# Seres Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Updates

March 2, 2021

*– SER-287 Phase 2b study in patients with mild-to-moderate ulcerative colitis has achieved target enrollment; topline data expected in mid-2021 –*

*– Continued enrollment in SER-109 open label study in recurrent C. difficile infection to support planned BLA filing; potential to be first FDA-approved microbiome therapeutic –*

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

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 2, 2021-- Seres Therapeutics, Inc., (Nasdaq: MCRB), a leading microbiome therapeutics company, today reported fourth quarter and full year 2020 financial results and provided business updates.

“Seres continues to make progress executing against our top corporate priorities. We are enrolling our open label study to support a Biologics License Application (BLA) for SER-109, a potential first-ever FDA approved microbiome therapeutic. We have also advanced our clinical pipeline and expanded our core microbiome therapeutic drug discovery and CMC capabilities,” said Eric Shaff, President and Chief Executive Officer of Seres.

“We enter 2021 with a strong balance sheet, poised to continue leading the microbiome therapeutic field. Our pipeline spans infectious diseases, inflammatory diseases, and oncology, and we look forward to continued progress during the year, including our development stage pipeline candidates and earlier stage drug discovery efforts. We are pleased to have achieved target enrollment for the SER-287 ECO-RESET Phase 2b study and look forward to obtaining topline results mid-year, an acceleration compared to our prior projections. Our SER-287 program is another embodiment of our mission to develop product candidates with the potential to fundamentally transform patients’ lives by providing substantial clinical benefit over today’s standard of care,” concluded 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 a high rate of sustained clinical response in our Phase 3 clinical trial by repairing the disrupted microbiome in patients with recurrent *C. difficile* infection (CDI).

In August 2020, Seres announced positive topline interim results from the SER-109 Phase 3 study, ECOSPOR III. The Phase 3 study (ClinicalTrials.gov identifier: NCT03183128) is a multicenter, randomized, placebo-controlled study that enrolled 182 patients with multiply recurrent CDI. Patients were randomized 1:1 to receive either SER-109 or placebo after standard of care antibiotic treatment. Final end-of-study 24-week results reiterated that ECOSPOR III achieved the study’s primary endpoint and demonstrated a sustained clinical response rate of approximately 88% at eight weeks post-treatment. SER-109 resulted in a 27% absolute reduction of recurrence of CDI compared to placebo at 8 weeks post-treatment, which is a relative risk reduction of 69%. SER-109 was well tolerated, with no treatment-related serious adverse events (SAEs) observed in the active arm and an adverse event profile comparable to placebo.

Following the topline Phase 3 study results, the FDA reaffirmed its prior position regarding the efficacy requirements to support an SER-109 BLA submission, which were exceeded by the positive SER-109 ECOSPOR III study results, as well as its prior position that the safety database should be at least 300 subjects. Seres believes that ECOSPOR III will be a single pivotal efficacy study supporting product registration.

In October 2020, Seres presented SER-109 Phase 3 topline results along with additional clinical data at the virtual American College of Gastroenterology (ACG) Annual Scientific Meeting. These new data demonstrated that the 12-week treatment difference between SER-109 and placebo remained consistent with the 8-week treatment difference. In addition, subsequent 24-week data demonstrate that the clinical effect of SER-109 is durable.

In January 2021, at the Keystone Symposium, Seres presented Phase 3 microbiome and metabolomic endpoint data that provide mechanistic support for the SER-109 efficacy observed. The study data demonstrate that SER-109 bacterial species rapidly engraft into the gastrointestinal tract; engraftment was observed as early as 1-week post-treatment and was durable through eight weeks, confirming the biological activity of SER-109. SER-109 administration also rapidly shifted the gastrointestinal metabolic landscape, including a significant decrease in primary bile acids and an increase in secondary bile acids, providing a mechanistic basis for inhibition of *C. difficile* spore germination and vegetative growth.

Seres is conducting an ongoing SER-109 open-label study 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. The Company continues to make progress activating new clinical sites and enrolling subjects into the study at clinical sites across the U.S. and Canada. Additional information is available at serescdiffstudy.com.

**SER-287 Phase 2b ECO-RESET study in ulcerative colitis:** SER-287, an oral microbiome therapeutic candidate consisting of a consortium of highly purified Firmicute spores, is designed to normalize the gastrointestinal microbiome of individuals with UC. Seres has obtained FDA Fast Track designation for SER-287 in active mild-to-moderate ulcerative colitis. SER-287 targets restructuring the microbiome to reduce proinflammatory activity and modulate UC-relevant inflammatory pathways, potentially providing a much-needed non-immunosuppressive treatment option to patients

suffering from ulcerative colitis. SER-287 has the potential to be used as both a monotherapy and potentially in combination with other approved agents.

