m. ET today; Presentation at Cowen conference at 1:30 p.m. ET today –

CAMBRIDGE, Mass., March 2, 2020 — Seres Therapeutics, Inc., (Nasdaq: MCRB) today reported fourth quarter and full year 2019 financial results and provided an operational update.

“Throughout 2019, we reinforced Seres’ leadership in microbiome therapeutics and advanced our robust pipeline toward multiple near-term readouts and secured an immuno-oncology collaboration with AstraZeneca. We also strengthened our balance sheet by adding approximately \$100 million of new capital to support our R&D programs through important milestones expected in 2020, including two late stage clinical readouts,” said Eric Shaff, President and Chief Executive Officer of Seres. “We are excited by the potential of *SER-287* for ulcerative colitis and *SER-109* for recurrent *C. difficile* infection. Both of these therapeutic candidates could represent first-in-class treatments with potential to fundamentally transform disease management. These readouts may also serve to further validate the tremendous promise of our microbiome therapeutics approach.”

Mr. Shaff continued: “We have been steadfast in our commitment to completing a rigorous *SER-109* Phase 3 study in a well-defined patient population and using an objective endpoint in order to generate valid, clinically meaningful study results. We are pleased that the ECOSPOR III study is nearly fully enrolled and we eagerly look forward to results in the middle of this year.”

Program and Corporate Updates

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. Seres’ *SER-109* manufacturing process inactivates vegetative bacteria and other potential pathogens that have been linked with FMT-associated disease transmission. Seres believes that this manufacturing process, which is unique to Seres, provides a critically important safety advantage. Enrollment in the Phase 3 ECOSPOR III study is over 95%

complete. All ECOSPOR III patients are required to undergo a rigorous *C. difficile* cytotoxin diagnostic test to confirm active *C. difficile* infection, both at entry into the study and at completion of treatment. The study is evaluating the efficacy and safety of SER-109 in 188 patients with recurrent *C. difficile* infection. Seres expects to report top-line results from ECOSPOR III in mid-2020. Based on discussions with the FDA, Seres believes that ECOSPOR III has the potential to be a single pivotal study supporting product registration. However, this would depend on the strength of the data, and additional safety data may be required.

SER-287 Phase 2b ECO-RESET study in ulcerative colitis: SER-287 is an oral, biologically-derived microbiome therapeutic candidate designed to normalize 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 and Seres expects to report top-line results in the second half of 2020. Based on FDA 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 (BLA) submission.

SER-301 clinical candidate for ulcerative colitis: Seres has nominated SER-301, a rationally designed, fermented microbiome therapeutic as a clinical candidate for ulcerative colitis. Next-generation, rationally designed microbiome therapeutics may provide important benefits that include the optimization of pharmacological properties for targeted diseases and streamlined manufacturing. The consortia of bacteria in SER-301 is designed to modify the microbiome and microbe-associated metabolites in the gastrointestinal tract to modulate anti-inflammatory immune pathways and to improve epithelial barrier integrity in patients with ulcerative colitis. The Company has initiated clinical development activities for a SER-301 Phase 1 study in patients with ulcerative colitis and plans to enroll subjects in Australia and New Zealand. Seres is entitled to a \$10 million milestone payment associated with the Phase 1 SER-301 clinical study initiation from its ongoing collaboration with Nestlé Health Science.

SER-401 Phase 1b study 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 patient response to checkpoint inhibitor immunotherapy. The ongoing placebo-controlled Phase 1b study, which is supported by the Parker Institute for Cancer Immunotherapy and The University of Texas MD Anderson Cancer Center, is evaluating the potential of 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.

Financial Results

Seres reported a net loss of \$70.3 million for the full year of 2019, as compared to a net loss of \$98.9 million for the prior year. Seres reported a net loss of \$18.8 million for the fourth quarter of 2019, as compared to a net loss of \$21.3 million for the same period in 2018. The fourth quarter net loss figure was inclusive of \$7.6 million in recognized revenue associated primarily with the Company's collaborations with Nestlé Health Science and AstraZeneca.

Research and development expenses for the fourth quarter of 2019 were \$21.0 million, as compared to \$24.8 million for the same period in 2018. The research and development expenses were 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 \$5.8 million, as compared to \$7.5 million for the same period in the prior year. General and administrative expenses were primarily due to headcount, professional fees and facility costs.

