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

May 16, 2016

SER-109 Phase 2 study enrollment complete; results expected in mid-2016

Academic collaborations further microbiome therapeutic leadership in immuno-oncology, rare genetic diseases and other indications

$120 million upfront payment obtained from Nestlé Health Science

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 16, 2016-- Seres Therapeutics Inc. (NASDAQ:MCRB), a leading microbiome therapeutics platform company, today reported first quarter 2016 financial results and provided an operational progress update.

"The first quarter was marked by strong progress extending our leadership position in the development of microbiome therapeutics," said Roger Pomerantz, M.D., President, CEO and Chairman of Seres. "Our clinical-stage programs are advancing rapidly. Enrollment is now complete in our ongoing SER-109 Phase 2 study in recurrent *Clostridium difficile* infection (CDI), and we look forward to study results in the middle of the year. Enrollment remains ongoing for the SER-287 Phase 1b study for ulcerative colitis. We have made excellent progress with SER-262, which we expect to be the first ever synthetic microbiome therapeutic candidate, and we expect to initiate a Phase 1b study in primary CDI in the middle of this year. The Company continues to be very active in collaborating with academic leaders to accelerate our efforts within our three focused franchises, infectious disease, inflammatory/immunology, and metabolic disease."

Recent Highlights:

- **Completion of enrollment in the ongoing SER-109 Phase 2 clinical study (May 2016):** The Phase 2 randomized, placebo-controlled study is designed to assess the efficacy and safety of SER-109 for the prevention of multiply recurrent CDI. Initial study results are expected in the middle of this year, and the Company plans to initiate a Phase 3 study in the second half of 2016.
- **SER-109 Expanded Access Program (EAP) initiation (May 2016):** The Company has initiated a SER-109 EAP at selected sites participating in the ongoing Phase 2 study. The EAP will enable eligible patients with recurrent CDI to have continued access to SER-109.
- **Thomas J. DesRosier appointed as Chief Legal Officer and Executive Vice President (May 2016):** DesRosier, a proven biopharma leader with deep experience representing and advising biopharmaceutical companies, will be responsible for global legal operations, as well as corporate compliance and quality assurance.
- **Broad collaboration agreement with Memorial Sloan Kettering Cancer Center (MSK) to develop microbiome therapeutics for hematopoietic stem cell transplantation (HSCT) and immuno-oncology treatment (May 2016).** The MSK collaboration will support the Company's efforts to develop first-in-field microbiome therapeutics in two diverse areas: (1) improving the morbidity and mortality outcomes of patients undergoing HSCT for treatment of cancer, by prevention of transplant related infections and graft versus host disease (GVHD); and (2) increasing the efficacy and safety of checkpoint inhibitors used for immuno-oncology treatment. The collaboration also provides the Company with a global license to MSK's intellectual property related to the use of bacterial compositions in treating HSCT patients and related areas, bolstering the Company's broad existing composition of matter and method of use patent estate.
- **Academic collaborations to support development of microbiome therapeutics for Inflammatory Bowel Disease (IBD) (May 2016):** The Company entered into two separate research collaborations with leading academic groups, St. Joseph's Hamilton, Ontario and the Medical University of Graz, to support the Company's ongoing development of the first potential microbiome therapeutics for IBD. The collaborations are expected to provide support for the Company's IBD therapeutic candidates, including the SER-301 program, a rationally-designed, preclinical stage therapeutic candidate comprising bacterial species cultured *in vitro.*
- **Academic collaboration with University of Pennsylvania researchers to support the development of microbiome therapeutics for IBD and rare genetic metabolic disorders, including urea cycle disorders (May 2016):** The Company entered into a multi-year collaboration with leading microbiome clinical-scientists from the University of Pennsylvania to perform research and clinical studies with rationally selected bacterial compositions in patients with ulcerative colitis, and with certain rare genetic metabolic diseases, including urea cycle disorders.

- **European Medicines Agency (EMA) SER-109 Phase 3 guidance (April 2016):** The EMA has provided initial guidance regarding SER-109 Phase 3 design that may lead to two Phase 3 studies being conducted to support SER-109 approval in the European Union. Discussions are continuing with EMA to determine the most effective manner to bring SER-109 to European patients as quickly and efficiently as possible.
- **Nestlé Health Science collaboration agreement executed and $120 million upfront payment obtained (February 2016).** The Company expects to receive an additional $30 million in development milestones during 2016.

Financial Results:

The Company reported a net loss of $19.7 million for the first quarter of 2016, as compared to a net loss of $8 million for the same period in 2015. The increase in net loss was driven primarily by continued growth in clinical and development spend as well as increased headcount, and ongoing development of our microbiome therapeutics platform.

