Seres Therapeutics Reports First Quarter 2025 Financial Results and Provides Business Updates

May 7, 2025

In line with recent FDA feedback, Seres expects to submit a Phase 2 study protocol to FDA in the coming weeks for SER-155 for the prevention of bloodstream infections (BSIs) in adults undergoing allogeneic hematopoietic stem cell transplant (allo-HSCT) for the treatment of hematological malignancies

SER-155 Phase 1b placebo-controlled study exploratory translational biomarker data reinforce intended mechanisms of action, consistent with clinical results that showed a significant reduction (77% relative risk reduction) in BSIs, and support broader potential for Seres' live biotherapeutics to address inflammatory and immune diseases

Seres advancing SER-155 strategic partnership discussions in support of further development in allo-HSCT and potential expansion into other target populations

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

CAMBRIDGE, Mass., May 07, 2025 (GLOBE NEWSWIRE) -- Seres Therapeutics, Inc. (Nasdaq: MCRB), (Seres or the Company), a leading live biotherapeutics company, today reported first quarter 2025 financial results and provided business updates.

"Advancing SER-155 through the next stage of development remains our top corporate priority, and we are making significant progress toward initiating the next clinical study," said Eric Shaff, President and Chief Executive Officer of Seres. "The clinical results generated to date underscore the potential of SER-155 to redefine the standard of care for allo-HSCT recipients and other vulnerable patients at risk of bloodstream infections—addressing a significant unmet medical need and representing substantial commercial opportunities. At the recent European Society for Blood and Marrow Transplantation conference, we obtained encouraging feedback from European transplant experts, consistent with the supportive views of U.S. based physicians, who highlighted that preventing BSIs remains a major unmet need in this patient population and expressed enthusiasm for both the safety and efficacy results reported in the SER-155 Phase 1b study. Notably, European clinicians also communicated their interest in participating in the further development of SER-155."

Mr. Shaff continued: "Guided by recent constructive FDA feedback and our aim to rapidly obtain clear and actionable SER-155 clinical results, we are preparing for a well-powered, placebo-controlled Phase 2 study, with a planned interim analysis. The efficacy and safety results of a successful Phase 2 study could support the design of, and advancement into, a subsequent single Phase 3 study for approval. We intend to submit a Phase 2 study protocol to the FDA in the coming weeks while we continue to actively engage in discussions seeking a partner to provide financial and other support and who shares our vision to realize the clinical and commercial value of SER-155."

Seres' partnership discussions are focused on supporting SER-155 clinical advancement to reduce the risk of bloodstream infections, including life-threatening and anti-microbial resistance (AMR) infections, in medically vulnerable patient populations. The Company believes that SER-155 and other cultivated live biotherapeutic candidates could be developed in additional patient populations beyond allo-HSCT, including autologous-HSCT patients, cancer patients with neutropenia, CAR-T recipients, individuals with chronic liver disease, solid organ transplant recipients, as well as patients in the intensive care unit and long-term acute care facilities.

Recent Highlights

SER-155 and Bloodstream Infection Prevention

- Based on recent US Food and Drug Administration (FDA) feedback and strategic considerations, Seres plans to advance SER-155 into a Phase 2 study that provides a time and capital-efficient path to obtaining clinical results and could support a subsequent Phase 3 study for product registration. Seres has selected a contract research organization, is planning for study start-up activities, and is manufacturing clinical trial material to support study initiation. The Company expects to submit a Phase 2 protocol to the FDA in the coming weeks. As previously noted, the Company requires additional capital to support the SER-155 Phase 2 study.

- The Phase 2 study is expected to target 248 participants and incorporate an adaptive design and an interim data analysis when approximately half of the enrolled participants have reached the primary endpoint. The Company expects to obtain the interim clinical results within 12 months following study initiation which it believes will facilitate timely engagement with the FDA on the design of a Phase 3 study and inform development in adjacent medically vulnerable patient populations.

