



**SERES**  
THERAPEUTICS™

Leading the Microbiome Revolution

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

- Initiated SER-109 Phase 3 study in patients with multiply recurrent *C. difficile* infection -
- SER-287 Phase 1b study in mild-to-moderate ulcerative colitis patients, failing first line therapy, fully enrolled; Top-line data read-out expected in the second half of 2017 -
- Conference call at 8 a.m. ET today -

**CAMBRIDGE, Mass., August 3, 2017** — [Seres Therapeutics, Inc.](#) (NASDAQ:MCRB) today reported second 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 continues to make excellent progress advancing our pipeline of clinical stage microbiome therapeutic candidates, and we believe we are on track to develop SER-109 as the first FDA-approved microbiome product,” said Roger J. Pomerantz, M.D., President, CEO and Chairman of Seres. “We recently initiated the SER-109 Phase 3 study in patients with multiply recurrent *C. difficile* infection and are working with alacrity to enroll the study. This Phase 3 study is the first pivotal trial of a microbiome drug candidate in this new field of medicine. We have also now fully enrolled our Phase 1b study of SER-287, the first microbiome therapeutic candidate for a chronic disease, in patients with mild-to-moderate ulcerative colitis, who are failing first line therapy, and are looking forward to obtaining microbiome and clinical data from the SER-287 trial in the second half of 2017.”

### **Recent Highlights and Events**

- **SER-109 ECOSPOR III Phase 3 study initiation:** Seres has initiated a SER-109 Phase 3 clinical study (ECOSPOR III), designed to enroll approximately 320 patients with multiply recurrent *Clostridium difficile* (*C. difficile*) infection, at sites in both the U.S. and Canada. Based on interactions with the U.S. Food and Drug Administration (FDA), ECOSPOR III has been designated a Phase 3 trial and the Company expects that this single pivotal study may support SER-109 registration and approval, for this Breakthrough Therapy- and Orphan Drug- designated drug candidate. Study participants are randomized 1:1 between SER-109 and placebo. Diagnosis of *C. difficile* infection for both study entry and for endpoint analysis is being confirmed by *C. difficile* cytotoxin assay. Patients in the

SER-109 arm receive a total SER-109 dose, administered over three days, approximately 10-fold higher than the dose used in the prior Phase 2 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.

- **SER-287 Phase 1b study fully enrolled:** Seres completed enrollment of its ongoing SER-287 Phase 1b clinical study of 58 patients suffering from mild-to-moderate ulcerative colitis who are failing current first line therapies. SER-287 is a biologically sourced Ecobiotic® microbiome therapeutic candidate with the potential to offer ulcerative colitis patients a novel, non-immunosuppressive treatment option. Top line study results are expected in the second half of 2017.
- **SER-262 Phase 1b study progress:** Seres is advancing the SER-262 Phase 1b, dose-escalating, first-in-human, clinical study in patients with primary *C. difficile* infection. SER-262, a rationally-designed, fermented, Ecobiotic® microbiome therapeutic candidate, is the first synthetically-derived and designed microbiome therapeutic candidate to reach clinical-stage development. Top-line data from the study are expected in early 2018.
- **Appointment of Willard Dere, M.D., to the Seres Board of Directors:** Dr. Dere brings more than two decades of scientific, clinical and strategic biopharmaceutical experience. He is currently Professor of Internal Medicine, Executive Director of Personalized Health and Co-director of the Center for Clinical and Translational Sciences at the University of Utah Health Sciences Center. Previously, Dr. Dere served at Amgen, where he held several positions including Head of Global Development and for a decade, Chief Medical Officer. During his career in the biopharmaceutical industry, Dr. Dere led the clinical development of numerous approved products in diverse therapeutic areas, including osteoporosis, inflammation, nephrology and oncology.

## Financial Results

Seres reported a net loss of \$28.0 million for the second quarter of 2017, as compared to a net loss of \$27.9 million for the same period in 2016. 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 \$3.0 million in recognized revenue associated with the Company's collaboration with Nestlé Health Science.

Research and development expenses for the second quarter were \$23.1 million, as compared to \$22.2 million for the same period in 2016. 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 and SER-155 preclinical programs.

