Seres Therapeutics Reports Third Quarter 2022 Financial Results and Provides Business Updates

November 2, 2022

– Biologics License Application (BLA) for investigational microbiome therapeutic SER-109 for recurrent C. difficile infection (rCDI) accepted for Priority Review by U.S. Food and Drug Administration (FDA) –

– PDUFA target action date is April 26, 2023, with anticipated launch soon thereafter –

– Additional SER-109 ECOSPOR III Phase 3 study results published in Journal of the American Medical Association, following initial publication in New England Journal of Medicine –

– SER-109 investor event highlighting rCDI market opportunity and launch preparations to be held December 8, 2022 –

– SER-155 cohort 1 enrollment complete; Company expects pre-planned review of safety data with DMSB before year end, with initial safety and pharmacological cohort 1 data reported in early 2023 –

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

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 2, 2022-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, today reported third quarter 2022 financial results and provided business updates.

“Our recent progress, highlighted by the FDA acceptance of our SER-109 BLA for Priority Review, brings us closer to potentially offering a transformative new medicine to individuals caught in the vicious cycle of recurrent *C. difficile* infection,” said Eric Shaff, President and Chief Executive Officer at Seres. “With a PDUFA date of April 26, 2023, we are closely engaging with the FDA and preparing for a potential product approval and commercial launch shortly thereafter. Alongside our collaborator, Aimmune Therapeutics, Inc., a Nestlé Health Science company, we are making excellent progress advancing educational efforts with physicians and payors in support of broad patient access, pending FDA approval. We look forward to hosting an investor event on December 8th to provide detailed information on the recurrent CDI market opportunity and our launch preparations."

Program and Corporate Updates

SER-109 Phase 3 program in recurrent *C. difficile* infection: SER-109, an investigational oral, live microbiome therapeutic, achieved its primary endpoint of superiority to placebo in reducing recurrence in patients with rCDI in the ECOSPOR III study. These results, initially published in the New England Journal of Medicine (NEJM), showed that 88% of SER-109 patients achieved a sustained clinical response compared to 60% on placebo at eight weeks. SER-109 was observed to be well tolerated with no drug-related serious adverse events in a Phase 3 study.

In October 2022, Seres announced the publication of additional ECOSPOR III results in the Journal of the American Medical Association (JAMA), highlighting that the clinical benefits of SER-109 in preventing recurrent rCDI were apparent as early as two weeks post-treatment and sustained for at least 24 weeks.

In June 2022, Seres reported positive confirmatory results from ECOSPOR IV, an open-label study of SER-109 in patients with rCDI (ClinicalTrials.gov identifier: NCT03183141) designed to expand the SER-109 safety database in support of the BLA filing. As recently presented at the IDWeek and American College of Gastroenterology (ACG) 2022 Annual Meetings, the ECOSPOR IV study evaluated adults with rCDI, providing 24-week data for an additional 263 subjects administered SER-109. ECOSPOR IV enrolled subjects with a clinical profile consistent with those commonly treated in clinical practice. The overall safety profile observed through the 24-week follow-up showed that SER-109 was well tolerated, consistent with the profile observed in ECOSPOR III.

In ECOSPOR IV, 91.3% of patients in the overall population achieved a sustained clinical response at eight weeks. Similarly low recurrence rates were observed in key subpopulations at eight weeks, including subjects with a first recurrence (6.5%), second recurrence (6.1%) and three or more recurrences (13.8%).

In October 2022, Seres announced its Biologics License Application for SER-109 was accepted for Priority Review by the FDA. A Prescription Drug User Fee Act (PDUFA) target action date has been set for April 26, 2023. The FDA has conveyed that they are not currently planning to hold an Advisory Committee Meeting to discuss the SER-109 application.

Seres has an active SER-109 expanded access program at various sites across the U.S. The program is designed to enable eligible adults with rCDI to obtain access to the investigational therapeutic prior to a potential FDA product approval.

