Seres Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Updates

March 13, 2025

Recent FDA feedback received on SER-155 allogeneic hematopoietic stem cell transplant (allo-HSCT) next study provides support for the proposed primary efficacy endpoint of reduction in bloodstream infections (BSIs) at day 30 post-HSCT; Company expects to submit draft study protocol to FDA in Q2 2025

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

Company advances SER-155 strategic partnership discussions to accelerate next study in allo-HSCT and support potential expansion into other target populations

With current cash, expected second installment payment from Nestlé, and based on current operating plans, Seres expects to fund operations into Q1 2026

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

CAMBRIDGE, Mass., March 13, 2025 (GLOBE NEWSWIRE) -- Seres Therapeutics, Inc. (Nasdaq: MCRB), (Seres or the Company), a leading live biotherapeutics company, today reported fourth quarter and full year 2024 financial results and provided business updates.

"We have made significant progress advancing SER-155 as a novel live biotherapeutic candidate designed to prevent life-threatening bloodstream infections in allo-HSCT recipients," said Eric Shaff, President and Chief Executive Officer of Seres. "Based on the strength of our Phase 1b placebo-controlled clinical results showing a relative risk reduction of 77% in bloodstream infections (BSIs), SER-155 received Breakthrough Therapy designation from the FDA. Our productive interactions with the FDA regarding plans to advance SER-155 in allo-HSCT patients have supported and informed our development plans. We are formulating the next SER-155 study design, which could be either a standalone Phase 2 or a Phase 2/3 seamless design, and plan to submit a draft protocol to the FDA in the second quarter of this year. Based on potential additional agency feedback and perspectives we expect to gain from further partnership discussions, we plan to decide upon the optimal path forward for further SER-155 development."

Mr. Shaff continued, "Recently released exploratory translational biomarker results from our SER-155 Phase 1b study provide supportive mechanistic data, consistent with the observed clinical results that showed a reduction in the risk of BSIs. We believe the data also offer further evidence of the potential of Seres' biotherapeutic approach to benefit patients living with inflammatory and immune diseases such as ulcerative colitis and Crohn's disease. The market opportunity for SER-155 is significant, with clinician and payer research indicating that SER-155, if approved, could result in rapid and deep utilization in allo-HSCT, as well as other sizable patient groups at high risk of BSIs. Our efforts and investments this year are focused on preparing for the next study of SER-155 in allo-HSCT and continued pursuit of an external partnership with a counterparty who shares our vision to maximize the SER-155 clinical and commercial opportunity."

Pipeline Highlights

- In September 2024, Seres reported topline clinical data from Cohort 2 of its SER-155 Phase 1b placebo-controlled study in patients undergoing allo-HSCT. Study results demonstrate that SER-155 was associated with a 77% relative risk reduction in bloodstream infections, a significant reduction in systemic antibiotic exposure, as well as a lower incidence of febrile neutropenia, in each case as compared to placebo, through day 100 post-HSCT. SER-155 was generally well tolerated, with no observed treatment-related serious adverse events.

- In December 2024, the US Food and Drug Administration (FDA) granted Breakthrough Therapy designation to SER-155 for reduction of bloodstream infections in adults undergoing allo-HSCT. Breakthrough Therapy designation grants access to senior management at FDA and more communication and guidance from FDA to expedite the development of medicines where preliminary clinical evidence indicates that a drug may demonstrate substantial improvement over existing therapies, on one or more clinically significant endpoints, and which are intended to treat a serious or life-threatening disease or condition.

- Seres recently received constructive feedback from the FDA regarding the development strategy for SER-155 in patients undergoing allo-HSCT. The FDA provided input on important elements of the next study, including a recommendation for a Phase 2 and support for a reduction in bloodstream infections 30 days post HSCT as the primary endpoint, and confirmed their expectations for the manufacture and control of SER-155. Incorporating the feedback, Seres is designing the next

SER-155 allo-HSCT study, which the Company believes could be either a standalone Phase 2, or a Phase 2 as part of a Phase 2/3 seamless design. Both development paths are expected to include an adaptive design, with meaningful interim data analysis, when approximately half of the enrolled patients have reached the primary endpoint timepoint, informing the study path forward and potential indication expansion. The next study protocol will preserve many elements of the successful SER-155 Phase 1b study. Seres plans to submit the draft protocol, which the Company anticipates will be informed by potential further FDA interaction and partnership discussions, to the FDA in Q2 2025 to obtain further feedback.

