



## Seres Therapeutics Reports First Quarter 2017 Financial Results and Provides Update on Operational Progress

May 4, 2017

- Pre-enrollment activities underway for SER-109 ECOSPOR III clinical study initiation; Company expects study start in mid-year -
- Continued pipeline progress with both SER-287 and SER-262 Phase 1b studies; Data read-outs expected in the second half of 2017 -
- Conference call at 8 a.m. ET today -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 4, 2017-- [Seres Therapeutics Inc.](#) (NASDAQ:MCRB) today reported first quarter 2017 financial results and provided a progress update on multiple microbiome clinical programs, including three clinical-stage therapeutic candidates seeking to address serious human diseases.

"Seres is making strong progress throughout our broad pipeline of microbiome therapeutics," said Roger J. Pomerantz, M.D., President, CEO and Chairman of Seres. "Following positive feedback from the FDA, we are working to rapidly initiate the SER-109 ECOSPOR III clinical study, and we expect study start in mid-year. This trial could potentially serve as the basis for the approval of SER-109, which may represent the first approved microbiome therapeutic. In addition, we have advanced our Phase 1b study of SER-287 in patients with ulcerative colitis, as well as our Phase 1b study of SER-262 in patients with primary *C. difficile* infection. We look forward to a highly data rich period ahead, with readouts from both the SER-287 and SER-262 studies expected in the second half of 2017."

### Recent Highlights and Events

- **SER-109 ECOSPOR III clinical study planning following positive Type B meeting with FDA:** Seres plans to initiate a new SER-109 clinical study (ECOSPOR III) in approximately 320 patients with multiply recurrent *Clostridium difficile* (*C. difficile*) infection. Study participants will be randomized 1:1 between SER-109 and placebo. Diagnosis of *C. difficile* infection for both study entry and for endpoint analysis will be confirmed by *C. difficile* cytotoxin assays. Patients in the SER-109 arm will receive a total SER-109 dose, administered over three days, approximately 10-fold higher than the dose used in the prior ECOSPOR study. ECOSPOR III will evaluate patients for 24 weeks and the primary endpoint will compare the *C. difficile* recurrence rate in subjects who receive SER-109 versus placebo at up to eight weeks after dosing. The FDA has agreed that this new trial may qualify as a pivotal study with achievement of a persuasive clinical effect and addressing FDA requirements, including clinical and statistical factors, an adequately sized safety database, and certain CMC parameters.

The ECOSPOR III study protocol has been finalized, and the protocol has already been cleared by several institutional review boards. Seres has completed substantial clinical site feasibility work and has selected the large majority of ECOSPOR III investigator sites. ECOSPOR III subjects will include *C. difficile* patients being treated as outpatients, as well as those treated as inpatients located in hospitals, rehabilitation facilities and long term care facilities. Seres plans to utilize over 100 clinical sites in both the U.S. and Canada. The company expects to initiate ECOSPOR III in mid 2017.

- **Medical meeting oral presentation:** Michele Trucks, M.D., Ph.D., Executive Vice President and Chief Medical Officer, delivered an oral presentation: SERES-004: *First placebo-controlled trial of an investigational oral microbiome drug (SER-109) to reduce recurrence of Clostridium difficile infection* at the 27th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) meeting in Vienna, Austria on April 22, 2017.
- **SER-287 Phase 1b study progress:** Seres is advancing the SER-287 Phase 1b clinical study in subjects with mild-to-moderate ulcerative colitis, failing first line therapies. SER-287 is a biologically sourced Ecobiotic® microbiome therapeutic candidate. Seres activated additional SER-287 Phase 1b study clinical sites and the study enrolled an increasing number of subjects. Study results continue to be expected in the second half of 2017.
- **SER-262 Phase 1b study progress:** Seres is advancing the SER-262 Phase 1b clinical study in patients with primary *C. difficile* infection. SER-262, an Ecobiotic®, rationally-designed, fermented microbiome therapeutic candidate, is the first synthetically-derived and designed microbiome therapeutic candidate to reach clinical-stage development. Additional SER-262 Phase 1b study subjects were enrolled. Top-line data for SER-262 continues to be expected in the second half of 2017.

## **Financial Results**

Seres reported a net loss of \$25.5 million for the first quarter of 2017, as compared to a net loss of \$19.7 million for the same period in 2016. The increase in first quarter net loss was driven primarily by continued growth in clinical and development expenses as well as increased headcount, and ongoing development of the Company's microbiome therapeutics platform. The first quarter net loss figure was inclusive of \$3.0 million in revenue recognized associated with the Company's collaboration with Nestlé Health Science.

Research and development expenses for the first quarter were \$20.1 million, as compared to \$15.4 million for the same period in 2016. The increase in research and development expense was primarily due to expenses related to our microbiome therapeutics platform, the clinical development of SER-109, SER-262 and SER-287, as well as the Company's preclinical programs.

General and administrative expenses for the first quarter were \$8.8 million, as compared to \$7.2 million for the same period in the prior year. The increase in general and administrative expense was primarily due to increased headcount, an increase in professional fees, and facility expansion to support overall growth.

The decrease in cash balance during the quarter was \$27.8 million. Seres ended the first quarter with approximately \$202.2 million in cash, cash equivalents and investments.

## **Conference Call Information**

Seres' management will host a conference call today, May 4, 2017, 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 11167224. To join the live webcast please visit the "Investors and Media" section of the Seres website at [www.serestherapeutics.com](http://www.serestherapeutics.com).

