Seres Therapeutics Reports Second Quarter 2020 Financial Results and Provides Business Updates

July 28, 2020

– Topline data from SER-109 Phase 3 study in recurrent C. difficile *infection expected in August 2020; Potential to be the single pivotal study supporting FDA product registration –*

– Company continues to advance multiple additional clinical-stage microbiome therapeutic programs, including SER-287, SER-301, SER-401 and SER-155 –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 28, 2020-- Seres Therapeutics, Inc. (Nasdaq: MCRB) today reported financial results from the second quarter ended June 30, 2020, and provided an operational update.

"In the coming weeks, we are eagerly looking forward to topline results from our SER-109 Phase 3 study in recurrent *C. difficile* infection. We believe that positive ECOSPOR III data would be an important advance for the *C. difficile* community. Recurrent *C. difficile* infection is a debilitating and deadly disease and there is a tremendous need for a safe, FDA-approved treatment that prevents disease recurrence. In addition, we expect that positive ECOSPOR III results would also be a validating milestone for Seres' pipeline of microbiome therapeutics. Based on prior FDA discussions, we expect that clinically compelling data could support a regulatory filing with the FDA for SER-109 product approval. The SER-109 Phase 3 study could potentially enable a first-in-class approved therapy designed to target the underlying cause of this devastating disease," said Eric D. Shaff, President and Chief Executive Officer at Seres. "In addition to SER-109, we have made continued progress advancing our pipeline of promising microbiome therapeutic development candidates, including SER-287, SER-301, SER-401 and SER-155. Each program is targeting a serious disease, and each has the potential to transform the standard of care. Across our portfolio, we are driving towards meaningful, clinically interpretable datasets to enable well-informed decisions on future development."

Program Updates and Corporate Highlights

SER-109 Phase 3 ECOSPOR III study in recurrent *C. difficile* infection (CDI): Seres previously reported the completion of enrollment in the SER-109 Phase 3 ECOSPOR III study (ClinicalTrials.gov identifier: NCT03183128). The multicenter placebo-controlled study enrolled 182 patients with multiply recurrent CDI who were randomized 1:1. ECOSPOR III study results remain blinded to the Company and topline study results are anticipated in August 2020.

Based on prior discussions with the U.S. Food & Drug Administration (FDA), Seres believes that ECOSPOR III has the potential to be the single pivotal study supporting product registration; however, this will depend on the strength of the data and additional safety data may be required.

All patients enrolled into ECOSPOR III were required to undergo a rigorous *C. difficile* cytotoxin diagnostic test to confirm active CDI, both at entry into the study and to confirm recurrence of CDI during the study. The primary objective of ECOSPOR III is to demonstrate a reduction of CDI recurrence at up to eight weeks following SER-109 administration.

SER-109 is an orally-administered, biologically-derived, microbiome therapeutic candidate designed to restore the gastrointestinal microbiome of patients with recurrent CDI. SER-109 has been granted Orphan Drug and Breakthrough Therapy designations by the FDA. With positive study results, the Company plans to meet with the FDA to discuss requirements for filing for product approval.

SER-109 is comprised of a highly purified consortia of spore-based commensal bacteria and manufactured under Good Manufacturing Practices conditions using stringent standards to ensure product quality and consistency. To maximize product safety, Seres utilizes a unique manufacturing process that inactivates numerous potential pathogens, including species of non-spore bacteria, such as *Escherichia coli*, and viruses such as SARS-CoV-2.

SER-287 Phase 2b ECO-RESET study in ulcerative colitis: SER-287 is an oral, biologically-derived microbiome therapeutic candidate designed to have pharmacological effects on multiple pathways relevant to ulcerative colitis that can be modulated by the gastrointestinal microbiome. Seres has obtained FDA Fast Track designation for SER-287 in active mild-to-moderate ulcerative colitis.

The SER-287 Phase 2b ECO-RESET induction study in patients with active mild-to-moderate ulcerative colitis remains ongoing. Seres has implemented a number of COVID-19 related mitigation strategies and the study continues to enroll patients. In recent weeks, the Company has observed an increase in ECO-RESET clinical site activity, the availability of endoscopies, and in the volume of clinical study subject screening.