- In January 2025, the Company 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. Results from this exploratory biomarker analysis showed that SER-155 was associated with lower levels of fecal albumin and lower concentrations of various plasma biomarkers associated with systemic inflammation (i.e., IFN-, TNF-α, IL-17, and IL-8) in the HSCT peri-transplant period, the period from the end of the first SER-155 treatment course through to neutrophil engraftment. The results support SER-155's intended mechanisms of action and reinforce the previously reported promising clinical study efficacy and safety data. These systemic inflammatory response observations further support the potential to develop Seres' live biotherapeutics to address inflammatory and immune diseases, including ulcerative colitis and Crohn's disease. The SER-155 biomarker results were presented as a poster at the February 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.

- Market research conducted with US healthcare professionals (HCPs) and payers supported the high unmet need to prevent BSIs in allo-HSCT patients. Both HCPs and payers indicated an awareness of the high clinical burden of BSIs, driven by the high frequency of occurrences and poor associated outcomes. Both groups cited a lack of efficacious prophylactic therapies and expressed significant ongoing concerns around the risk of BSIs, febrile neutropenia, sepsis, and antibiotic-resistant infections. The observed degree of SER-155 risk reduction of BSIs and related clinical benefits were seen as clinically meaningful and supportive of a strong value proposition. US payers shared an expectation that coverage of SER-155 would be under the outpatient pharmacy benefit, given its oral administration, which would allow for dosing outside of the inpatient hospital setting. SER-155 in allo-HSCT alone represents a significant commercial opportunity based on market research indicating broad adoption by clinicians of an efficacious and well-tolerated option to prevent BSIs in these patients. There are an estimated 9,300 allo-HSCT procedures conducted annually in the US. The European Society for Bone Marrow Transplant recently updated its incidence estimates for Europe, reporting approximately 20,000 procedures in 2023. The opportunity in Europe is expected to be similarly robust to the US, driven by shared market dynamics such as unmet need and cost of HSCT and BSIs to the healthcare system.

- Seres continues to evaluate broader opportunities to address life-threatening infections, including anti-microbial resistance (AMR) infections, for SER-155 and other cultivated live biotherapeutic candidates, including pipeline candidate SER-147, 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. The Company is also exploring targeting inflammatory and immune diseases, specifically ulcerative colitis and Crohn's disease, with support from the Crohn's & Colitis Foundation.

Recent Corporate Updates

- In September 2024, Seres announced the sale of its VOWST business to Société des Produits Nestlé S.A (SPN, and with certain of its affiliates, collectively, Nestlé Health Science or Nestlé). Seres received gross proceeds of approximately $175 million, including payment of an up-front, prepaid milestone and equity investment, less approximately $20 million in settlement of net obligations payable to Nestlé. Seres received an installment payment of $50 million in January 2025 and expects to receive a second installment payment of $25 million (less up to approximately $1.5 million in employment-related obligations) in July 2025, subject to the Company's material compliance with its transition obligations. The Company is also eligible to receive future milestone payments of up to $275 million based on VOWST worldwide net sales.

- In February 2025, the Company appointed Hans-Juergen Woerle, M.D., as a director and member of the Science and Clinical Development Committee. Dr. Woerle is the Chief Medical Officer and Chief Scientific Officer at Nestlé Health Science S.A. His appointment fulfills the rights granted to Nestlé upon their equity investment in Seres pursuant to the VOWST transaction in September 2024.

Anticipated Upcoming Milestones and Events

- Submit to FDA a draft protocol for the next study of SER-155 in allo-HSCT in Q2 2025.

- Present SER-155 Phase 1b clinical and exploratory translational biomarker data as a Top 100 abstract at the European Bone Marrow Transplant meeting in March 2025, facilitating engagement with potential European investigators in support of the Company's planned global study. Additionally, exploratory translational biomarker data from across Seres' programs, including in allo-HSCT and IBD, have been accepted for poster presentations at Digestive Disease Week (DDW) in May 2025.

- Expecting receipt of a $25 million (less approximately $1.5 million in employment related obligations) installment payment from Nestlé in July 2025.

