Seres Therapeutics Reports Second Quarter 2021 Financial Results and Provides Business Updates

August 3, 2021

– SER-109 open-label study in patients with recurrent C. difficile infection on track to achieve enrollment target in late Q3 2021 –

– SER-109 co-commercialization agreement with Nestlé Health Science provides $310 million in upfront and contingent approval milestones, additional $225 million in contingent sales milestones, and future payments equal to 50% of profits –

– Microbiome analyses from SER-287 Phase 2b ulcerative colitis study anticipated in H2 2021 –

– Continued clinical development progress with SER-155 and SER-301, next-generation rationally designed pipeline candidates –

– Conference call at 8:30 a.m. ET today –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 3, 2021-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome company developing a novel class of multifunctional bacterial therapeutics designed to functionally interact with host cells and tissues to treat disease, today reported second quarter 2021 financial results and provided business updates.

"We have made strong progress advancing SER-109, which we expect will become the first-ever FDA-approved microbiome therapeutic. We are nearing target enrollment in our open-label safety study and preparing to file a Biologics License Application (BLA) to support SER-109 product approval. In addition, we recently entered into a license agreement with Nestlé Health Science to co-commercialize SER-109 in North America, which we believe will most effectively bring SER-109 to patients suffering from recurrent CDI. Furthermore, this transaction provides Seres with substantial capital to extend our leadership position in the development of our platform technologies and pipeline of microbiome therapeutics, including SER-301 and SER-155, as well as our preclinical stage programs," said Eric Shaff, President and Chief Executive Officer of Seres. "Earlier this month we announced topline clinical results from our SER-287 donor-derived investigational microbiome candidate Phase 2b study in ulcerative colitis. We look forward to learning more about this trial from the microbiome results anticipated during the second half of this year, and we expect these scientific data to inform both the continued advancement of our microbiome therapeutic approach in UC and future development candidates more broadly."

Program and Corporate Updates

SER-109 Phase 3 ECOSPOR III study in recurrent *C. difficile* infection: SER-109, an investigational oral, live microbiome therapeutic, achieved its primary endpoint of superiority to placebo in reducing CDI recurrence at week 8 in Seres' Phase 3 clinical trial in patients with recurrent *C. difficile* infection (CDI).

In May, Seres presented final 24-week clinical data from the pivotal SER-109 Phase 3 ECOSPOR III study as a poster of distinction at the Digestive Disease Week® 2021 conference. Study results demonstrated that SER-109 significantly reduced recurrence rates compared to placebo over 24 weeks (21.3% vs. 47.3%, respectively). SER-109 was observed to be well tolerated, with no treatment-related serious adverse events observed in the active arm and an adverse event profile comparable to placebo.

Seres is conducting an ongoing open-label study of SER-109 in patients with recurrent CDI (ClinicalTrials.gov identifier: NCT03183128), which also admits patients with a single recurrence of CDI, to expand the SER-109 safety database. Based on U.S. Food and Drug Administration (FDA) commentary, Seres believes the ECOSPOR III efficacy results should support a BLA filing as a single pivotal study supporting product registration and expects to reach target enrollment for the safety database late in the third quarter of 2021.

Seres continues to execute activities necessary to support a SER-109 BLA submission, while also preparing for a successful product launch with Nestlé Health Science. The Company believes that a substantial commercial opportunity exists for SER-109. Each recurrence of CDI has been estimated to result in approximately $34,000 in direct healthcare expenses. There are approximately 170,000 cases of recurrent CDI annually in the U.S.

In July, Seres announced that it had entered into an agreement with Nestlé Health Science to jointly commercialize SER-109 in the United States and Canada. Under the terms of the agreement, Seres received an upfront license payment of $175 million, and is eligible for an additional $125 million upon FDA approval of SER-109 and $10 million upon approval in Canada. The agreement includes sales target milestones which, if achieved, could total up to $225 million. Seres will be responsible for development and pre-commercialization costs in the U.S. Upon commercialization, Seres will be entitled to an amount equal to 50% of the commercial profits.

SER-287 Phase 2b ECO-RESET study in ulcerative colitis: In July, Seres announced topline results from the Phase 2b ECO-RESET study evaluating SER-287, a donor-derived investigational microbiome therapeutic candidate, in patients with mild-to-moderate ulcerative colitis (UC). The SER-287 Phase 2b ECO-RESET study was a randomized, placebo-controlled, three-arm induction trial that enrolled 203 patients with active mild-to-moderate UC who had inadequate response or loss of response on prior therapy. The study did not meet its primary endpoint of improving clinical remission rates compared to placebo. Both dosing regimens of SER-287 were generally well tolerated. Given the lack of a clinical efficacy signal identified in ECO-RESET, the Company decided to close the open-label and maintenance portions of the study. The Company expects to obtain SER-287 Phase 2b study microbiome data in H2 2021.

