
**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 2, 2018

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))
-
-

Item 2.02. Results of Operations and Financial Condition.

On August 2, 2018, Seres Therapeutics, Inc. (the “Company”) announced its financial results for the quarter ended June 30, 2018. 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 2, 2018

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 2, 2018

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 Operational Updates

- *Company preparing to initiate SER-287 Phase 2b study for ulcerative colitis -*
- *Initiation of SER-401 clinical study expected in patients with metastatic melanoma treated with checkpoint inhibitors by year end -*
- *Recent Seres R&D event highlighted microbiome scientific leadership across several clinical and preclinical programs -*
- *Conference call at 8:30 a.m. ET today -*

CAMBRIDGE, Mass., August 2, 2018 — Seres Therapeutics, Inc. (NASDAQ:MCRB) today reported second quarter 2018 financial results and provided an operational update.

“Seres has made excellent progress across our deep pipeline of early and late, clinical and preclinical stage microbiome programs, and we were pleased to demonstrate the depth of our scientific leadership in this new therapeutic modality at our recent investor R&D event highlighting how we can change immunological tone using microbiome drugs.” said Roger J. Pomerantz, M.D., President, CEO and Chairman of Seres. “We continue to execute our SER-109 Phase 3 clinical study in patients with multiply-recurrent *C. difficile* infection. Following constructive meetings with the FDA, we are nearing initiation of a SER-287 Phase 2b clinical study in patients with active mild-to-moderate ulcerative colitis. Based on our FDA interactions, we expect the SER-287 Phase 2b study could be a pivotal trial that may serve as one of two required studies for product registration. We are also advancing work with our collaborators at MD Anderson Cancer Center and the Parker Institute for Immunotherapy to begin a Phase 1b study with SER-401 by year end to assess the potential for this microbiome therapy to augment clinical responses to checkpoint inhibitors in patients with metastatic melanoma.”

Recent Highlights and Events

- **New analysis of clinical samples and preclinical data presented at May 24th R&D event:** Seres provided an overview of its R&D approach to developing novel microbiome therapeutics and presented new scientific data regarding its scientific platform and its clinical and preclinical stage programs. Data were presented highlighting two bacterial pathways involving bile acid and tryptophan metabolism that modulate the immune

system and were correlated with clinical outcome in the SER-287 Phase 1b study. Recent transcriptomic data from mucosal biopsies taken before and after SER-287 administration provides additional clinical evidence linking SER-287 administration to the modulation of host pathways, including innate immune signaling, epithelial barrier integrity, antibacterial defenses, and short chain fatty acid metabolism. Seres remains the only company with human clinical microbiome data sets, which are critical in determining mechanism of action, and the rational design of follow-on drugs. Seres also provided an overview of the published clinical data from its collaborators at MD Anderson Cancer Center and its own pre-clinical data supporting the potential for microbiome therapeutics to augment checkpoint inhibitor drugs in the PD-(L)1 pathway. The R&D day presentation is available on the Investor & Media section of Seres' website and is expected to be archived for at least the next 21 days.

- **SER-287 late stage development activity:** The Company expects to initiate the planned SER-287 Phase 2b clinical study in patients with active mild-to-moderate ulcerative colitis (UC) in the coming months. The SER-287 Phase 1b placebo-controlled induction study of 58 patients with mild-to-moderate active UC who were failing current therapies demonstrated that SER-287 administration resulted in a dose-dependent improvement of both clinical remission rates and endoscopic scores. The SER-287 safety and tolerability profile was favorable, with no imbalance in adverse events in patients treated with SER-287, as compared to placebo. Analyses of study microbiome data demonstrated that SER-287 induced dose-dependent engraftment of SER-287-derived bacterial species and identified specific bacterial signatures linked to remission. SER-287 has been granted Orphan Drug Designation by the Food & Drug Administration (FDA) for the treatment of UC in pediatric patients.
- **Digestive Disease Week 2018 conference attendance:** Seres presented various data sets and held a scientific symposium highlighting SER-287 clinical and microbiome results as well as the promise of microbiome therapeutics for UC, and other forms of inflammatory bowel disease.
- **Continued execution of the SER-109 ECOSPOR III Phase 3 study:** Seres continues to enroll its SER-109 Phase 3 clinical study in patients with multiply-recurrent *C. difficile* infection, at sites in both the U.S. and Canada. Several factors have impacted enrollment including primary use of *C. difficile* toxin testing to increase the accuracy of proper patient inclusion, the widespread availability of unapproved and unregulated fecal microbiota transplantation, and the fact that multiply recurrent *C. difficile* infection is an orphan disease. It remains premature to provide an estimate for the timing of study enrollment completion. The Company has made various operational changes to further expedite study execution. ECOSPOR III has been designated a Phase 3 trial and the Company expects that this single pivotal study could support SER-109 registration and approval. SER-109 has been designated by the FDA as a Breakthrough Therapy and has also been given Orphan Drug Designation.
- **Preparations for SER-401 immuno-oncology clinical study:** In collaboration with the Parker Institute for Cancer Immunotherapy and MD Anderson Cancer Center, Seres is preparing to initiate a clinical study later this year to evaluate the potential for SER-401, a microbiome therapy, to augment checkpoint inhibitor response in patients with metastatic melanoma. We expect this to be the first microbiome drug study in the Immuno-oncology therapeutic area.