- In April 2025, Seres presented SER-155 Phase 1b clinical and exploratory biomarker results at the 5th annual meeting of the European Society for Blood and Marrow Transplantation (EBMT). The Company's presented poster was recognized by the EBMT scientific organizing committee and obtained the Best Clinical Poster Award.

- In February 2025, clinical and exploratory biomarker results from Seres' biotherapeutic programs were presented as a

poster at the 2025 Tandem Transplantation & Cellular Therapy Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and Center for International Blood and Marrow Transplant Research (CIBMTR). SER-155 Phase 1b clinical study data were also featured in an oral presentation in the Best Abstracts in Infectious Diseases track at the Tandem meeting.

Development of Biotherapeutics for the Treatment of Inflammatory and Immune Diseases

- In January 2025, Seres reported exploratory translational biomarker data from its SER-155 Phase 1b study which provided evidence supporting the intended therapeutic mechanisms, including promotion of intestinal epithelial barrier integrity to reduce the potential of bacterial translocation into the bloodstream, and reduction of systemic inflammatory responses. These results reinforce previously reported promising SER-155 clinical study efficacy and safety data. The epithelial barrier and systemic inflammatory response data also further support the potential to develop Seres' live biotherapeutics to address inflammatory and immune diseases, including ulcerative colitis and Crohn's disease.
- In May 2025, Seres presented data at the Digestive Disease Week (DDW) conference highlighting: (1) preclinical and clinical data that enable identification of patients with a disease etiology linked to the gastrointestinal microbiome, and (2) the identification of microbiome-based biomarkers that are predictive of response and suitable for patient selection and stratification in clinical trials. The Company's poster, entitled "Candidate Biomarkers of Microbiome Disruption for Patient Selection or Stratification in Clinical Trials of Microbiome Therapies in Ulcerative Colitis" received a Poster of Distinction award in the Microbiome and Microbial Therapies subgroup. The Company believes that the data generated suggest that live biotherapeutics could provide a novel modality that could benefit patients living with gut-related inflammatory and immune diseases that are not effectively addressed today. Furthermore, research indicates that specific patient subpopulations optimally suited for biotherapeutic-based treatments may be identifiable. Seres' research has been supported by the Crohn's & Colitis Disease Foundation.
- Seres is exploring options to advance the development of its investigational live biotherapeutics in inflammatory and immune diseases, including ulcerative colitis and Crohn's disease.

Recent Corporate Update

- On April 21, 2025, Seres effected a 1-for-20 reverse stock split of its common stock. Trading of Seres common stock on The Nasdaq Global Select Market commenced on a split-adjusted basis on April 22, 2025. On May 6, 2025, the Company was notified by the Nasdaq Listing Qualifications staff that it has regained compliance with the Nasdaq Bid Price Requirement.

Anticipated Upcoming Milestones and Events

- Provide updates regarding SER-155 partnership discussions
- Submit to FDA a protocol for a SER-155 Phase 2 study in allo-HSCT in the coming weeks
- Present additional SER-155 clinical results at the American Society of Clinical Oncology (ASCO) 2025 conference taking place from May 30 to June 3, 2025
- Expecting receipt of the $25 million (less approximately $1.5 million in employment related obligations) installment payment from Nestlé in July 2025

Financial Results

The Company has classified all historical operating results for the VOWST business within discontinued operations in the consolidated statements of operations for the comparative period presented (3 months ended March 31, 2024). There is no ongoing activity in the current period related to discontinued operations.

- Seres reported net income from continuing operations of $32.7 million for the first quarter of 2025, as compared to a net loss from continuing operations of $32.9 million for the same period in 2024. The net income in 2025 is primarily driven by the previously announced $50.0 million installment payment received from Nestlé in January, consistent with the Company fulfilling its transition obligations.
- Research and development (R&D) expenses for the first quarter of 2025 were $11.8 million, compared with $19.5 million for the first quarter of 2024. The decrease in R&D expenses was primarily driven by lower personnel expenses, a decrease in platform investments, and a decrease in expenses related to SER-155 Phase 1b study.
- General and administrative (G&A) expenses for the first quarter of 2025 were $11.9 million, compared with $14.9 million for the first quarter of 2024. The decrease in G&A expenses was primarily a result of lower personnel and contractor expenses and other cost management activities.

