

**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): August 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)

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 August 6, 2019, Seres Therapeutics, Inc. (the “Company”) announced its financial results for the quarter ended June 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 August 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: August 6, 2019

By: /s/ Thomas J. DesRosier

Name: Thomas J. DesRosier

Title: Chief Legal Officer and Executive Vice President



Seres Therapeutics Reports Second Quarter Financial Results and Provides Progress Update

- Four significant microbiome program milestones expected during 2020, including readouts from two late-stage development programs –
- Completed public offering of common stock, raising net proceeds of \$61M and extending the operating runway into 2021 –
- Conference call at 8:00 a.m. ET today –

CAMBRIDGE, Mass., Aug. 6, 2019 — Seres Therapeutics, Inc. (Nasdaq: MCRB) today reported second quarter 2019 financial results and provided business updates.

“We remain focused on the execution of our clinical programs and we look forward to a data-rich 2020 with four significant expected milestones including: SER-287 Phase 2b readout in mild-to-moderate ulcerative colitis; SER-109 Phase 3 readout in recurrent *C. difficile* infection; SER-401 Phase 1b readout in metastatic melanoma; and the advancement of our rationally-designed, fermented SER-301 program into clinical development for ulcerative colitis,” said Eric D. Shaff, President and Chief Executive Officer at Seres. “We are also pleased to have strengthened Seres’ balance sheet through a public equity offering, giving us the resources needed to operate the Company into 2021 and to reach multiple important value inflection points,” continued Mr. Shaff.

Program Updates and Corporate Highlights

- **SER-287 Phase 2b ECO-RESET study in ulcerative colitis:** SER-287 is an oral, donor-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 was initiated in December 2018 and is expected to enroll approximately 201 patients with mild-to-moderate ulcerative colitis. 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. Seres expects to report Phase 2b ECO-RESET study top line results in the third quarter of 2020.
- **SER-109 Phase 3 ECOSPOR III study in recurrent *C. difficile* infection:** SER-109 is an oral, donor-derived 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. ECOSPOR III is designed to evaluate 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. Seres expects to report SER-109 ECOSPOR III top line study results in early 2020.

- **SER-401 Phase 1b in metastatic melanoma:** SER-401 is an oral, donor-derived microbiome therapeutic candidate comprising a bacterial signature similar to that observed in checkpoint inhibitor immunotherapy responders. 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 augment response to nivolumab, an approved anti-PD-1 checkpoint inhibitor therapy, and will assess a variety of biological measures of response. Seres expects to obtain SER-401 Phase 1b preliminary study results in the second half of 2020.
- **SER-301 preclinical candidate:** Seres also continues to advance its rationally-designed, fermented microbiome drug discovery and development capabilities. These efforts are focused on advancing SER-301, a preclinical therapeutic candidate for ulcerative colitis, into clinical development. The Company is entitled to a \$10 million milestone payment associated with the initiation of SER-301 clinical development from its ongoing collaboration with Nestlé Health Science. Seres expects to file an Investigational New Drug (IND) application and initiate clinical development for SER-301 in early 2020.
- **Public equity offering (June 2019):** Seres completed a public equity offering of common stock, resulting in net proceeds of \$60.6 million. The financing involved both new and existing investors, including from a new fund managed by Flagship Pioneering.
- **Appointment of Stephen Berenson to its Board of Directors (August 2019):** Mr. Berenson is a managing partner at Flagship Pioneering and previously spent his career as an investment banker at J.P. Morgan.

Financial Results

Seres reported a net loss of \$10.8 million for the second quarter of 2019, as compared to a net loss of \$27.8 million for the same period in 2018. The second quarter net loss was driven primarily by clinical and development expenses, personnel expenses and ongoing development of the Company's microbiome therapeutics platform. The second quarter net loss figure was inclusive of \$12.5 million in recognized revenue associated primarily with the Company's collaborations with Nestlé Health Science and AstraZeneca.

Research and development expenses for the second quarter of 2019 were \$17.9 million, as compared to \$24.1 million for the same period in 2018. 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 second quarter of 2019 were \$5.6 million, as compared to \$8.7 million for the same period in 2018. General and administrative expenses were primarily due to headcount, professional fees and facility costs.

Seres ended the second quarter with approximately \$102.2 million in cash and cash equivalents that included the first of three \$6.7 million annual installment payments due under the terms of the collaboration with AstraZeneca. In June 2019 the Company completed a public equity offering of common stock, resulting in net proceeds of \$60.6M.