The SER-287 Phase 2b ECO-RESET study is a randomized, placebo-controlled, three-arm induction trial designed to enroll 201 patients with active mild-to-moderate ulcerative colitis who have failed prior therapy. In arm A, patients receive a short course of vancomycin preconditioning followed by ten weeks of the same daily regimen used in the arm of the Phase 1b trial that showed the highest clinical remission rate. In arm B, patients receive vancomycin preconditioning followed by two weeks of the SER-287 daily regimen as in the first arm, followed by eight weeks of a lower dose of SER-287. In arm C, patients receive placebo.

The SER-287 Phase 2b ECO-RESET induction study in patients with active mild-to-moderate ulcerative colitis has achieved target enrollment. Topline study results are anticipated in mid-2021. The timing of anticipated study results represents an acceleration compared to the Company's prior expectations.

**Publication of SER-287 Phase 1b study results:** The Phase 1b study results demonstrated that SER-287 administration was associated with high rates of clinical remission, endoscopic improvement, modulation of the gastrointestinal microbiome, and a favorable tolerability profile. The paper, titled "A Phase 1b Safety Study of SER-287, a Spore-Based Microbiome Therapeutic, For Active Mild-To-Moderate Ulcerative Colitis," was published as the highlighted cover article in the January 2021 print edition of the leading journal *Gastroenterology*.

**SER-301 Phase 1b study in adults with mild-to-moderate ulcerative colitis:** In November 2020, the Company dosed the first patient in its Phase 1b study for SER-301, an investigational oral, rationally-designed, cultivated microbiome therapeutic and study enrollment is ongoing. SER-301 is being evaluated in a Phase 1b study in adults with mild-to-moderate ulcerative colitis. 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 ulcerative colitis. SER-301 was designed using Seres' reverse translation discovery and development platforms. The design incorporated learnings from the SER-287 Phase 1b study related to the bacterial species and the microbiome functional signatures associated with clinical efficacy. Additionally, the design 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 our broader clinical portfolio and confirmed using our nonclinical human-cell based assays and in vivo models.

In December 2020, Seres received a $10 million milestone payment associated with the Phase 1b SER-301 clinical study initiation from Nestlé Health Science, the Company's ex-North American collaborative partner for this program.

**SER-155 Phase 1b clinical study activities:** SER-155 is an investigational oral, rationally-designed, cultivated microbiome therapeutic designed to prevent or reduce mortality due to gastrointestinal infections, bacteremia, and graft versus host disease (GvHD) in immunocompromised patients, including patients receiving allogeneic hematopoietic stem cell transplantation. SER-155 is a consortium of bacterial species selected 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. Seres continues to advance SER-155 toward a Phase 1b clinical study in collaboration with Memorial Sloan Kettering Cancer Center.

**SER-401 Phase 1b study in metastatic melanoma:** SER-401 is an orally-administered, live microbiome therapeutic candidate comprising bacteria that reflect the bacterial signature in the gastrointestinal microbiome associated with patient response to checkpoint inhibitor immunotherapy. SER-401 Phase 1b study enrollment has been impacted by COVID-19-related operation disruptions and enrollment has been slower than anticipated. Further development plans for SER-401 are being assessed by Seres and its study collaborators, the Parker Institute for Cancer Immunotherapy and MD Anderson Cancer Center.

**Financial Results**

Seres reported a net loss of $89.1 million for the full year of 2020, as compared to a net loss of $70.3 million for the prior year. Seres reported a net loss of $18.3 million for the fourth quarter of 2020, as compared to a net loss of $18.8 million for the same period in 2019.

Research and development expenses for the fourth quarter of 2020 were $24.9 million, as compared to $21.0 million for the same period in 2019. The research and development expenses were primarily related to Seres' microbiome therapeutics platform, the clinical development of SER-109 and SER-287, as well as the Company's immuno-oncology efforts.

General and administrative expenses for the fourth quarter were $10.6 million, as compared to $5.8 million for the same period in the prior year. General and administrative expenses were primarily due to headcount, including costs related to infrastructure supporting commercialization, professional fees and facility costs.

Seres ended the 2020 year with approximately $303.4 million in cash, cash equivalents and short and long-term investments.

