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

November 8, 2017

– Positive results from SER-287 Phase 1b study in mild-to-moderate Ulcerative Colitis; Company to move program into further development –

– Company awarded CARB-X grant to advance SER-155 for allogeneic stem cell and solid organ transplantation –

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

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 8, 2017-- Seres Therapeutics, Inc.,(NASDAQ:MCRB) today reported third 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 and the SER-155 preclinical program for patients receiving solid organ and stem cell transplants.

“Seres continues to make excellent progress advancing both our clinical stage and preclinical stage microbiome pipeline assets. We obtained encouraging clinical results with SER-287 demonstrating proof of concept in Ulcerative Colitis, and we continued to enroll our SER-109 Phase 3 and SER-262 Phase 1b programs for *C. difficile* infection. In addition, we were awarded a grant to advance our preclinical program SER-155, for allogeneic stem cell and solid organ transplant patients,” said Roger J. Pomerantz, M.D., President, CEO and Chairman of Seres. “In the coming months, we look forward to obtaining microbiome data from the SER-287 Phase 1b study and we plan to move SER-287 forward in Ulcerative Colitis. In early 2018, we anticipate results from the SER-262 Phase 1b study in primary *C. difficile* infection.”

Recent Highlights and Events

- **Positive clinical results from SER-287 Phase 1b study:** Seres reported positive topline results from a SER-287 Phase 1b placebo-controlled induction study in patients with mild-to-moderate Ulcerative Colitis (UC) who were failing current first line therapies. SER-287 is a biologically sourced Ecobiotic® microbiome therapeutic candidate with the potential to offer UC patients a novel, non-immunosuppressive treatment option. SER-287 administration resulted in a dose-dependent improvement of both clinical remission rates and endoscopic scores.

  The highest efficacy was observed in the vancomycin pre-treatment, daily SER-287 arm of the study. Based on an intent-to-treat ‘observed data’ analysis, 40% (6 of 15 subjects) reached clinical remission; in the placebo group 10% (1 of 10) achieved this endpoint. Based on an intent-to-treat ‘missing data counted as failure,’ where the use of prohibited additional UC therapies was also counted as failure in the analysis, 40% (6 of 15 subjects) reached clinical remission; in the placebo group 0% (0 of 11) achieved this endpoint. This result was statistically significant (p-value = 0.0237). In addition to the clinical remission endpoint, compelling treatment effects of a similar magnitude were also observed on direct endoscopic measures in both statistical analyses.

  The SER-287 Phase 1b results were also analyzed under the new U.S. Food and Drug Administration (FDA) definition for clinical remission and endoscopy, and the efficacy results for the SER-287 daily arm compared to the placebo arm were found to be highly compelling. Even in this modestly sized initial trial of SER-287, the results were statistically significant when analyzed by the missing data counted as failure approach. Per the new FDA definition, clinical response is not defined, nor recommended as a primary endpoint.

  High clinical response placebo rates that were not differentiated from the SER-287 treatment arms were observed. Clinical response is a subjective endpoint that is prone to high variability and high placebo rates, as previously observed in several other UC trials. As a result, response rates are difficult to interpret in UC clinical studies, particularly those from modestly-sized trials. In the most recently available FDA regulatory guidance, the agency now recommends the use of clinical remission, and not clinical response, as the primary endpoint in UC registrational studies.

  The SER-287 safety and tolerability profile was favorable, and study results demonstrated no imbalance in adverse events in patients treated with SER-287 as compared to patients treated with placebo. There were no drug-related serious adverse events associated with SER-287.

  Microbiome data, a co-primary endpoint of the study, are expected in the coming months. Seres intends to work to rapidly advance SER-287 into further development for UC. The Company also continues to assess development in Crohn’s

disease and pediatric forms of inflammatory bowel disease.

- **Ongoing progress with SER-109 ECOSPOR III Phase 3 study:** Seres is advancing its SER-109 Phase 3 clinical study, which plans to enroll approximately 320 patients with multiply recurrent *C. difficile* infection, at sites in both the U.S. and Canada. The SER-109 Phase 3 study obtained clinical trial application clearance from Health Canada, and Canadian clinical sites are expected to be opened in the coming weeks. Based on interactions with the 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. SER-109 has been designated by the FDA as a Breakthrough Therapy and also has obtained Orphan Drug designation.
- **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. Topline data from the study are expected in early 2018.
- **CARB-X grant award:** Seres was awarded a CARB-X (Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator) grant to support early development efforts for preclinical-stage program SER-155, to prevent antibiotic-resistant bacterial infections and graft versus host disease in patients who have received either allogeneic stem cell or solid organ transplantation. The CARB-X grant provides Seres with up to $2.5 million of research funding with potential for an additional $3.1 million upon completion of milestones.

Financial Results

Seres reported a net loss of $6.9 million for the third quarter of 2017, as compared to a net loss of $18.7 million for the same period in 2016. The third quarter net loss was driven primarily by clinical and development expenses, personnel expenses, and ongoing development of the Company's microbiome therapeutics platform. The third quarter net loss figure was inclusive of $23.0 million in recognized revenue associated with the Company's collaboration with Nestlé Health Science.