- **Completion of SER-262 clinical study:** Seres obtained clinical data from the final patient cohort (cohort 8 of 8) of the SER-262 Phase 1b study in patients with primary *C. difficile* infection. SER-262 is the first rationally-designed, fermented microbiome therapeutic candidate to be evaluated in clinical development. The full study clinical data remains consistent with the top line results from the first 7 cohorts which have previously been reported. The observed recurrence rate of *C. difficile* was statistically significantly lower in patients treated with vancomycin and SER-262, as compared to those patients treated with metronidazole and SER-262. Phase 1b microbiome data suggest that treatment with vancomycin, followed by SER-262, results in more robust and kinetically more rapid engraftment, and thus may lead to corresponding clinical efficacy. Microbiome and metabolomic analyses from the study remain ongoing. Seres plans to present full study results at an upcoming medical conference.

Financial Results

Seres reported a net loss of \$27.8 million for the second quarter of 2018, as compared to a net loss of \$28.0 million for the same period in 2017. 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 \$4.6 million in recognized revenue primarily associated with the Company's collaboration with Nestlé Health Science.

Research and development expenses for the second quarter were \$24.1 million, as compared to \$23.1 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, SER-262 and SER-287, as well as the Company's SER-301, SER-155 and immuno-oncology preclinical programs.

General and administrative expenses for the second quarter were \$8.7 million, as compared to \$8.4 million for the same period in the prior year. General and administrative expenses were primarily due to headcount, professional fees, and facility costs.

The decrease in cash, cash equivalents and investments balance during the quarter was \$26.1 million. Seres ended the second quarter with approximately \$96.1 million in cash, cash equivalents and investments. Current resources are expected to fund the Company into the second quarter of 2019. This estimate does not include a \$20.0 million milestone payment that the Company expects to receive with the start of the SER-287 Phase 2b study.

Conference Call Information

Seres' management will host a conference call today, August 2, 2018, 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 8181429. Accompanying slides will be made available on the Seres website prior to the call. 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' lead 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 multiply recurrent *C. difficile* infection. SER-287 has successfully completed a Phase 1b study in patients with mild-to-moderate ulcerative colitis. Seres is developing SER-262, the first ever synthetic microbiome therapeutic candidate, in a Phase 1b study in patients with primary *C. difficile* infection. Seres is also developing SER-401 to augment the efficacy of immuno-oncology treatment. For more information, please visit www.serestherapeutics.com. Follow us on Twitter @SeresTx.

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 May 9, 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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands, except share and per share data)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 57,960	\$ 36,088
Investments	38,106	113,895
Prepaid expenses and other current assets	5,471	5,095
Total current assets	101,537	155,078
Property and equipment, net	29,904	32,931
Restricted cash	1,513	1,513
Total assets	<u>\$ 132,954</u>	<u>\$ 189,522</u>
Liabilities and Stockholders' Equity/(Deficit)		
Current liabilities:		
Accounts payable	\$ 5,158	\$ 7,033
Accrued expenses and other current liabilities	13,651	12,513
Deferred revenue - related party	17,962	12,079
Total current liabilities	36,771	31,625
Lease incentive obligation, net of current portion	8,119	8,989
Deferred Rent	2,231	2,233
Deferred revenue, net of current portion - related party	97,959	84,847
Other long-term liabilities	1,129	1,129
Total liabilities	<u>146,209</u>	<u>128,823</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at June 30, 2018 and December 31, 2017; no shares issued and outstanding at June 30, 2018 and December 31, 2017	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized at June 30, 2018 and December 31, 2017; 40,754,681 and 40,571,015 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	40	40
Additional paid-in capital	332,870	324,376
Accumulated other comprehensive loss	(29)	(146)
Accumulated deficit	(346,136)	(263,571)
Total stockholders' equity/(deficit)	<u>(13,255)</u>	<u>60,699</u>
Total liabilities and stockholders' equity	<u>\$ 132,954</u>	<u>\$ 189,522</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>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Revenue:				
Collaboration revenue - related party	\$ 4,271	\$ 3,014	\$ 8,037	\$ 6,029
Grant revenue	341	—	546	—
Total revenue	<u>4,612</u>	<u>3,014</u>	<u>8,583</u>	<u>6,029</u>
Operating expenses:				
Research and development expenses	24,053	23,060	47,513	43,203
General and administrative expenses	8,695	8,370	17,472	17,132
Total operating expenses	<u>32,748</u>	<u>31,430</u>	<u>64,985</u>	<u>60,335</u>
Loss from operations	<u>(28,136)</u>	<u>(28,416)</u>	<u>(56,402)</u>	<u>(54,306)</u>
Other income (expense):				
Interest income	349	615	696	1,390
Other income (expense)	—	(217)	—	(576)
Total other income, net	<u>349</u>	<u>398</u>	<u>696</u>	<u>814</u>
Net loss	<u>\$ (27,787)</u>	<u>\$ (28,018)</u>	<u>\$ (55,706)</u>	<u>\$ (53,492)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.68)</u>	<u>\$ (0.69)</u>	<u>\$ (1.37)</u>	<u>\$ (1.32)</u>
Weighted average common shares outstanding, basic and diluted	<u>40,661,464</u>	<u>40,394,605</u>	<u>40,645,040</u>	<u>40,381,643</u>
Other comprehensive (loss) income:				
Unrealized (loss) gain on investments, net of tax of \$0	77	\$ (25)	\$ 117	\$ (27)
Total other comprehensive (loss) income	<u>77</u>	<u>(25)</u>	<u>117</u>	<u>(27)</u>
Comprehensive loss	<u>\$ (27,710)</u>	<u>\$ (28,043)</u>	<u>\$ (55,589)</u>	<u>\$ (53,519)</u>

IR or PR Contact:

Carlo Tanzi, Ph.D., Seres Therapeutics, 617-203-3467
Vice President, Investor Relations and Corporate Communications
ctanzi@serestherapeutics.com

###