SER-301 clinical candidate for ulcerative colitis: Seres has nominated SER-301, an oral, rationally-designed, fermented microbiome therapeutic, as a clinical candidate for ulcerative colitis. Innovative and novel manufacturing methods have been utilized to produce SER-301. The composition includes strains delivered in spore form, as well as strains fermented in non-spore, vegetative form and delivered using enterically-protected technology designed to release in the colon. The consortium of bacteria in SER-301 is designed to modify the microbiome and microbe-associated metabolites in the gastrointestinal tract to modulate pathways linked to gastrointestinal inflammation and to improve epithelial barrier integrity in patients with ulcerative colitis.

The Company has initiated clinical development and continues to execute on activities for a SER-301 Phase 1 study in patients with ulcerative colitis. That study is planned to enroll subjects in Australia and New Zealand later this year. Seres is entitled to receive a $10 million milestone payment associated with the Phase 1 SER-301 clinical study initiation from Nestlé Health Science, the Company's collaborative partner for this program.

SER-401 Phase 1b study in metastatic melanoma: SER-401 is an orally-administered, biologically-derived, live microbiome therapeutic candidate comprising bacteria that reflect the bacterial signature in the gastrointestinal microbiome associated with patient response to checkpoint inhibitor immunotherapy.

The ongoing placebo-controlled Phase 1b study in patients with metastatic melanoma is supported by the Parker Institute for Cancer Immunotherapy and the University of Texas MD Anderson Cancer Center. The trial is evaluating the potential of SER-401 to improve clinical response to nivolumab, an approved anti-PD-1 checkpoint inhibitor therapy, and will evaluate safety, efficacy and tumor biopsies for various biomarkers of response.

SER-155 Phase 1b clinical study activities: Seres is working to advance SER-155, an oral, rationally designed, fermented microbiome therapeutic, into a Phase 1b clinical study. SER-155 is designed to prevent mortality due to gastrointestinal infections, bacteremia and graft versus host disease (GvHD) in immunocompromised patients, including in patients receiving allogeneic hematopoietic stem cell transplantation. SER-155 is a consortium of bacterial species designed using microbiome biomarker data from human clinical data, human cell-based assays and *in vivo* disease models. The composition aims to decrease infection and translocation of antibiotic-resistant bacteria in the gastrointestinal tract and modulate host immune responses to decrease GvHD.

The SER-155 program is supported by a CARB-X grant that provides financial and operational support through Phase 1b clinical development. The Company intends to move SER-155 into a Phase 1b study later this year in collaboration with Memorial Sloan Kettering Cancer Center.

Chief Commercial and Strategy Officer appointment: In June, Seres announced that Terri Young, Ph.D., R.Ph., was appointed as Executive Vice President and Chief Commercial and Strategy Officer. Dr. Young joins Seres with over 20 years of commercial and marketing leadership experience, having successfully led the growth of several important biopharmaceutical products.

Financial Results

Seres reported a net loss of $20.7 million for the second quarter of 2020, as compared with a net loss of $10.8 million for the same period in 2019. 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.

Research and development expenses for the second quarter of 2020 were $20.1 million, compared with $17.9 million for the same period in 2019. The research and development expenses were primarily related to Seres' late stage SER-109 and SER-287 clinical development programs.

General and administrative expenses for the second quarter of 2020 were $6.5 million, compared with $5.6 million for the same period in 2019. General and administrative expenses were primarily due to consulting fees and professional fees and included expenses to support SER-109 commercialization readiness activities.

Seres ended the second quarter with approximately $63.9 million in cash, cash equivalents and investments compared with $75.1 million at the end of the first quarter 2020. Cash resources are expected to fund operating expenses and capital expenditure requirements, excluding net cash flows from future business development activities or potential incoming milestone payments, into the second quarter of 2021.

Seres will not be holding a conference call with today's quarterly update and does not intend to meet with investors until the pending SER-109 Phase 3 study results are reported. Seres intends to hold a conference call following release of the SER-109 Phase 3 study results.