## **About Seres Therapeutics**

Seres Therapeutics, Inc. 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 natural state of bacterial diversity and function is imbalanced. The Phase 2 study of Seres' program SER-109 has been completed in multiply recurrent *Clostridium difficile* infection. Seres' second clinical candidate, SER-287, is being evaluated in a Phase 1b study in patients with mild-to-moderate ulcerative colitis (UC). Seres is also developing SER-262, the first ever synthetic microbiome therapeutic candidate, in a Phase 1b study in patients with primary CDI. For more information, please visit [www.serestherapeutics.com](http://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 without limitation statements regarding the timing, design, and potential results of the ECOSPOR III study for SER-109, the potential for the ECOSPOR III study to qualify as a pivotal study, the timing and results of our clinical trials, and dysbiosis as an underlying cause of disease.

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, which may not be available; our limited operating history; the unpredictable nature of our early stage development efforts for marketable drugs; the unproven approach to therapeutic intervention of our microbiome therapeutics; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; potential delays in enrollment of patients which could affect the receipt of necessary regulatory approvals; potential delays in regulatory approval, which would impact the ability to commercialize our product candidates and affect our ability to generate revenue; any fast track or Breakthrough Therapy designation may not lead to faster development, regulatory approval or marketing approval; our possible inability to receive orphan drug designation should we choose to seek it; our reliance on third parties to conduct our clinical trials and the potential for those third parties to not perform satisfactorily; our reliance on third parties to manufacture our product candidates, which may delay, prevent or impair our development and commercialization efforts; our lack of experience in manufacturing our product candidates; the potential failure of our product candidates to be accepted on the market by the medical community; our lack of experience selling, marketing and distributing products and our lack of internal capability to do so; failure to compete successfully against other drug companies; potential competition from biosimilars; failure to obtain marketing approval internationally; post-marketing restrictions or withdrawal from the market; anti-kickback, fraud, abuse, and other healthcare laws and regulations exposing us to potential criminal sanctions; recently enacted or future legislation; compliance with environmental, health, and safety laws and regulations; protection of our proprietary technology; protection of the confidentiality of our trade secrets; changes in United States patent law; potential lawsuits for infringement of third-party intellectual property; our patents being found invalid or unenforceable; compliance with patent regulations; claims challenging the inventorship or ownership of our patents and other intellectual property; claims asserting that we or our employees misappropriated a third-party's intellectual property or otherwise claiming ownership of what we regard as our intellectual property; adequate protection of our trademarks; ability to attract and retain key executives; managing our growth could result in difficulties; risks associated with international operations; potential system failures; the price of our common stock may fluctuate substantially; our executive officers, directors, and principal stockholders have the ability to control all matters submitted to the stockholders; a significant portion of our total outstanding shares are eligible to be sold into the market; unfavorable or lacking analyst research or reports; and we are currently subject to securities class action litigation. 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 16, 2017 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)

	March 31, 2017	December 31, 2016
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 41,899	\$ 54,539
Investments	145,174	138,704
Prepaid expenses and other current assets	5,188	5,126
Total current assets	<u>192,261</u>	<u>198,369</u>
Property and equipment, net	36,089	36,125
Long-term investments	15,099	36,752
Restricted cash	1,401	1,400
Total assets	<u>\$ 244,850</u>	<u>\$ 272,646</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	5,636	7,587
Accrued expenses and other current liabilities	9,550	10,812
Deferred revenue - related party	12,058	12,058
Total current liabilities	<u>27,244</u>	<u>30,457</u>
Lease incentive obligation, net of current portion	10,295	10,730
Deferred rent	2,117	2,072
Deferred revenue, net of current portion - related party	93,741	96,756
Total liabilities	<u>133,397</u>	<u>140,015</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at March 31, 2017 and December 31, 2016; no shares issued and outstanding at March 31, 2017 and December 31, 2016	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized at March 31, 2017 and December 31, 2016; 40,386,878 and 40,355,753 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	40	40
Additional paid-in capital	311,229	306,931
Accumulated other comprehensive income	(151)	(149)
Accumulated deficit	(199,665)	(174,191)
Total stockholders' equity	<u>111,453</u>	<u>132,631</u>
Total liabilities and stockholders' equity	<u>\$ 244,850</u>	<u>\$ 272,646</u>

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

	<b>Three Months Ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
Revenue:		
Collaboration revenue - related party	\$ 3,015	\$ 2,710
Total revenue	<u>3,015</u>	<u>2,710</u>
Operating expenses:		
Research and development expenses	\$ 20,143	\$ 15,416
General and administrative expenses	8,762	7,210
Total operating expenses	<u>28,905</u>	<u>22,626</u>
Loss from operations	(25,890)	(19,916)
Other income (expense):		
Interest income	775	268
Other income (expense):	(359)	(56)
Total other income, net	<u>416</u>	<u>212</u>
Net loss	<u>\$ (25,474)</u>	<u>\$ (19,704)</u>

Net loss per share attributable to common stockholders, basic and diluted	\$ (0.63)	\$ (0.50)
Weighted average common shares outstanding, basic and diluted	<u>40,368,536</u>	<u>39,186,130</u>
Other comprehensive (loss) income:		
Unrealized (loss) gain on investments, net of tax of \$0	(2)	78
Total other comprehensive (loss) income	(2)	78
Comprehensive loss	<u>\$ (25,476)</u>	<u>\$ (19,626)</u>

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Source: Seres Therapeutics Inc.

**IR or PR Contact:**

Seres Therapeutics  
 Carlo Tanzi, Ph.D., 617-203-3467  
 Head of Investor Relations and Corporate Communications  
[ctanzi@serestherapeutics.com](mailto:ctanzi@serestherapeutics.com)