- Manufacturing services expenses were $3.5 million for the first quarter of 2025. These costs relate to the provision of manufacturing services under the transition services agreement with Nestlé. The associated reimbursement received from Nestlé related to these expenses is recognized in other (expense) income, net.

- On April 21, 2025, the Company effected a 1-for-20 reverse stock split of its common stock. The reverse stock split had no impact on the number of authorized shares or the par value of preferred and common stock. All share and per share amounts in the financial statements have been retroactively adjusted, for all periods presented, to give effect to the reverse stock split.

Cash Runway
As of March 31, 2025, Seres had $58.8 million in cash and cash equivalents. Based on the Company's current cash, the anticipated second installment payment to be received from Nestlé in July 2025, transaction-related obligations and current operating plans, the Company expects to fund operations into the first quarter of 2026.

Conference Call Information
Seres' management will host a conference call today, May 7, 2025, at 8:30 a.m. ET. The conference call may be accessed by calling 1-800-715-9871 (international callers dial 1-646-307-1963) and referencing the conference ID number 4618787. 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 SER-155
SER-155 is an investigational, oral, live biotherapeutic designed to decolonize gastrointestinal (GI) pathogens, improve epithelial barrier integrity, and induce immune homeostasis, to prevent bacterial bloodstream infections, including those that can harbor antimicrobial resistance (AMR), as well as other pathogen associated negative clinical outcomes, in patients undergoing allogeneic hematopoietic stem cell transplantation (allo-HSCT).

SER-155 has been evaluated in a Phase 1b placebo-controlled study in patients undergoing allo-HSCT, which demonstrated a significant reduction in both bacterial bloodstream infections (BSIs) (77% relative risk reduction) and systemic antibiotic exposure, as well as lower incidence of febrile neutropenia. SER-155 has received Breakthrough Therapy designation for the reduction of bloodstream infections in adults undergoing allo-HCST and Fast Track designation for reducing the risk of infection and graft-versus-host disease in patients undergoing allo-HCST. The early development of the program was supported by Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), a global non-profit partnership accelerating antibacterial products to address drug-resistant bacteria.