About Seres Therapeutics

Seres Therapeutics, Inc., (Nasdaq: MCRB) 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 state of bacterial diversity and function is imbalanced. Seres' SER-109 program has obtained Breakthrough Therapy and Orphan Drug designations from the FDA and is in Phase 3 development for recurrent *C. difficile* infection. Seres' SER-287 program has obtained Fast Track and Orphan Drug designation from the U.S. Food and Drug Administration and is being evaluated in a Phase 2b study in patients with active mild-to-moderate ulcerative colitis. Seres' SER-109 program has obtained Breakthrough Therapy and Orphan Drug designations from the FDA and is in Phase 3 development for recurrent *C. difficile* infection. Seres is developing SER-401 in a Phase 1b study in patients with metastatic melanoma, SER-301 for ulcerative colitis, and SER-155 to prevent mortality due to gastrointestinal infections, bacteremia and graft versus host disease. For more information, please visit www.serestherapeutics.com.

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 the timing, results and initiation of our clinical studies, the potential for any of the Company's studies to serve as a pivotal trial to enable a BLA submission, the receipt of future milestone payments, the potential impact of any of Seres' development candidates, the potential impact of the COVID-19 pandemic, the sufficiency of the Company's cash resources to fund operating expenses and capital expenditure requirements, the availability of additional cash resources and other statements that are not historical facts.

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; the impact of the COVID-19 pandemic; our unproven approach to therapeutic intervention; the lengthy, expensive and uncertain process of clinical drug development; 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; the success of our leadership transition; our ability to retain key personnel and to manage our growth; and our management and principal stockholders have the ability to control or significantly influence our business. 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 7, 2020, 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)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 61,536	$ 65,126
Investments	2,404	29,690
Prepaid expenses and other current assets	5,847	3,588
Accounts receivable	2,929	1,785
Total current assets	72,716	100,189
Property and equipment, net	16,305	19,495
Operating lease assets	10,257	11,356
Restricted investments	1,400	1,400
Total assets	$ 100,678	$ 132,440
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 4,163	$ 4,859
Accrued expenses and other current liabilities	10,604	10,884
Operating lease liabilities	4,788	4,456
Deferred revenue - related party	19,040	20,960
Deferred revenue	5,653	4,834
Total current liabilities	44,248	45,993
Note payable, net of discount	24,863	24,648
Operating lease liabilities, net of current portion	13,181	15,676
Deferred revenue, net of current portion - related party	80,383	89,111
Deferred revenue, net of current portion	2,826	4,834
Other long-term liabilities	752	502
Total liabilities	166,253	180,764
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2020 and December 31, 2019; no shares issued and outstanding at June 30, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at June 30, 2020 and December 31, 2019; 75,131,834 and 70,143,252 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	75	70
Additional paid-in capital	434,593	411,255
Accumulated other comprehensive income	1	—
Accumulated deficit	(500,244)	(459,649)
Total stockholders' deficit	(65,575)	(48,324)
Total liabilities and stockholders' deficit	$ 100,678	$ 132,440

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue:				
Collaboration revenue - related party	$ 5,186	$ 10,454	$ 10,648	$ 17,069
Grant revenue	831	260	1,570	706
Collaboration revenue	28	1,817	2,016	2,077
Total revenue	6,045	12,531	14,234	19,852
Operating expenses:				
Research and development expenses	20,099	17,905	41,842	40,792
General and administrative expenses	6,491	5,574	12,629	13,069
Restructuring expenses	—	—	—	1,492

Total operating expenses	26,590	23,479	54,471	55,353
Loss from operations	(20,545)	(10,948)	(40,237)	(35,501)
Other (expense) income:				
Interest income	74	189	233	409
Interest expense	(719)	—	(1,435)	—
Other income	476	—	844	—
Total other (expense) income, net	(169)	189	(358)	409
Net loss	$ (20,714)	$ (10,759)	$ (40,595)	$ (35,092)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.28)	$ (0.24)	$ (0.56)	$ (0.81)
Weighted average common shares outstanding, basic and diluted	73,306,248	45,140,830	72,063,881	43,095,686
Net loss	(20,714)	(10,759)	(40,595)	(35,092)
Other comprehensive loss:				
Unrealized gain on investments, net of tax of $0	11	—	1	—
Total other comprehensive gain	11	—	1	—
Comprehensive loss	$ (20,703)	$ (10,759)	$ (40,594)	$ (35,092)

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