**Conference Call Information**

Seres' management team will host a conference call today, March 2, 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 7338026. 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 platform 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' SER-287 program has obtained Fast Track and Orphan Drug designations from the FDA and is being evaluated in a Phase 2b study in patients with active mild-to-moderate ulcerative colitis. Seres is evaluating SER-401 in a Phase 1b study in patients with metastatic melanoma, 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 potential market for SER-109, the impact of the microbiome and metabolomic data on our other programs, the potential approval of SER-109 and its potential status as a first-in-class therapeutic, the timing of our clinicial studies, the safety results observed to-date in our clinical studies, the promise of our microbiome therapeutics, the potential impact of the COVID-19 pandemic, 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, 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 November 9, 2020, and our other reports filed with the SEC, including the Annual 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.**
**CONSOLIDATED BALANCE SHEETS**
**(In thousands, except share and per share data)**

| | December 31, | |
|---|---|---|
| | **2020** | **2019** |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 116,049 | $ 65,126 |
| Short term investments | 137,567 | 29,690 |
| Prepaid expenses and other current assets | 5,774 | 3,588 |
| Accounts receivable | 9,387 | 1,785 |
| Total current assets | 268,777 | 100,189 |
| Property and equipment, net | 13,897 | 19,495 |
| Operating lease assets | 9,041 | 11,356 |
| Restricted investments | 1,400 | 1,400 |
| Long term investments | 49,825 | — |
| Total assets | $ 342,940 | $ 132,440 |
| **Liabilities and Stockholder's Equity (Deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 4,018 | $ 4,859 |
| Accrued expenses and other current liabilities | 14,226 | 10,884 |
| Operating lease liabilities | 5,115 | 4,456 |
| Short term portion of note payable, net of discount | 454 | — |
| Deferred revenue - related party | 22,602 | 20,960 |
| Deferred revenue | — | 4,834 |
| Total current liabilities | 46,415 | 45,993 |
| Long term portion of note payable, net of discount | 24,639 | 24,648 |
| Operating lease liabilities, net of current portion | 10,561 | 15,676 |
| Deferred revenue, net of current portion - related party | 85,572 | 89,111 |
| Deferred revenue, net of current portion | — | 4,834 |
| Other long-term liabilities | 1,003 | 502 |
| Total liabilities | 168,190 | 180,764 |
| Commitments and contingencies | | |
| Stockholders' equity (deficit): | | |

| | | |
|---|---|---|
| Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2020 and 2019; no shares issued and outstanding at December 31, 2020 and 2019 | — | — |
| Common stock, $0.001 par value; 200,000,000 shares authorized at December 31, 2020 and 2019; 91,459,239 and 70,143,252 shares issued and outstanding at December 31, 2020 and 2019 | 91 | 70 |
| Additional paid-in capital | 723,482 | 411,255 |
| Accumulated other comprehensive loss | (47) | — |
| Accumulated deficit | (548,776) | (459,649) |
| Total stockholders' equity (deficit) | 174,750 | (48,324) |
| Total liabilities and stockholders' equity (deficit) | $ 342,940 | $ 132,440 |

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| Revenue: | | | |
| Collaboration revenue - related party | $ 11,897 | $ 27,188 | $ 26,917 |
| Grant revenue | 4,157 | 1,102 | 1,350 |
| Collaboration revenue | 17,161 | 6,215 | — |
| Total revenue | 33,215 | 34,505 | 28,267 |
| Operating expenses: | | | |
| Research and development expenses | $ 90,570 | $ 80,141 | $ 95,955 |
| General and administrative expenses | 30,775 | 24,748 | 32,596 |
| Restructuring expenses | — | 1,492 | — |
| Total operating expenses | 121,345 | 106,381 | 128,551 |
| Loss from operations | (88,130) | (71,876) | (100,284) |
| Other (expense) income: | | | |
| Interest income | 946 | 1,033 | 1,172 |
| Interest expense | (2,924) | (502) | — |
| Other income | 981 | 1,066 | 170 |
| Total other (expense) income, net | (997) | 1,597 | 1,342 |
| Net loss | $ (89,127) | $ (70,279) | $ (98,942) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (1.12) | $ (1.24) | $ (2.43) |
| Weighted average common shares outstanding, basic and diluted | 79,789,220 | 56,649,220 | 40,743,492 |
| Other comprehensive (loss) income: | | | |
| Unrealized (loss) gain on investments, net of tax of $0 | (47) | — | 146 |
| Total other comprehensive income (loss) | (47) | — | 146 |
| Comprehensive loss | $ (89,174) | $ (70,279) | $ (98,796) |

View source version on businesswire.com: https://www.businesswire.com/news/home/20210302005375/en/

**PR Contact**

Kristin Ainsworth
kainsworth@serestherapeutics.com

**IR Contact**

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

Source: Seres Therapeutics, Inc.