About Seres Therapeutics
Seres Therapeutics, Inc. (Nasdaq: MCRB) is a clinical-stage company focused on improving patient outcomes in medically vulnerable populations through novel live biotherapeutics. Seres led the successful development and approval of VOWST™, the first FDA-approved orally administered microbiome therapeutic, which was sold to Nestlé Health Science in September 2024. The Company is developing SER-155, which has received Breakthrough Therapy designation for the reduction of bloodstream infections in adults undergoing allo-HSCT and Fast Track designation for reducing the risk of infection and graft-versus-host disease in adults undergoing allo-HSCT, and which has demonstrated a significant reduction in bloodstream infections and related complications (as compared to placebo) in a Phase 1b clinical study in patients undergoing allo-HSCT. SER-155 and the Company's other pipeline programs are designed to target multiple disease-relevant pathways and are manufactured from standard clonal cell banks via cultivation, rather than from the donor-sourced production process used for VOWST. In addition to allo-HSCT, the Company intends to evaluate SER-155 and other cultivated live biotherapeutic candidates in other medically vulnerable patient populations including autologous-HSCT patients, cancer patients with neutropenia, CAR-T recipients, individuals with chronic liver disease, solid organ transplant recipients, as well as patients in the intensive care unit and long-term acute care facilities. For more information, 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 statements about: the timing and results of our clinical studies and data readouts; future product candidates, clinical development plans and commercial opportunities; communications with, feedback from, or submissions to the FDA; compliance with Nasdaq requirements; upcoming presentations; future payments related to the VOWST sale; operating plans and our future cash runway; our ability to secure a partnership and/or generate or obtain additional capital or financing; our planned strategic focus; anticipated timing of any of the foregoing; and other statements that 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: (1) our need for additional funding; (2) our ability to continue as a going concern; (3) we have incurred significant losses, are not currently profitable and may never become profitable; (4) our history of operating losses; (5) the expected payments from the VOSWT sale are subject to risks and uncertainties; (6) we may not be able to realize the anticipated benefits of the VOWST sale, and may face new challenges as a smaller, less diversified company; (7) we have in the past and may in the future receive notice of the failure to satisfy a continued listing rule from The Nasdaq Stock Market LLC; (8) our novel approach to therapeutic intervention; (9) our reliance on third parties to conduct our clinical trials and manufacture our product candidates; (10) our ability to achieve market acceptance necessary for commercial success; (11) the competition we will face; (12) our ability to protect our intellectual property; and (13) 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 (SEC), on March 13, 2025, 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, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 58,849	$ 30,793
Accounts receivable due from SPN - related party	2,761	2,068
Prepaid expenses and other current assets (1)	4,468	5,813
Total current assets	66,078	38,674
Property and equipment, net	10,547	11,534
Operating lease assets	78,858	80,903
Restricted cash	8,668	8,668
Other non-current assets	31	31
Total assets	$ 164,182	$ 139,810
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,168	$ 4,079
Accrued expenses and other current liabilities	6,220	10,719
Accrued liabilities due to SPN - related party	13,886	17,750
Operating lease liabilities	9,049	8,674
Total current liabilities	31,323	41,222
Operating lease liabilities, net of current portion	80,499	82,966
Other long-term liabilities	1,895	1,838
Total liabilities	113,717	126,026
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2025 and December 31, 2024; no shares issued and outstanding at March 31, 2025 and December 31, 2024	—	—
Common stock, $0.001 par value; 360,000,000 shares authorized at March 31, 2025 and December 31, 2024; 8,732,187 and 8,650,227 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	9	9
Additional paid-in capital	995,873	991,874
Accumulated other comprehensive loss		—
Accumulated deficit	(945,417)	(978,099)
Total stockholders' equity	50,465	13,784
Total liabilities and stockholders' equity	$ 164,182	$ 139,810

[1] Includes $1,622 as of March 31, 2025 and $2,683 as of December 31, 2024 of unbilled receivable from SPN (related party) related to certain costs of the transition services performed by the Company.

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

	Three Months Ended March 31,	
	2025	2024
Operating expenses:		
Research and development expenses	$ 11,821	$ 19,494
General and administrative expenses	11,888	14,944
Manufacturing services	3,527	—
Total operating expenses	27,236	34,438
Loss from operations	(27,236)	(34,438)
Other income (expense):		
Gain on sale of VOWST Business	52,181	—
Interest income	618	1,648

Interest expense	—	(618)
Other income (2)	7,119	505
Total other income, net	59,918	1,535
Net income (loss) from continuing operations	$ 32,682	$ (32,903)
Net (loss) from discontinued operations, net of tax	$ —	$ (7,230)
Net income (loss) and comprehensive income (loss)	$ 32,682	$ (40,133)
Net income (loss) from continuing operations per share attributable to common stockholders - basic	$ 3.76	$ (4.50)
Net (loss) from discontinued operations per share attributable to common stockholders - basic	$ —	$ (0.99)
Net income (loss) per share attributable to common stockholders - basic	$ 3.76	$ (5.49)
Net income (loss) from continuing operations per share attributable to common stockholders - diluted	$ 3.75	$ (4.50)
Net (loss) from discontinued operations per share attributable to common stockholders - diluted	$ —	$ (0.99)
Net income (loss) per share attributable to common stockholders - diluted	$ 3.75	$ (5.49)
Weighted average common shares outstanding - basic	8,703,221	7,305,026
Weighted average common shares outstanding - diluted	8,714,701	7,305,026

[2] Includes $6,309 for the three months ended March 31, 2025 related to reimbursement received from SPN (related party) for transition services provided by the Company.

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Source: Seres Therapeutics, Inc.