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

May 4, 2022

– SER-109 open label study results, including safety and efficacy data, including in over 260 individuals enrolled with recurrent C. difficile infection, anticipated in Q2 2022 –

– FDA agreement obtained for rolling SER-109 Biologics License Application (BLA) plan; filing completion on track for mid-2022 –

– SER-109 pre-commercialization activities underway, including medical education and payer engagement –

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

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 4, 2022-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, today reported first quarter 2022 financial results and provided business updates.

"Seres continued to make important progress toward bringing SER-109 to patients suffering with recurrent *C. difficile* infection (rCDI). Given the robust profile of SER-109 observed in our Phase 3 study, we expect the product to have a significant impact on rCDI, a serious disease with approximately 170,000 cases annually in the US. We look forward to meaningful additional clinical data, including in first recurrence CDI patients, from our SER-109 open label study later this quarter, supporting a mid-2022 completion of our BLA submission with the U.S. Food and Drug Administration (FDA)," said Eric Shaff, President and Chief Executive Officer at Seres. "We are also advancing our commercialization efforts alongside our collaborator, Aimmune Therapeutics, Inc., a Nestlé Health Science company, in anticipation of a potential SER-109 product launch in the first half of 2023."

"In tandem, we are excited about our earlier stage pipeline and continue to enroll our Phase 1b clinical study of SER-155 designed to evaluate safety, microbiome alterations, and the impact on infections and/or graft versus host disease (GvHD) in adult subjects who are undergoing allogeneic hematopoietic stem cell transplantation (allo-HSCT). Preclinical activities are also underway for additional Infection Protection development candidates, leveraging our prior compelling clinical data in this therapeutic category, for indications such as cancer neutropenia, solid organ transplant, and antimicrobial resistant infections more broadly," continued Mr. Shaff.

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 in patients with rCDI.

Seres has achieved target enrollment in an open-label study of SER-109 in patients with rCDI (ClinicalTrials.gov identifier: NCT03183141), which also enrolled over 25% of patients with a single recurrence of rCDI, to expand the SER-109 database in support of the planned BLA filing. Study results are anticipated in Q2 2022. The FDA recently endorsed Seres' plans regarding a rolling BLA submission for SER-109. Seres intends to begin the BLA rolling submission in the coming weeks, and to complete the BLA submission, including data from the open-label study, in mid-2022.

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 SER-109 prior to a potential FDA product approval.

The Company continues to prepare for a successful product launch with Aimmune Therapeutics, Inc., a Nestlé Health Science company, who will be leading commercialization efforts. The Company believes that a substantial commercial opportunity exists for SER-109. The cost of a patient with recurrence of CDI has been estimated to result in approximately $34,000 in annual direct healthcare expenses; this does not include the substantial indirect costs associated with this disease. There are approximately 170,000 cases of rCDI annually in the U.S. and CDI results in over 20,000 deaths.

Seres continues to execute pre-commercialization activities in collaboration with Aimmune Therapeutics, including market education and data dissemination to the medical community. Medical Affairs led engagement of key opinion leaders has increased following the publication of the SER-109 Phase 3 data in the *New England Journal of Medicine*. In addition, activities have been initiated to engage payers in accordance with FDA guidance on pre-approval information exchange.

In January 2022, the *New England Journal of Medicine (NEJM)* published data from the SER-109 Phase 3 ECOSPOR III study evaluating SER-109 for the treatment of rCDI. The publication highlights key results including that SER-109 was superior to placebo in reducing CDI recurrence, with 88% of SER-109 patients achieving a sustained clinical response compared to 60% on placebo. SER-109 was well tolerated, with a side effect profile comparable to placebo and no serious drug-related adverse events observed.

SER-155 Phase 1b clinical study activities: In December 2021, Seres announced the enrollment of the first patient in the Company's Phase 1b clinical study of SER-155 designed to evaluate safety, microbiome alterations, and the impact on infections and/or GvHD associated with SER-155 in adult subjects who are undergoing allo-HSCT. In April 2022, the SER-155 Data and Safety Monitoring Committee met as part of a planned data review, and approved a recommendation to continue with enrollment in Cohort 1 based on an evaluation of available safety data. The study is being conducted with Memorial Sloan Kettering Cancer Center and the University of Chicago with additional sites expected to be added soon.