Seres continues to execute pre-commercialization activities in collaboration with Aimmune Therapeutics, including appropriate market education and data dissemination to the medical community. In addition, activities are ongoing to engage payers in accordance with FDA guidance on pre-approval information exchange. The Company has SER-109 drug supply ready in anticipation of product approval and continues to make progress expanding commercial-scale production of SER-109 to prepare for anticipated future market demand. An ongoing agreement with Bacthera, a global leader in biopharmaceutical product manufacturing, is designed to increase longer-term SER-109 product supply and adds to existing manufacturing capabilities.

Seres plans to host a SER-109 investor event, including participation by Aimmune, focused on the rCDI market opportunity and launch preparations on December 8, 2022.

SER-155 Phase 1b clinical study activities: Seres continues to advance a Phase 1b clinical study of SER-155 designed to evaluate safety and microbiome drug pharmacology. The trial will also assess the impact on infections and/or graft versus host disease (GvHD) associated with SER-155 in adult subjects who are undergoing allogeneic hematopoietic stem cell transplantation (allo-HSCT). SER-155 is an investigational oral, rationally designed, cultivated microbiome therapeutic designed to reduce the incidence of gastrointestinal (GI) infections, bloodstream infections, and GvHD in patients receiving allo-HSCT. The study is currently being conducted at Memorial Sloan Kettering Cancer Center, University of Chicago Medical Center, Harvard Medical School - Massachusetts General Hospital Cancer Center, Mayo Clinic (Scottsdale, Arizona) and with additional leading medical centers to be added.

Seres recently completed enrollment of cohort 1 and anticipates conducting a pre-planned meeting with the study's Data and Safety Monitoring Board (DSMB) to review SER-155 cohort 1 safety data by the end of the year. In addition, the Company plans to announce initial safety and pharmacological data, including drug bacterial species engraftment from cohort 1, in early 2023.

SER-155 is a consortium of bacterial species selected using Seres' reverse translation discovery and development platform technologies. 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 the colonization and abundance of bacterial pathogens that can harbor antibiotic-resistant and to enhance epithelial barrier integrity in the GI tract to both reduce the likelihood of pathogen translocation and decrease the incidence of bloodstream infections. Further, SER-155 is designed to modulate host immune responses to decrease GvHD.

Infection Protection research: The Company continues to conduct research to bring forward new clinical candidates related to using microbiome therapeutics as a novel approach for Infection Protection for medically compromised individuals, including those with cancer neutropenia, cirrhosis, or solid organ transplant. Preclinical studies are evaluating the potential to reduce the abundance of targeted pathogens to decrease the potential for pathogen transmission, strengthen epithelial barriers to further reduce translocation and the frequency of bloodstream infections, and to modulate immune responses to tackle medical complications such as graft versus host disease GvHD. The Company plans to announce an additional Infection Protection clinical development program in 2023.

Ulcerative Colitis (UC) research: The Company previously reported clinical, microbiome and metabolomic data from the SER-287 Phase 2b study and the first cohort of its SER-301 Phase 1b study. Available data for these investigational microbiome therapeutics suggest that there may be an opportunity to utilize biomarker-based patient selection and stratification for future studies. Research activities remain ongoing to inform potential further development activities.

Registered direct common stock offering: In July 2022, the Company closed a registered direct equity offering of its common stock resulting in proceeds, net of placement agent fees, of approximately $96.7 million.

Financial Results

Seres reported a net loss of $60.0 million for the third quarter of 2022, as compared with net income of $68.2 million for the same period in 2021.

Research and development expenses for the third quarter of 2022 were $43.1 million, compared with $39.9 million for the same period in 2021. The research and development expenses were primarily related to Seres' late-stage SER-109 clinical development program and manufacturing costs, as well as personnel expenses.

General and administrative expenses for the third quarter of 2022 were $18.4 million, compared with $19.6 million for the same period in 2021. General and administrative expenses were primarily related to personnel expenses, professional fees, including SER-109 commercial readiness and pre-launch expenses, and facility costs.

As of September 30, 2022, Seres had approximately $233.0 million in cash, cash equivalents and marketable securities as compared with $291.2 million at the end of 2021.