SER-301 Phase 1b study in adults with mild-to-moderate ulcerative colitis: Seres is enrolling its Phase 1b study for SER-301, an investigational

oral, rationally-designed, cultivated microbiome therapeutic. SER-301 is being evaluated in adults with mild-to-moderate UC. The study is being conducted in Australia and New Zealand and is designed to enroll approximately 65 subjects. The study objectives are to evaluate drug safety and pharmacokinetics and to evaluate clinical remission and other measures of efficacy as secondary endpoints.

The consortia of bacteria in SER-301 is designed to modify the microbiome and microbe-associated metabolites in the gastrointestinal tract and modulate pathways linked to gastrointestinal inflammation and epithelial barrier integrity in patients with UC. SER-301 was designed and optimized using Seres' reverse translation discovery and development platforms. The SER-301 composition incorporated insights on the engraftment dynamics of different bacteria and also the association of specific bacteria with the modulation of inflammatory and immune pathways in human subjects that have been observed across Seres' broader clinical portfolio and confirmed using Seres' nonclinical human-cell based assays and in vivo models.

SER-155 Phase 1b clinical study activities: In June, Seres announced that the FDA had indicated that studies for SER-155 may proceed under an Investigational New Drug application. Seres expects to soon begin enrolling a SER-155 Phase 1b clinical study in collaboration with Memorial Sloan Kettering Cancer Center and the University of Chicago.

SER-155 is an investigational oral, rationally-designed, cultivated microbiome therapeutic designed to reduce the incidence of gastrointestinal infections, bacteremia, and graft versus host disease (GvHD) in immunocompromised patients, including patients receiving allogeneic hematopoietic stem cell transplantation (allo-HSCT). SER-155 is a consortium of bacterial species selected using Seres' reverse translation discovery and development platforms. The design incorporates microbiome biomarker data from human clinical data and nonclinical human cell-based assays and in vivo disease models. The SER-155 composition aims to decrease infection and translocation of antibiotic-resistant bacteria in the gastrointestinal tract and modulate host immune responses to decrease GvHD.

In June, Seres announced data from its collaboration with the University of Cologne demonstrating that decreased microbiome diversity in allo-HSCT recipients is associated with poor clinical outcomes including mortality and increased incidence of intestinal GvHD. The data were presented at the 2021 American Society of Clinical Oncology Annual Meeting. A separate poster presentation, including data from a collaboration with Memorial Sloan Kettering Cancer Center, established a significant association between microbiome composition and response to immune checkpoint inhibitor treatment in patients who have metastatic melanoma, metastatic lung, urothelial, or renal cancer.

Appointment of Chief Financial Officer and Head of Business Development: In May, Seres announced that David Arkowitz was appointed as Executive Vice President, Chief Financial Officer (CFO) and Head of Business Development. Mr. Arkowitz brings to Seres more than 30 years of finance, operations, business development and commercial leadership experience in the life sciences and biotech industries. He joins Seres from Flexion Therapeutics, Inc., where he served as CFO. Prior to Flexion, Mr. Arkowitz served as Chief Operating Officer and CFO at Visterra, Inc., a biotech company that was acquired by Otsuka Pharmaceutical Co. He previously served as CFO at Mascoma Corporation, AMAG Pharmaceuticals Inc. and Idenix Pharmaceuticals Inc., and held additional leadership positions within each company. Earlier, Mr. Arkowitz spent more than 13 years at Merck & Co., Inc. where he held roles of increasing responsibility, including Vice President and Controller of the U.S. operations, Controller of the global research and development division, and CFO of the Canadian subsidiary. Mr. Arkowitz earned a B.A. in mathematics from Brandeis University and a M.B.A. in finance from Columbia University Business School.

Financial Results

Seres reported a net loss of $48.3 million for the second quarter of 2021, as compared with a net loss of $20.7 million for the same period in 2020. 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 2021 were $36.0 million, compared with $20.1 million for the same period in 2020. The research and development expenses were primarily related to Seres' late-stage SER-109 and SER-287 clinical development programs, as well as personnel expenses.

General and administrative expenses for the second quarter of 2021 were $17.5 million, compared with $6.5 million for the same period in 2020. General and administrative expenses were primarily due to personnel expenses, professional fees and facility costs.

