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): May 7, 2020

SERES THERAPEUTICS, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-37465**	**27-4326290**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

200 Sidney Street **Cambridge, MA**	**02139**
(Address of Principal Executive Offices)	**(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))

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**

Item 2.02. Results of Operations and Financial Condition.

On May 7, 2020, Seres Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2020 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 No.	Description
99.1	Press Release issued on May 7, 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: May 7, 2020

By: /s/ Thomas J. DesRosier
Name: Thomas J. DesRosier
Title: Chief Legal Officer and Executive Vice President

Seres Therapeutics Reports First Quarter 2020 Financial Results and Provides Business Updates

– Data from Phase 3 study of SER-109 in recurrent C. difficile infection expected mid-2020; Potential to be the single pivotal study supporting product registration with the FDA –

– Webcast SER-109 investor event to be held May 27 –

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

CAMBRIDGE, Mass., May 7, 2020 — Seres Therapeutics, Inc. (Nasdaq: MCRB) today reported financial results from the first quarter ended March 31, 2020 and provided an operational update.

"We were pleased to have recently achieved the important milestone of completing enrollment of our SER-109 Phase 3 ECOSPOR III clinical study in recurrent *C. difficile* infection, and we look forward to topline results from this study mid-year. In preparation for successful SER-109 clinical data, we are working to prepare for a potential FDA regulatory submission and executing commercial readiness activities," said Eric D. Shaff, President and Chief Executive Officer at Seres. "During the last several months, the COVID-19 pandemic has presented unprecedented challenges around the world. Amidst the complexity of the current environment, we are very pleased to be advancing toward our Phase 3 data on plan and on time. We continue to monitor the impact on Company operations and are carefully reviewing our development plans, including for our ongoing SER-287 and SER-401 studies. Our objective is to advance these programs toward meaningful, clinically interpretable data readouts as rapidly as possible."

Program Updates and Corporate Highlights

Corporate impact of COVID-19: Seres is closely monitoring how the COVID-19 pandemic is affecting the Company and a number of actions have been implemented to protect employee safety and continuation of business operations. Administrative employees continue their work from home, while laboratory research and development activity remains ongoing, with modifications made to prioritize employee safety.

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 (CDI).

This first-in-field microbiome therapeutic candidate has been granted Orphan Drug and Breakthrough Therapy designations by the U.S. Food and Drug Administration (FDA).

On March 30, Seres reported the completion of enrollment in the Phase 3 ECOSPOR III study (ClinicalTrials.gov identifier: NCT03183128), a multicenter, randomized 1:1, placebo-controlled study in patients with multiply recurrent CDI. ECOSPOR III has enrolled 182 patients.

All enrolled patients are required to undergo a rigorous *C. difficile* cytotoxin diagnostic test to confirm active CDI, both at entry into the study and to confirm recurrence of *C. difficile* infection during the study. The primary endpoint of ECOSPOR III is the reduction of CDI recurrence at up to eight weeks following SER-109 administration.

The FDA has issued several safety alerts related to fecal microbiota transplantation (FMT) and the risk of pathogen transmission including warnings related to multi-drug resistant organisms (MDROs) and SARS-CoV-2, the virus linked to COVID-19 (including: June 18, 2019 Alert; March 12, 2020 Alert; and March 23, 2020 Alert; April 9, 2020 Alert). Unapproved FMT is widely used under an FDA Enforcement Discretion policy for the treatment of recurrent CDI that is not responsive to standard therapies.

SER-109 is fundamentally distinct from FMT and is comprised of a highly purified consortia of spore-based commensal bacteria and manufactured under Good Manufacturing Practices (GMP) conditions using stringent standards to ensure product quality and consistency. To maximize product safety, Seres utilizes a unique manufacturing process that inactivates numerous potential pathogens, including species of non-spore bacteria, such as *Escherichia coli*, and viruses such as SARS-CoV-2.

Seres expects to report top-line results from ECOSPOR III in mid-2020. Based on prior discussions with the FDA, Seres believes that ECOSPOR III has the potential to be the single pivotal study supporting product registration; however, this will 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.

The SER-287 Phase 2b ECO-RESET induction study in patients with active mild-to-moderate ulcerative colitis remains ongoing. COVID-19 has impacted clinical operations and slowed enrollment. Seres has implemented a number of mitigation strategies to continue operational progress, including providing increased clinical support to clinical sites and additional flexibility regarding data capture. The Company is also evaluating various options consistent with the goal of obtaining a high-quality, clinically meaningful dataset.

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. Innovative, novel manufacturing methods have been utilized to produce SER-301. The composition includes strains delivered in spore form, as well as strains fermented in non-spore, vegetative form and delivered using enterically-protected technology designed to release in the colon. 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 improve epithelial barrier integrity in patients with ulcerative colitis.

The Company has initiated clinical development and continues to execute on activities for a SER-301 Phase 1 study in patients with ulcerative colitis. The study is planned to enroll subjects in Australia and New Zealand later this year. Seres is entitled to receive a $10 million milestone payment associated with the Phase 1 SER-301 clinical study initiation from Nestlé Health Science, the Company's collaborative partner for this program.

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.