Cash use in the second quarter declined relative to prior periods as a result of the cost cutting corporate changes implemented earlier this year. Seres expects the lower expense levels incurred this quarter to be a proxy for subsequent quarters leading up to the clinical readouts expected in 2020. 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 first quarter of 2021.

Conference Call Information

Seres' management will host a conference call today, Aug. 6, 2019, at 8:00 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 7773387. 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. 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, Seres' plan to file an IND application for SER-301, the receipt of future milestone payments, the potential impact of any of Seres' development candidates, the reduction in patient enrollment in the SER-109 Phase 3 trial leading to expedited results, 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 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on May 2, 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>June 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 102,230	\$ 85,820
Prepaid expenses and other current assets	5,160	6,845
Accounts receivable	1,604	—
Total current assets	<u>108,994</u>	<u>92,665</u>
Property and equipment, net	22,945	26,294
Operating lease assets	12,640	—
Restricted investments	1,400	1,400
Restricted cash	114	113
Total assets	<u>\$ 146,093</u>	<u>\$ 120,472</u>
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 4,764	\$ 6,415
Accrued expenses and other current liabilities	10,589	15,207
Operating lease liabilities	4,449	—
Deferred revenue - related party	20,582	20,419
Deferred revenue	2,689	—
Total current liabilities	<u>43,073</u>	<u>42,041</u>
Operating lease liabilities, net of current portion	17,969	—
Lease incentive obligation, net of current portion	—	6,776
Deferred rent	—	2,216
Deferred revenue, net of current portion - related party	99,608	116,840
Deferred revenue, net of current portion	2,752	—
Other long-term liabilities	659	644
Total liabilities	<u>164,061</u>	<u>168,517</u>
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at June 30, 2019 and December 31, 2018; no shares issued and outstanding at June 30, 2019 and December 31, 2018	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized at June 30, 2019 and December 31, 2018; 69,913,410 and 40,936,735 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	70	41
Additional paid-in capital	406,424	341,284
Accumulated deficit	<u>(424,462)</u>	<u>(389,370)</u>
Total stockholders' deficit	<u>(17,968)</u>	<u>(48,045)</u>
Total liabilities and stockholders' deficit	<u>\$ 146,093</u>	<u>\$ 120,472</u>

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Revenue:				
Collaboration revenue - related party	\$ 10,454	\$ 4,271	\$ 17,069	\$ 8,037
Grant revenue	260	341	706	546
Revenue	<u>1,817</u>	<u>—</u>	<u>2,077</u>	<u>—</u>
Total revenue	<u>12,531</u>	<u>4,612</u>	<u>19,852</u>	<u>8,583</u>
Operating expenses:				
Research and development expenses	17,905	24,053	40,792	47,513
General and administrative expenses	5,574	8,695	13,069	17,472
Restructuring expenses	—	—	1,492	—
Total operating expenses	<u>23,479</u>	<u>32,748</u>	<u>55,353</u>	<u>64,985</u>
Loss from operations	<u>(10,948)</u>	<u>(28,136)</u>	<u>(35,501)</u>	<u>(56,402)</u>
Other income (expense):				
Interest income (expense), net	189	349	409	696
Total other income (expense), net	<u>189</u>	<u>349</u>	<u>409</u>	<u>696</u>
Net loss	<u>\$ (10,759)</u>	<u>\$ (27,787)</u>	<u>\$ (35,092)</u>	<u>\$ (55,706)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.24)</u>	<u>\$ (0.68)</u>	<u>\$ (0.81)</u>	<u>\$ (1.37)</u>
Weighted average common shares outstanding, basic and diluted	<u>45,140,830</u>	<u>40,661,464</u>	<u>43,095,686</u>	<u>40,645,040</u>
Net loss	<u>(10,759)</u>	<u>(27,787)</u>	<u>(35,092)</u>	<u>(55,706)</u>
Other comprehensive income:				
Unrealized gain on investments, net of tax of \$0	\$ —	\$ 77	\$ —	\$ 117
Total other comprehensive income	<u>—</u>	<u>77</u>	<u>—</u>	<u>117</u>
Comprehensive loss	<u>\$ (10,759)</u>	<u>\$ (27,710)</u>	<u>\$ (35,092)</u>	<u>\$ (55,589)</u>

IR and PR Contact

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