In the first quarter, the Company recognized $2.7 million of the $120 million upfront payment received from an affiliate of Nestlé Health Science as revenue with the remaining $117.3 million recorded as deferred revenue at March 31, 2016. This deferred revenue amount, as well as future reimbursement for shared Phase 3 development expenses, will be recognized over the estimated 10-year collaboration development period. Potential additional development, regulatory, and commercial payments are expected to be recognized as revenue in the period in which the milestones are achieved. In addition, potential commercial royalties are expected to be recognized as revenue in the period in which they are earned.

Research and development expenses for the first quarter of 2016 were $15.4 million, as compared to $5.6 million for the same period in 2015. The increase in R&D expense was primarily due to expenses related to our microbiome therapeutics platform and the clinical development of SER-109, SER-262 and SER-287. General and administrative expenses for the first quarter were $7.2 million, as compared to $2.6 million for the same period in 2015. The increase in G&A expense was primarily due to increased headcount and facility expansion to support overall growth, as well as other costs associated with operating as a public company.

As of March 31, 2016, the Company had approximately $303 million in cash, cash equivalents and investments, which includes the $120 million upfront payment received from Nestlé Health Science. Cash usage during the quarter was $21.8 million compared to $9.9 million for the same period in 2015. This increase was driven primarily by expenses related to increased headcount and expanded R&D activities.

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' most advanced program, SER-109, has successfully completed a Phase 1b/2 study demonstrating a clinical benefit in patients with recurring *Clostridium difficile* infection (CDI) and is currently being evaluated in a Phase 2 study in recurring CDI. The FDA has granted SER-109 Orphan Drug, as well as Breakthrough Therapy, designations. Seres' second clinical candidate, SER-287, is being evaluated in a Phase 1b study in patients with mild-to-moderate ulcerative colitis (UC). 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 sufficiency of the Company's existing cash resources, the development of its various product candidates, the commercialization of its CDI therapeutic candidates, the timing and results of clinical trials, the value and impact of the agreement with Nestlé, expected milestone payments under the agreement with Nestlé and potential benefits and outcomes of the Company's collaborations with MSKCC, the University of Pennsylvania, St. Joseph's Hamilton, Ontario and the Medical University of Graz.

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 may be 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 14, 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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands, except share and per share data)

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 193,228	$ 73,933
Investments	110,050	131,149
Prepaid expenses and other current assets	3,568	2,528
Total current assets	306,846	207,610
Property and equipment, net	16,082	7,751
Restricted cash	1,540	1,539
Total assets	$ 324,468	$ 216,900
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	5,763	5,397
Accrued expenses and other current liabilities	7,059	5,523
Deferred revenue - related party	12,000	—
Total current liabilities	24,822	10,920
Lease incentive obligation	4,527	586
Deferred revenue, net of current portion - related party	105,290	—
Total liabilities	134,639	11,506
Commitments and contingencies		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2016 and December 31, 2015; no shares issued and outstanding at March 31, 2016 and December 31, 2015	—	—
Stockholders' equity:		
Common stock, $0.001 par value; 200,000,000 shares authorized at March 31, 2016 and December 31, 2015; 39,218,702 and 39,082,017 shares issued and outstanding at March 31, 2016 and December 31, 2015 , respectively	39	39
Additional paid-in capital	291,998	287,937
Accumulated other comprehensive income	108	30
Accumulated deficit	(102,316)	(82,612)
Total stockholders' equity	189,829	205,394
Total liabilities and stockholders' equity	$ 324,468	$ 216,900

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

	Three Months Ended March 31,	
	2016	2015
Revenue:		
Collaboration revenue - related party	$ 2,710	$ —
Total revenue	2,710	—
Operating expenses:		
Research and development expenses	$ 15,416	5,561
General and administrative expenses	7,210	2,606
Total operating expenses	22,626	8,167
Loss from operations	(19,916)	(8,167)
Other income (expense):		

Interest income	268	49
Interest expense	(56)	(66)
Revaluation of preferred stock warrant liability	—	213
Total other income, net	212	196
Net loss	$ (19,704)	$ (7,971)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.50)	$ (1.15)
Weighted average common shares outstanding, basic and diluted	39,186,130	6,912,725
Other comprehensive income:		
Unrealized gain on investments, net of tax of $0	78	31
Total other comprehensive income	78	31
Comprehensive loss	$ (19,626)	$ (7,940)

View source version on businesswire.com: http://www.businesswire.com/news/home/20160516005375/en/

Source: Seres Therapeutics Inc.

Seres Therapeutics
Carlo Tanzi, Ph.D., 617-203-3467
Head of Investor Relations and Corporate Communications
Ctanzi@serestherapeutics.com