SER-155 composition selected: Seres has advanced SER-155, a rationally designed, fermented microbiome therapeutic toward clinical development. SER-155 is designed to prevent mortality due to gastrointestinal infections, bacteremia and graft versus host disease (GvHD) in immunocompromised patients, including in patients receiving allogeneic hematopoietic stem cell transplantation. SER-155 is a consortium of bacterial species that incorporates biomarkers from human clinical data and preclinical assessment using human cell-based assays and *in vivo* disease models. The composition is designed to decrease infection and translocation of antibiotic resistant bacteria in the gastrointestinal tract, and modulate host immune responses to decrease GvHD.

The SER-155 program is supported by a CARB-X grant that provides financial and operational support through Phase 1b clinical development. The Company intends to move SER-155 into a Phase 1b study later this year in collaboration with Memorial Sloan Kettering Cancer Center.

Chief Medical Officer appointment: In April, Series announced that Lisa von Moltke, M.D., FCP, was appointed as Executive Vice President and Chief Medical Officer. Dr. von Moltke joins Seres with an extensive career that includes senior leadership positions at Alkermes, Sanofi Genzyme and Millennium Pharmaceuticals/Takeda Oncology.

Board of Directors appointment: In March, Seres announced that Paul Biondi, Executive Partner at Flagship Pioneering, was appointed to its Board of Directors.

Upcoming investor events: Seres plans to hold a webcast conference call on May 27, 2020 with a focus on the SER-109 program ahead of the Phase 3 ECOSPOR III study readout. Further details will be provided closer to the event. The Company also plans to participate in the Jefferies 2020 Healthcare Conference in early June.

Financial Results

Seres reported a net loss of $19.9 million for the first quarter of 2020, as compared with a net loss of $24.3 million for the same period in 2019. The first quarter net loss was driven primarily by clinical and development expenses, personnel expenses and ongoing development of the Company's microbiome therapeutics platform. The first quarter net loss was inclusive of $8.2 million in recognized revenue associated primarily with the Company's collaborations with Nestlé Health Science and AstraZeneca.

Research and development expenses for the first quarter of 2020 were $21.7 million, compared with $22.9 million for the same period in 2019. The research and development expenses were primarily related to Seres' late stage SER-109 and SER-287 clinical development programs.

General and administrative expenses for the first quarter of 2020 were $6.1 million, compared with $7.5 million for the same period in 2019. General and administrative expenses were primarily due to headcount, professional fees and facility costs.

Seres ended the first quarter with approximately $75.1 million in cash, cash equivalents and investments compared with $94.8 million at December 31, 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, May 7, 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 9143286. 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 approximately 21 days.

Seres also plans to hold a webcast conference call on May 27, 2020 with a focus on the SER-109 program. Further details will be provided closer to the event.

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-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' 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 developing SER-401 in a Phase 1b study in patients with metastatic melanoma, SER-301 for ulcerative colitis, and SER-155 to prevent mortality due to gastrointestinal infections, bacteremia and graft versus host disease. 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 potential impact of the COVID-19 pandemic, 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-K filed with the Securities and Exchange Commission, or SEC, on March 2, 2020, our Current Report on form 8-K filed with the SEC on March 18, 2020, 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)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 54,857	$ 65,126
Investments	20,237	29,690
Prepaid expenses and other current assets	3,385	3,588
Accounts receivable	2,084	1,785
Total current assets	80,563	100,189
Property and equipment, net	17,836	19,495
Operating lease assets	10,820	11,356
Restricted investments	1,400	1,400
Total assets	$ 110,619	$ 132,440
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 5,521	$ 4,859
Accrued expenses and other current liabilities	9,141	10,884
Operating lease liabilities	4,623	4,456
Deferred revenue - related party	19,974	20,960
Deferred revenue	4,855	4,834
Total current liabilities	44,114	45,993
Note payable, net of discount	24,754	24,648
Operating lease liabilities, net of current portion	14,444	15,676
Deferred revenue, net of current portion - related party	84,635	89,111
Deferred revenue, net of current portion	3,641	4,834
Other long-term liabilities	680	502
Total liabilities	172,268	180,764
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2020 and December 31, 2019; no shares issued and outstanding at March 31, 2020 and December 31, 2019.	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at March 31, 2020 and December 31, 2019; 71,671,067 and 70,143,252 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	72	70
Additional paid-in capital	417,819	411,255
Accumulated other comprehensive income (loss)	(10)	—
Accumulated deficit	(479,530)	(459,649)
Total stockholders' deficit	(61,649)	(48,324)
Total liabilities and stockholders' deficit	$ 110,619	$ 132,440

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

	Three Months Ended March 31,	
	2020	2019
Revenue:		
Collaboration revenue - related party	$ 5,462	$ 6,615
Grant revenue	739	446
Collaboration revenue	1,988	260
Total revenue	8,189	7,321
Operating expenses:		
Research and development expenses	21,743	22,887
General and administrative expenses	6,138	7,495
Restructuring expenses	—	1,492
Total operating expenses	27,881	31,874
Loss from operations	(19,692)	(24,553)
Other income (expense):		
Interest income	159	220
Interest expense	(716)	—
Other income	368	—
Total other income (expense), net	(189)	220
Net loss	$ (19,881)	$ (24,333)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.28)	$ (0.59)
Weighted average common shares outstanding, basic and diluted	70,821,514	41,027,824
Net loss	(19,881)	(24,333)
Other comprehensive loss:		
Unrealized loss on investments, net of tax of $0	$ (10)	$ —
Total other comprehensive loss	(10)	—
Comprehensive loss	$ (19,891)	$ (24,333)

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