



Seres Therapeutics Reports Third Quarter 2016 Financial Results and Provides Operational Progress Update

November 10, 2016

- Analyses of SER-109 Phase 2 results on track for completion by year end;
Company intends to discuss proposed future SER-109 clinical development plans with the FDA -

- Pipeline progress with SER-287 and SER-262 Phase 1b study execution;
data read-outs continue to be expected in 2017 -

- New microbiome patent strengthens the Company's intellectual property estate -

- Conference call at 8:00 a.m. ET today -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 10, 2016-- Seres Therapeutics Inc., (NASDAQ:MCRB), a leading microbiome therapeutics platform Company, today reported third quarter 2016 financial results and provided an update on multiple clinical programs, including three clinical-stage candidates seeking to address multiple medical indications.

"Our focus has been on completing data analyses related to the previously reported SER-109 Phase 2 study results in patients with multiply recurrent *C. difficile* infection," said Roger Pomerantz, M.D., President, CEO and Chairman of Seres, "We expect to complete these efforts by year end and subsequently plan to meet with the FDA to discuss our findings and proposed plans for further SER-109 clinical development."

Dr. Pomerantz continued: "Seres also continues to advance our broad pipeline of microbiome therapeutic candidates, including a SER-287 Phase 1b study in patients with ulcerative colitis, and a Phase 1b study of SER-262, the first synthetically derived microbiome therapeutic candidate, in patients with primary *C. difficile* infection. We look forward to obtaining SER-287 and SER-262 study results in 2017."

Recent Highlights and Events

- **SER-109 Phase 2 study execution and analyses:** Seres continues to conduct analyses to better understand the previously reported SER-109 Phase 2 interim study data. The Phase 2 study enrolled 89 subjects in a randomized, double-blind, placebo-controlled 24-week study conducted to evaluate the safety and efficacy of SER-109 in patients with multiply recurrent *Clostridium difficile* (CDI) infection. Interim, eight-week, primary endpoint results demonstrated that the relative risk of CDI recurrence for the placebo population, compared to the SER-109 population, was not statistically significant. All patients from the SER-109 Phase 2 have now completed their 24-week end of study visit, and full study clinical results are expected in early 2017. The Company also continues to obtain results from the SER-109 Phase 2 open label extension study. Seres intends to complete its full SER-109 study analyses and then discuss plans for further SER-109 clinical development with the U.S. Food and Drug Administration (FDA). The Company expects to provide an update on the SER-109 program in early 2017.
- **Ongoing progress with SER-287 Phase 1b study execution:** Seres continues to advance the SER-287 Phase 1b study in subjects with mild-to-moderate ulcerative colitis. SER-287 is a biologically sourced Ecobiotic® microbiome therapeutic candidate that has been formulated for chronic administration. Additional SER-287 Phase 1b study clinical sites were activated and increasing numbers of study subjects were enrolled. Study results are expected in 2017.
- **Ongoing progress with SER-262 Phase 1b study execution:** Seres continues to advance the SER-262 Phase 1b clinical study in patients with primary CDI 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 clinical sites were activated and increasing numbers of study subjects were enrolled. Study results are expected in 2017.
- **Preclinical microbiome program research:** Seres continues to advance its preclinical efforts, working in collaboration with existing academic collaborators, including projects targeting: hematopoietic stem cell transplantation and immunology treatment, with Memorial Sloan Kettering Cancer Center; liver diseases including primary sclerosing cholangitis and Non-Alcoholic Steatohepatitis (NASH), with Mayo Clinic; inflammatory bowel disease (IBD), with the University of Pennsylvania, Medical University of Graz, Austria and the Research Institute of St. Joseph's Hamilton; and obesity and metabolic syndrome, with the Massachusetts General Hospital of the Harvard Medical School.
- **Additional microbiome patent issued:** Seres continues to strengthen its intellectual property estate related to microbiome

therapeutics. The United States Patent and Trademark Office issued a new patent (#9,446,080), assigned to Seres, covering the use of a composition of bacterial spores to treat gastrointestinal diseases associated with dysbiosis of the microbiome. The patent provides coverage through at least 2034.

- **Manufacturing facility construction progress:** Seres continues to broaden its differentiated microbiome drug development capabilities. The construction of a new manufacturing facility capable of the manufacture and formulation of microbiome therapeutic candidates is near completion. The Company continues to perform activities to support full validation of the new facility.