Conference Call Information

Seres' management will host a conference call today, November 2, 2022, at 8:30 a.m. ET. To access the conference call, please dial 800-715-9871 (domestic) or 646-307-1963 (international) and reference Conference ID 8315051. 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 to prevent further recurrences of C. difficile infection and has potential to become a first-in-class FDA-approved oral microbiome therapeutic. Seres is evaluating SER-155 in a Phase 1b study in patients receiving allogeneic hematopoietic stem cell transplantation to reduce incidences of gastrointestinal infections, bloodstream infections and graft-versus-host disease as well as additional preclinical stage programs targeting Infection Protection in medically compromised patients. The Company is also conducting research to inform further development of microbiome therapeutics for ulcerative colitis.

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 potential

approval and launch of SER-109; the anticipated indication for SER-109; the anticipated supply of SER-109; the potential for microbiome therapeutics to protect against infection; the timing of clinical results; our development plans; and other statements which are not historical fact.

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; and our ability to retain key personnel and to manage our growth. 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 (SEC), on August 3, 2022, 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)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 205,398	$ 180,002
Short term investments	27,605	110,704
Prepaid expenses and other current assets	14,510	12,922
Total current assets	247,513	303,628
Property and equipment, net	19,484	17,938
Operating lease assets	23,747	18,208
Restricted cash	8,185	8,000
Restricted investments	1,401	1,401
Long term investments	—	495
Other non-current assets	11,538	5,189
Total assets	$ 311,868	$ 354,859
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,449	$ 13,735
Accrued expenses and other current liabilities (1)	59,169	45,094
Operating lease liabilities	7,333	6,610
Deferred revenue - related party	4,868	16,819
Total current liabilities	81,819	82,258
Long term portion of note payable, net of discount	50,857	24,643
Operating lease liabilities, net of current portion	17,850	17,958
Deferred revenue, net of current portion - related party	92,796	86,998
Other long-term liabilities (2)	961	11,495
Total liabilities	244,283	223,352
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2022 and December 31, 2021; no shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at September 30, 2022 and December 31, 2021; 124,410,917 and 91,889,418 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	124	92
Additional paid-in capital	863,294	745,829
Accumulated other comprehensive loss	(118)	(60)
Accumulated deficit	(795,715)	(614,354)
Total stockholders' equity	67,585	131,507
Total liabilities and stockholders' equity	$ 311,868	$ 354,859

[1] Includes related party amounts of $34,112 and $21,098 at September 30, 2022 and December 31, 2021, respectively

[2] Includes related party amounts of $0 and $10,585 at September 30, 2022 and December 31, 2021, respectively

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME
(unaudited, in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue:				
Collaboration revenue - related party	$ 3,444	$ 126,725	$ 6,153	$ 136,636
Grant revenue	—	$ —	—	1,070
Total revenue	3,444	126,725	6,153	137,706
Operating expenses:				
Research and development expenses	43,116	39,882	126,700	105,139
General and administrative expenses	18,384	19,563	57,290	48,755
Collaboration (profit) loss sharing - related party	1,051	(1,127)	346	(1,127)
Total operating expenses	62,551	58,318	184,336	152,767
(Loss) income from operations	(59,107)	68,407	(178,183)	(15,061)
Other (expense) income:				
Interest income	865	590	1,644	2,385
Interest expense	(1,727)	(744)	(4,140)	(2,172)
Other expense	(33)	(35)	(682)	(729)
Total other (expense) income, net	(895)	(189)	(3,178)	(516)
Net (loss) income	$ (60,002)	$ 68,218	$ (181,361)	$ (15,577)
Net (loss) income per share attributable to common stockholders, basic	$ (0.49)	$ 0.74	$ (1.77)	$ (0.17)
Net (loss) income per share attributable to common stockholders, diluted	$ (0.49)	$ 0.72	$ (1.77)	$ (0.17)
Weighted average common shares outstanding, basic	122,527,275	91,757,614	102,380,700	91,649,035
Weighted average common shares outstanding, diluted	122,527,275	94,953,117	102,380,700	91,649,035
Other comprehensive income (loss):				
Unrealized gain (loss) on investments, net of tax of $0	140	(1)	(56)	58
Currency translation adjustment	(2)	—	(2)	—
Total other comprehensive income (loss)	138	(1)	(58)	58
Comprehensive (loss) income	$ (59,864)	$ 68,217	$ (181,419)	$ (15,519)

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