Research and development expenses for the third quarter were $22.2 million, as compared to $24.1 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, SER-155 and immuno-oncology preclinical programs.

General and administrative expenses for the third quarter were $8.1 million, as compared to $8.0 million for the same period in the prior year. General and administrative expenses were primarily due to headcount, professional fees, and facility costs.

During the third quarter, the Company received a $20.0 million milestone payment associated with the start of the SER-109 Phase 3 study, under its collaboration agreement with Nestlé.

The decrease in our cash, cash equivalents and investments balance during the quarter was $3.9 million. Seres ended the third quarter with approximately $171.3 million in cash, cash equivalents and investments.

Conference Call Information

Seres' management will host a conference call today, November 8, 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 1184039. Accompanying slides will be made available on the Seres website prior to the call. To join the live webcast, please visit the "Investors and Media" section of the Seres website at www.serestherapeutics.com.

A webcast replay will be available on the Seres website beginning approximately two hours after the event and will be archived for approximately 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' 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 has successfully completed 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. 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 potential advancement of our preclinical program SER-155 and the benefits of any collaboration therein, the timing and results of additional data from the SER-287 Phase 1b study, the timing and potential advancement of SER-287, the potential development of programs in Crohn's disease or pediatric forms of inflammatory bowel disease, the enrollment of patients in ECOSPOR III, the potential for ECOSPOR III to support SER-109 registration and approval, the timing and results of the SER-262 Phase 1b study, the potential to receive future milestone payments under the CARB-X grant, and any benefits resulting from the CARB-X grant.

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; our limited operating history; our unproven approach to therapeutic intervention; the lengthy, expensive, and uncertain process of clinical drug development, including potential delays in regulatory approval; our reliance on third parties and collaborators to conduct our clinical trials, manufacture our product candidates, and develop and commercialize our product candidates, if approved; our lack of experience in manufacturing, selling, marketing, and distributing our product candidates; failure to compete successfully against other drug companies; protection of our proprietary technology and the confidentiality of our trade secrets; potential lawsuits for, or claims of, infringement of third-party intellectual property or challenges to the ownership of our intellectual property; our patents being found invalid or unenforceable; risks associated with international operations; our ability to retain key personnel and to manage our growth; the potential volatility of our common stock; our management and principal stockholders have the ability to control or significantly influence our business; 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 3, 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)

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 46,025	$ 54,539
Investments	125,274	138,704
Prepaid expenses and other current assets	5,346	5,126
Total current assets	176,645	198,369
Property and equipment, net	33,724	36,125
Long-term investments	—	36,752
Restricted cash	1,513	1,400
Total assets	$ 211,882	$ 272,646
Liabilities and Stockholders’ Equity		
Current liabilities:		
Accounts payable	$ 5,380	$ 7,587
Accrued expenses and other current liabilities	9,594	10,812
Deferred revenue - related party	12,058	12,058
Total current liabilities	27,032	30,457
Lease incentive obligation, net of current portion	9,424	10,730
Deferred rent	2,202	2,072
Deferred revenue, net of current portion - related party	87,712	96,756
Total liabilities	126,370	140,015
Commitments and contingencies		
Stockholders’ equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2017 and December 31, 2016; no shares issued and outstanding at September 30, 2017 and December 31, 2016	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at September 30, 2017 and December 31, 2016; 40,512,639 and 40,355,753 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	40	40
Additional paid-in capital	320,189	306,931
Accumulated other comprehensive loss	(99)	(149)
Accumulated deficit	(234,618)	(174,191)
Total stockholders’ equity	85,512	132,631
Total liabilities and stockholders’ equity	$ 211,882	$ 272,646

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,	
	2017	2016	2017	2016
Revenue:				
Collaboration revenue - related party	$ 23,015	$ 13,015	$ 29,044	$ 18,730

Total revenue	23,015	13,015	29,044	18,730
Operating expenses:				
Research and development expenses	22,210	24,143	65,413	61,733
General and administrative expenses	8,119	7,967	25,251	24,163
Total operating expenses	30,329	32,110	90,664	85,896
Loss from operations	(7,314)	(19,095)	(61,620)	(67,166)
Other income (expense):				
Interest income	502	719	1,892	1,483
Other income (expense)	(123)	(312)	(699)	(620)
Total other income, net	379	407	1,193	863
Net loss	$ (6,935)	$ (18,688)	$ (60,427)	$ (66,303)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.17)	$ (0.46)	$ (1.49)	$ (1.67)
Weighted average common shares outstanding, basic and diluted	40,494,049	40,235,623	40,419,522	39,676,085
Other comprehensive (loss) income:				
Unrealized (loss) gain on investments, net of tax of $0	$ 77	$ (150)	$ 50	$ (97)
Total other comprehensive (loss) income	77	(150)	50	(97)
Comprehensive loss	$ (6,858)	$ (18,838)	$ (60,377)	$ (66,400)

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