Financial Results

Seres reported a net loss of \$18.7 million for the third quarter of 2016, as compared to a net loss of \$14.6 million for the same period in 2015. The increase in 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 third quarter net loss figure was inclusive of \$13.0 million in revenue recognized associated with the Company's collaboration with Nestlé Health Science.

Research and development expenses for the third quarter were \$24.1 million, as compared to \$9.9 million for the same period in 2015. 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 third quarter were \$8.0 million, as compared to \$4.7 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 \$16.0 million. The change in cash balance includes receipt of a \$10 million milestone payment from Nestlé Health Science associated with the start of the SER-262 Phase 1b study. Seres ended the third quarter with approximately \$256.5 million in cash, cash equivalents and investments.

Conference Call Information

Seres' management will host a conference call today, November 10, 2016, at 8:00 a.m. ET, to discuss financial results, recent progress and future outlook. A webcast of the conference call may be accessed in the Investors & Media section of Seres' website at www.serestherapeutics.com. To access the conference call, please dial 844-277-9450 (domestic) or 336-525-7139 (international) and reference the conference ID number 9944547. A webcast replay will be available on the Seres website beginning approximately two hours after the event and will be archived for 21 days.

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' program SER-109 continues to be evaluated in a Phase 2 study in multiply recurrent *Clostridium difficile* (CDI) 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. 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 and results of our clinical trials, the timing of the analyses of the SER-109 Phase 2 study data, our SER-109 development plans, identification, development and potential success of our microbiome therapeutic candidates, the completion and success of our manufacturing facility, the potential success of our microbiome therapeutic approach, and dysbiosis of the microbiome 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on August 11, 2016 and our other reports filed with the SEC, including the Form 10-Q that we intend to file 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)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 55,611	\$ 73,933
Investments	147,768	131,149
Prepaid expenses and other current assets	5,055	2,528
Total current assets	208,434	207,610
Property and equipment, net	34,560	7,751
Long-term investments	53,098	—
Restricted cash	1,422	1,539
Total assets	<u>\$ 297,514</u>	<u>\$ 216,900</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,228	\$ 5,397
Accrued expenses and other current liabilities	15,623	5,523
Deferred revenue - related party	12,027	—
Total current liabilities	31,878	10,920
Lease incentive obligation, net of current portion	10,740	586
Deferred rent	1,381	—
Deferred revenue, net of current portion - related party	99,518	—
Total liabilities	143,517	11,506
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at September 30, 2016 and December 31, 2015; no shares issued and outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized at September 30, 2016 and December 31, 2015; 40,355,753 and 39,082,017 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	40	39
Additional paid-in capital	302,939	287,937
Accumulated other comprehensive income	(67)	30
Accumulated deficit	(148,915)	(82,612)
Total stockholders' equity	153,997	205,394
Total liabilities and stockholders' equity	<u>\$ 297,514</u>	<u>\$ 216,900</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue:				
Collaboration revenue - related party	\$ 13,015	\$ —	\$ 18,730	\$ —

Total revenue	13,015	—	18,730	—
Operating expenses:				
Research and development expenses	24,143	9,850	61,733	24,195
General and administrative expenses	7,967	4,711	24,163	10,873
Total operating expenses	32,110	14,561	85,896	35,068
Loss from operations	(19,095)	(14,561)	(67,166)	(35,068)
Other income (expense):				
Interest income	719	172	1,483	372
Interest expense	(312)	(231)	(620)	(443)
Revaluation of preferred stock warrant liability	—	\$ —	—	(7)
Total other income (expense), net	407	(59)	863	(78)
Net loss	\$ (18,688)	\$ (14,620)	\$ (66,303)	\$ (35,146)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.46)	\$ (0.38)	\$ (1.67)	\$ (1.92)
Weighted average common shares outstanding, basic and diluted	40,235,623	38,980,839	39,676,085	18,292,002
Other comprehensive income:				
Unrealized gain/(loss) on investments, net of tax of \$0	\$ (150)	\$ (33)	\$ (97)	\$ (10)
Total other comprehensive income	(150)	(33)	(97)	(10)
Comprehensive loss	\$ (18,838)	\$ (14,653)	\$ (66,400)	\$ (35,156)

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Seres Therapeutics

Carlo Tanzi, Ph.D., 617-203-3467

Head of Investor Relations and Corporate Communications

Ctanzi@serestherapeutics.com