General and administrative expenses for the second quarter were \$8.4 million, as compared to \$9.0 million for the same period in the prior year. General and administrative expenses were primarily due to headcount, professional fees, and facility costs.

The Company expects to account for receipt of the previously disclosed \$20.0 million milestone payment associated with the start of the SER-109 Phase 3 study, under its collaboration agreement with Nestlé, in the third quarter of 2017.

The decrease in cash balance during the quarter was \$27.0 million. Seres ended the second quarter with approximately \$175.2 million in cash, cash equivalents and investments.

### **Conference Call Information**

Seres' management will host a conference call today, August 3, 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 62118608. 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. 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. Seres' clinical candidate SER-287 is being evaluated in a Phase 1b study in patients with mild-to-moderate ulcerative colitis. Seres is also developing SER-262, the first ever synthetic microbiome therapeutic candidate, in a Phase 1b study in patients with primary *C. difficile* infection. 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 of data for our clinical studies, the design of our clinical studies, whether we are on track in our clinical development plans, any potential approval or registration of our various therapeutic candidates, the objective for SER-109 to meaningfully reduce the risk of recurrence of *C. diff.* infection, the potential for SER-287 to offer a novel, non-immunosuppressive treatment option for ulcerative colitis patients, and the timing of accounting for the Nestlé SER-109 Phase 3 milestone payment.

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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on May 4, 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)

	June 30, 2017	December 31, 2016
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 33,642	\$ 54,539
Investments	137,570	138,704
Prepaid expenses and other current assets	4,839	5,126
Total current assets	176,051	198,369
Property and equipment, net	34,813	36,125
Long-term investments	3,962	36,752
Restricted cash	1,513	1,400
Total assets	<u>\$ 216,339</u>	<u>\$ 272,646</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 3,889	\$ 7,587
Accrued expenses and other current liabilities	9,718	10,812
Deferred revenue - related party	12,058	12,058
Total current liabilities	25,665	30,457
Lease incentive obligation, net of current portion	9,859	10,730
Deferred rent	2,159	2,072
Deferred revenue, net of current portion - related party	90,727	96,756
Total liabilities	128,410	140,015
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at June 30, 2017 and December 31, 2016; no shares issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized at June 30, 2017 and December 31, 2016; 40,412,035 and 40,355,753 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	40	40
Additional paid-in capital	315,748	306,931
Accumulated other comprehensive loss	(176)	(149)
Accumulated deficit	(227,683)	(174,191)
Total stockholders' equity	87,929	132,631
Total liabilities and stockholders' equity	<u>\$ 216,339</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)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
<b>Revenue:</b>				
Collaboration revenue - related party	\$ 3,014	\$ 3,004	\$ 6,029	\$ 5,714
Total revenue	3,014	3,004	6,029	5,714
<b>Operating expenses:</b>				
Research and development expenses	23,060	22,174	43,203	37,590
General and administrative expenses	8,370	8,970	17,132	16,180
Total operating expenses	31,430	31,144	60,335	53,770
Loss from operations	(28,416)	(28,140)	(54,306)	(48,056)
<b>Other income (expense):</b>				
Interest income	615	495	1,390	763
Other income (expense)	(217)	(268)	(576)	(324)
Total other income, net	398	227	814	439
Net loss	<u>\$ (28,018)</u>	<u>\$ (27,913)</u>	<u>\$ (53,492)</u>	<u>\$ (47,617)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.69)</u>	<u>\$ (0.70)</u>	<u>\$ (1.32)</u>	<u>\$ (1.21)</u>
Weighted average common shares outstanding, basic and diluted	<u>40,394,605</u>	<u>39,600,344</u>	<u>40,381,643</u>	<u>39,393,238</u>
<b>Other comprehensive (loss) income:</b>				
Unrealized (loss) gain on investments, net of tax of \$0	\$ (25)	\$ (25)	\$ (27)	\$ 53
Total other comprehensive (loss) income	(25)	(25)	(27)	53
Comprehensive loss	<u>\$ (28,043)</u>	<u>\$ (27,938)</u>	<u>\$ (53,519)</u>	<u>\$ (47,564)</u>

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