Seres Therapeutics Reports Fourth Quarter and Full Year 2016 Financial Results and Provides Operational Progress Update

March 16, 2017

- Positive SER-109 Type B FDA meeting -

- Company to initiate new Phase 2 SER-109 clinical trial that, as agreed to by the FDA, may qualify as a Pivotal Study with achievement of a persuasive clinical effect and addressing FDA requirements -

- Continued pipeline progress with both SER-287 and SER-262 Phase 1b studies; Both data read-outs expected in the second half of 2017 -

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

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 16, 2017-- Seres Therapeutics Inc., (NASDAQ:MCRB), a leading microbiome therapeutics platform company, today reported fourth quarter and full year 2016 financial results and provided an update on multiple clinical programs, including three clinical-stage candidates seeking to address multiple serious medical indications. In a separate announcement today, Seres provided an update on plans to initiate a new SER-109 clinical study following its positive FDA Type B meeting.

“Seres has made important progress across all of our microbiome clinical programs,” said Roger J. Pomerantz, M.D., President, CEO and Chairman of Seres. “Following the completion of our comprehensive analyses of the SER-109 study results, we had very productive discussions with the FDA, in which we gained highly positive and constructive guidance on further SER-109 clinical development. If the new ECOSPOR III study achieves a persuasive clinical effect and addresses FDA requirements, we would expect to be able to file for SER-109 product registration.”

Dr. Pomerantz continued, “We also advanced our robust pipeline of microbiome clinical candidates and we anticipate the results of two Phase 1b clinical trials during the second half of this year, including our study of SER-287 in patients with ulcerative colitis and our study of SER-262, the first synthetically derived microbiome candidate to reach clinical development, in patients with primary *C. difficile* infection.”

Recent Highlights and Events

- **Positive SER-109 Type B meeting with FDA and plan for new SER-109 clinical study:** 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 assay. 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.
- **Key findings from SER-109 Phase 2 study analyses:** Seres announced the results of its in-depth analyses of the previously reported SER-109 Phase 2, eight-week clinical study data in patients with multiply recurrent *C. difficile* infection.
- **Ongoing progress with SER-287 Phase 1b study:** Seres continued to advance the SER-287 Phase 1b clinical study in subjects with mild-to-moderate ulcerative colitis who have failed first line therapy. SER-287 is a biologically sourced Ecobiotic® microbiome therapeutic candidate. Additional SER-287 Phase 1b study clinical sites were activated and increasing numbers of study subjects are being enrolled. Study results are expected in the second half of 2017.
- **Ongoing progress with SER-262 Phase 1b study:** Seres continued to advance 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 clinical sites were activated and increasing numbers of study subjects are being enrolled. Study results are expected in the second half of 2017.
- **Preclinical microbiome program research:** Seres continued to advance its preclinical efforts, working in collaboration with existing world-class academic researchers, including projects targeting hematopoietic stem cell transplantation and immuno-oncology 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) and rare genetic metabolic diseases, 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 continued to strengthen its intellectual property estate related to microbiome therapeutics. The United States Patent and Trademark Office issued a new patent (#9,585,921), assigned to Seres, covering compositions for treating multiple gastrointestinal diseases associated with dysbiosis of the microbiome.
- **Manufacturing facility completed:** Seres continued to broaden its differentiated microbiome therapeutic development capabilities. The construction of a new facility capable of the manufacture and formulation of microbiome therapeutic candidates was completed and is now fully operational.

Financial Results

The company reported a net loss of $91.6 million for the full year, as compared to a net loss of $54.8 million for the prior year. Seres reported a net loss of $25.3 million for the fourth quarter of 2016, as compared to a net loss of $19.6 million for the same period in 2015. The increase in fourth 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 fourth 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 full year of 2016 were $82 million, as compared to $38.1 million for the prior year. R&D expenses for the fourth quarter of 2016 were $20.3 million, as compared to $13.9 million for the same period in 2015. The increase in R&D expense was primarily due to expenses related to the company's 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 full year of 2016 were $32.6 million, as compared to $16.8 million for the prior year. G&A expenses for the fourth quarter of 2016 were $8.5 million, as compared to $5.9 million for the same period in 2015. The increase in G&A 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 $26.5 million. Seres ended the fourth quarter with approximately $230.0 million in cash, cash equivalents and investments.

Financial Expectations

Based on the company's current operating plan, Seres expects that its existing cash resources will enable it to fund operating expenses and capital expenditure requirements, excluding cash inflows or outflows from future business development activities, through 2018.

Conference Call Information

Seres' management will host a conference call today, March 16, 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 84302413. To join the live webcast and access slides to accompany the conference call, please visit the "Investors and Media" section of the Seres website at 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. 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 our SER-109 development plans, 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, the potential benefits of our business collaborations, dysbiosis as an underlying cause of disease, the benefits of any of our issued patents, and our cash flow and business forecasts.

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 November 10, 2016 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.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31,	
	2016	**2015**
Assets		
Current assets:		
Cash and cash equivalents	$ 54,539	$ 73,933
Investments	138,704	131,149
Prepaid expenses and other current assets	5,126	2,528
Total current assets	198,369	207,610
Property and equipment, net	36,125	7,751
Long-term investments	36,752	—
Restricted cash	1,400	1,539
Total assets	$ 272,646	$216,900
Liabilities and Stockholder's Equity		
Current liabilities:		
Accounts payable	$ 7,587	$ 5,397
Accrued expenses and other current liabilities	10,812	5,523
Deferred revenue - related party	12,058	—
Total current liabilities	30,457	10,920
Lease incentive obligation, net of current portion	10,730	586
Deferred rent	2,072	—
Deferred revenue, net of current portion - related party	96,756	—
Total liabilities	140,015	11,506
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2016 and 2015; no shares issued and outstanding at December 31, 2016 and 2015	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at December 31, 2016 and 2015; 40,355,753 and 39,082,017 shares issued and outstanding at December 31, 2016 and 2015	40	39
Additional paid-in capital	306,931	287,937
Accumulated other comprehensive income (loss)	(149)	30
Accumulated deficit	(174,191)	(82,612)
Total stockholders' equity	132,631	205,394
Total liabilities, convertible preferred stock and stockholders' equity	$ 272,646	$216,900

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

	Year Ended December 31,		
	2016	**2015**	**2014**
Revenue:			

Collaboration revenue - related party	$ 21,766	$ —	$ —
Total revenue	21,766	—	—
Operating expenses:			
Research and development expenses	$ 81,989	38,095	10,718
General and administrative expenses	32,616	16,761	4,364
Total operating expenses	114,605	54,856	15,082
Loss from operations	(92,839)	(54,856)	(15,082)
Other income (expense):			
Interest income	2,229	638	—
Interest expense	(969)	(555)	(209)
Revaluation of preferred stock warrant liability	—	(7)	(1,418)
Total other income (expense), net	1,260	76	(1,627)
Net loss	$ (91,579)	(54,780)	(16,709)
Accretion of convertible preferred stock to redemption value	—	—	(1,291)
Net loss attributable to common stockholders	$ (91,579)	$ (54,780)	$ (18,000)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.30)	$ (2.33)	$ (2.67)
Weighted average common shares outstanding, basic and diluted	39,846,928	23,532,400	6,748,037
Other comprehensive income (loss):			
Unrealized gain (loss) on investments, net of tax of $0	(179)	30	—
Total other comprehensive income (loss)	(179)	30	—
Comprehensive loss	$ (91,758)	$ (54,750)	$ (18,000)

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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