SER-155 is an investigational oral, rationally designed, cultivated microbiome therapeutic designed to reduce the incidence of gastrointestinal infections, bloodstream infections, and GvHD in patients receiving 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 the colonization and translocation of antibiotic-resistant bacteria in the gastrointestinal tract to decrease the incidence of bloodstream infections and additionally to modulate host immune responses to decrease GvHD. In addition to SER-109, SER-155 represents Seres' second active development program in its Infection Protection franchise.

Infection Protection investor event: In January 2022, Seres held a webcast event that highlighted development of microbiome therapeutics as a novel approach for Infection Protection in medically compromised individuals. Building upon SER-109, and in addition to SER-155, Seres is also evaluating additional preclinical stage programs in indications such as cancer neutropenia, solid organ transplant, and antimicrobial resistant infections more broadly.

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 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.

Financial Results

Seres reported a net loss of $56.6 million for the first quarter of 2022, as compared with a net loss of $35.5 million for the same period in 2021.

Research and development expenses for the first quarter of 2022 were $39.6 million, compared with $29.3 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 first quarter of 2022 were $18.6 million, compared with $11.7 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.

Seres ended the first quarter of 2022 with approximately $248.0 million in cash, cash equivalents and investments as compared with $291.2 million at the end of 2021.

Conference Call Information

Seres' management will host a conference call today, May 4, 2022, at 8:30 a.m. ET. To access the conference call, please dial 877-270-2148 (domestic) or 412-902-6510 (international) and reference the Seres Therapeutics conference call. 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 reduce the recurrence of *C. difficile* infection and has potential to become a first-in-class FDA-approved 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 of SER-109 and its status as a first-in-class therapeutic; the timing of a BLA filing and potential product launch; the market for SER-109; the anticipated indication and potential impact of microbiome therapeutics; the ability to utilize biomarker-based patient selection in UC development; plans, timing and potential impact of the release of additional preclinical and clinical data; our development opportunities; the ultimate safety and efficacy data for our products; the potential benefits of our collaborations; 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 1, 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)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 153,192	$ 180,002
Short term investments	94,809	110,704
Prepaid expenses and other current assets	15,249	12,922
Total current assets	263,250	303,628
Property and equipment, net	19,066	17,938
Operating lease assets	26,246	18,208
Restricted cash	8,185	8,000
Restricted investments	1,401	1,401
Long term investments	—	495
Other non-current assets	1,741	5,189
Total assets	$ 319,889	$ 354,859
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,791	$ 13,735
Accrued expenses and other current liabilities (1)	48,278	45,094
Operating lease liabilities	6,849	6,610
Deferred revenue - related party	20,441	16,819
Total current liabilities	82,359	82,258
Long term portion of note payable, net of discount	50,437	24,643
Operating lease liabilities, net of current portion	20,346	17,958
Deferred revenue, net of current portion - related party	81,883	86,998
Other long-term liabilities (2)	3,908	11,495
Total liabilities	238,933	223,352
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2022 and December 31, 2021; no shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at March 31, 2022 and December 31, 2021; 92,210,305 and 91,889,418 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	92	92
Additional paid-in capital	752,057	745,829
Accumulated other comprehensive loss	(215)	(60)
Accumulated deficit	(670,978)	(614,354)
Total stockholders' equity	80,956	131,507
Total liabilities and stockholders' equity	$ 319,889	$ 354,859

[1] Includes related party amounts of $29,809 and $21,098 at March 31, 2022 and December 31, 2021, respectively

[2] Includes related party amounts of $2,981 and $10,585 at March 31, 2022 and December 31, 2021, respectively

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

	Three Months Ended March 31,	
	2022	2021
Revenue:		
Collaboration revenue - related party	$ 1,493	$ 4,648
Grant revenue	—	1,070
Total revenue	1,493	5,718
Operating expenses:		
Research and development expenses	39,649	29,303
General and administrative expenses	18,571	11,741
Collaboration (profit) loss sharing - related party	(976)	—
Total operating expenses	57,244	41,044

Loss from operations	(55,751)	(35,326)
Other (expense) income:		
Interest income	384	966
Interest expense	(912)	(696)
Other expense	(345)	(409)
Total other (expense) income, net	(873)	(139)
Net loss	$ (56,624)	$ (35,465)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.61)	$ (0.39)
Weighted average common shares outstanding, basic and diluted	92,164,419	91,527,800
Other comprehensive (loss) income:		
Unrealized (loss) gain on investments, net of tax of $0	(155)	32
Total other comprehensive (loss) income	(155)	32
Comprehensive loss	$ (56,779)	$ (35,433)

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