As of June 30, 2021, Seres had approximately $229.4 million in cash, cash equivalents and marketable securities. The June 30, 2021, cash balance does not include the upfront fee of $175.0 million that has been received by Seres following the SER-109 Co-Commercialization License Agreement announced on July 1, 2021, with Nestlé Health Science. As a result, the June 30, 2021, pro-forma cash balance, inclusive of the upfront fee from Nestlé, was approximately $404 million.

Conference Call Information

Seres' management will host a conference call today, August 3, 2021, at 8:30 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 6519859. To join the live webcast, please visit the "Investors and News" 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 at least 21 days.

About Seres Therapeutics

Seres Therapeutics, Inc., (Nasdaq: MCRB) is a leading microbiome therapeutics company developing a novel class of multifunctional bacterial consortia that are designed to functionally interact with host cells and tissues to treat disease. Seres' SER-109 program achieved the first-ever positive pivotal clinical results for a targeted microbiome drug candidate and has obtained Breakthrough Therapy and Orphan Drug designations from the FDA. The SER-109 program is being advanced for the treatment of recurrent *C. difficile* infection and has potential to become a first-in-class FDA-approved microbiome therapeutic. Seres is evaluating SER-301 in a Phase 1b study in patients with 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 safety,

efficacy and regulatory and clinical progress of our product candidates; the potential market for SER-109; the potential approval of SER-109; the timing of study enrollment; and its potential status as a first-in-class therapeutic; the ultimate success and ability to achieve targets and receive milestones payments from the Nestlé Health Science agreement; the timing and impact of microbiome analysis from the SER-287 study; the timing and development of our early stage pipeline, the promise of our microbiome therapeutics; our development plans; 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 and manufacture our product candidates, if approved; 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 4, 2021, 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, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 73,997	$ 116,049
Short term investments	140,556	137,567
Prepaid expenses and other current assets	8,751	5,774
Accounts receivable	1,251	9,387
Total current assets	224,555	268,777
Property and equipment, net	15,047	13,897
Operating lease assets	12,415	9,041
Restricted investments	2,150	1,400
Long term investments	14,879	49,825
Other non-current assets	602	—
Total assets	$ 269,648	$ 342,940
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,450	$ 4,018
Accrued expenses and other current liabilities	18,913	14,226
Operating lease liabilities	5,675	5,115
Short term portion of note payable, net of discount	6,298	454
Deferred revenue - related party	19,829	22,602
Total current liabilities	56,165	46,415
Long term portion of note payable, net of discount	19,036	24,639
Operating lease liabilities, net of current portion	13,828	10,561
Deferred revenue, net of current portion - related party	78,434	85,572
Other long-term liabilities	1,119	1,003
Total liabilities	168,582	168,190
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2021 and December 31, 2020; no shares issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at June 30, 2021 and December 31, 2020; 91,713,810 and 91,459,239 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	92	91
Additional paid-in capital	733,533	723,482
Accumulated other comprehensive income (loss)	12	(47)
Accumulated deficit	(632,571)	(548,776)
Total stockholders' equity	101,066	174,750
Total liabilities and stockholders' equity	$ 269,648	$ 342,940

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,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Collaboration revenue - related party	$ 5,263	$ 5,186	$ 9,911	$ 10,648
Grant revenue	—	831	1,070	1,570
Collaboration revenue	—	28	—	2,016
Total revenue	5,263	6,045	10,981	14,234
Operating expenses:				
Research and development expenses	35,954	20,099	65,257	41,842
General and administrative expenses	17,451	6,491	29,192	12,629
Total operating expenses	53,405	26,590	94,449	54,471
Loss from operations	(48,142)	(20,545)	(83,468)	(40,237)
Other (expense) income:				
Interest income	829	74	1,795	233
Interest expense	(732)	(719)	(1,428)	(1,435)
Other (expense) income	(285)	476	(694)	844
Total other (expense) income, net	(188)	(169)	(327)	(358)
Net loss	$ (48,330)	$ (20,714)	$ (83,795)	$ (40,595)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.53)	$ (0.28)	$ (0.91)	$ (0.56)
Weighted average common shares outstanding, basic and diluted	91,659,829	73,306,248	91,593,845	72,063,881
Net loss	(48,330)	(20,714)	(83,795)	(40,595)
Other comprehensive income (loss):				
Unrealized gain on investments, net of tax of $0	27	11	59	1
Total other comprehensive income (loss)	27	11	59	1
Comprehensive loss	$ (48,303)	$ (20,703)	$ (83,736)	$ (40,594)

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PR

Kristin Ainsworth
kainsworth@serestherapeutics.com

IR

Carlo Tanzi, Ph.D.
ctanzi@serestherapeutics.com

Source: Seres Therapeutics, Inc.