Seres ended the fourth quarter with approximately \$94.8 million in cash, cash equivalents and investments, an increase sequentially from the \$83.8 million reported for the end of the third quarter. The fourth quarter cash position included the second of three \$6.7 payments from AstraZeneca related to the Company's ongoing immuno-oncology agreement, as well as the first tranche of \$25 million received upon the closing of the previously announced debt agreement.

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 second quarter of 2021.

Conference Call Information

Seres' management will host a conference call today, March 2, 2020, 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 6751427. 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 and SER-301 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 and results of each of Seres' 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 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 risks of operating internationally; 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 November 5, 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.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31,	
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 65,126	\$ 85,820
Investments	29,690	—
Prepaid expenses and other current assets	3,588	6,845
Accounts receivable	1,785	—
Total current assets	<u>100,189</u>	<u>92,665</u>
Property and equipment, net	19,495	26,294
Operating lease assets	11,356	—
Restricted investments	1,400	1,400
Restricted cash	—	113
Total assets	<u>\$ 132,440</u>	<u>\$ 120,472</u>
Liabilities and Stockholder's Deficit		
Current liabilities:		
Accounts payable	\$ 4,859	\$ 6,415
Accrued expenses and other current liabilities	10,884	15,207
Operating lease liabilities	4,456	—
Deferred revenue - related party	20,960	20,419
Deferred revenue	4,834	—
Total current liabilities	<u>45,993</u>	<u>42,041</u>
Note payable, net of discount	24,648	—
Operating lease liabilities, net of current portion	15,676	—
Lease incentive obligation, net of current portion	—	6,776
Deferred rent	—	2,216
Deferred revenue, net of current portion - related party	89,111	116,840
Deferred revenue, net of current portion	4,834	—
Other long-term liabilities	502	644
Total liabilities	<u>180,764</u>	<u>168,517</u>
Commitments and contingencies		
Stockholders' (deficit):		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at December 31, 2019 and 2018; no shares issued and outstanding at December 31, 2019 and 2018	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized at December 31, 2019 and 2018; 70,143,252 and 40,936,735 shares issued and outstanding at December 31, 2019 and 2018	70	41
Additional paid-in capital	411,255	341,284
Accumulated other comprehensive income (loss)	—	—
Accumulated deficit	<u>(459,649)</u>	<u>(389,370)</u>
Total stockholders' deficit	<u>(48,324)</u>	<u>(48,045)</u>
Total liabilities and stockholders' deficit	<u>\$ 132,440</u>	<u>\$ 120,472</u>

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

	Year Ended December 31,		
	2019	2018	2017
Revenue:			
Collaboration revenue - related party	\$ 27,188	\$ 26,917	\$ 32,100
Grant revenue	1,102	1,350	—
Collaboration revenue	6,215	—	—
Total revenue	<u>34,505</u>	<u>28,267</u>	<u>32,100</u>
Operating expenses:			
Research and development expenses	\$ 80,141	\$ 95,955	\$ 89,455
General and administrative expenses	24,748	32,596	34,040
Restructuring expenses	1,492	—	—
Total operating expenses	<u>106,381</u>	<u>128,551</u>	<u>123,495</u>
Loss from operations	<u>(71,876)</u>	<u>(100,284)</u>	<u>(91,395)</u>
Other income (expense):			
Interest income	1,033	1,172	1,590
Interest expense	(502)	—	—
Other income	1,066	170	425
Total other income (expense), net	<u>1,597</u>	<u>1,342</u>	<u>2,015</u>
Net loss	<u>\$ (70,279)</u>	<u>\$ (98,942)</u>	<u>\$ (89,380)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (1.24)</u>	<u>\$ (2.43)</u>	<u>\$ (2.21)</u>
Weighted average common shares outstanding, basic and diluted	<u>56,649,220</u>	<u>40,743,492</u>	<u>40,449,410</u>
Other comprehensive income (loss):			
Unrealized gain (loss) on investments, net of tax of \$0	—	146	3
Total other comprehensive income (loss)	<u>—</u>	<u>146</u>	<u>3</u>
Comprehensive loss	<u>\$ (70,279)</u>	<u>\$ (98,796)</u>	<u>\$ (89,377)</u>

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