Financial Results
In the December 31, 2024 financial statements, the Company has classified the VOWST business as discontinued operations in the consolidated balance sheet for the comparative period (December 31, 2023), and all historical operating results for the VOWST business are reflected within discontinued operations in the consolidated statements of operations for all periods presented.

- Seres reported a net loss from continuing operations of $125.8 million for the full year 2024, as compared to a net loss from continuing operations of $190.1 million for 2023. Seres reported a net loss from continuing operations of $15.7 million for the fourth quarter of 2024, as compared to a net loss from continuing operations of $34.7 million for the same period in 2023.

- Research and development (R&D) expenses for the year ended December 31, 2024 were $64.6 million, compared with $117.6 million for the same period in 2023. The year-over-year decrease in R&D expenses was primarily driven by lower personnel expenses and a decrease in platform investments as the Company focuses on its lead program, SER-155. R&D expenses for the fourth quarter of 2024 were $12.8 million, compared with $23.0 million for the fourth quarter of 2023.

- General and administrative (G&A) expenses for the year ended December 31, 2024 were $53.2 million, compared with $77.5 million for the same period in 2023. The year-over-year decrease in G&A expenses was primarily a result of reduced personnel and contractor expenses and cost management activities. G&A expenses for the fourth quarter of 2024 were $12.5 million, compared with $14.0 million for the fourth quarter of 2023.

- Manufacturing Services expenses, a new category in 2024, were $3.5 million for the year and the quarter ended December 31, 2024. 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.

- Net income from discontinued operations, net of tax, was $125.9 million for 2024, as compared to $76.4 million for the same period in 2023. The difference was primarily the result of the gain on the sale of the VOWST business, net of tax, of approximately $146.7 million, which was recognized upon completion of the VOWST sale in September 2024.

Cash Runway
As of December 31, 2024, Seres had $30.8 million in cash and cash equivalents. Based on the Company's current cash (including the $50 million installment payment received from Nestlé in January 2025), an 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, March 13, 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 6331602. 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 tolerance to prevent bacterial bloodstream and antimicrobial resistant (AMR) infections, 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) 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; future payments related to the VOWST sale; operating plans and our future cash runway; our ability to secure a partnership and/or generate additional capital; 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 received a 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.
CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands, except share and per share data)

	December 31,	
	2024	**2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 30,793	$ 127,965
Accounts receivable due from SPN - related party	2,068	—
Prepaid expenses and other current assets (1)	5,813	8,049
Current assets of discontinued operations	—	39,396
Total current assets	38,674	175,410
Property and equipment, net	11,534	17,614
Operating lease assets	80,903	90,417
Restricted cash	8,668	8,185
Restricted investments	—	1,401
Other non-current assets	31	2,187
Non-current assets of discontinued operations (2)	—	63,386
Total assets	$ 139,810	$ 358,600
Liabilities and Stockholder's Equity		
Current liabilities:		
Accounts payable	$ 4,079	$ 3,641
Accrued expenses and other current liabilities	10,719	22,509
Accrued liabilities due to SPN - related party	17,750	—
Operating lease liabilities	8,674	5,587
Current liabilities of discontinued operations (3)	—	66,922
Total current liabilities	41,222	98,659
Long term portion of note payable, net of discount	—	101,544
Operating lease liabilities, net of current portion	82,966	91,652
Warrant liability	—	546
Other long-term liabilities	1,838	1,628
Non-current liabilities of discontinued operations	—	109,427

Total liabilities	126,026	403,456
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2024 and 2023; no shares issued and outstanding at December 31, 2024 and 2023	—	—
Common stock, $0.001 par value; 360,000,000 and 240,000,000 shares authorized at December 31, 2024 and 2023, respectively; 173,008,198 and 135,041,467 shares issued and outstanding at December 31, 2024 and 2023, respectively	173	135
Additional paid-in capital	991,710	933,244
Accumulated deficit	(978,099)	(978,235)
Total stockholders' equity (deficit)	13,784	(44,856)
Total liabilities and stockholders' equity	$ 139,810	$ 358,600

[1] Includes $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. See Note 3, *Discontinued Operations and TSA*, for further details.

[2] Includes $38,877 as of December 31, 2023 of milestones related to the construction of the Company's dedicated manufacturing suite at BacThera AG, or Bacthera.

[3] Includes related party amounts of $35,783 at December 31, 2023.

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

	Year Ended December 31,		
	2024	**2023**	**2022**
Operating expenses:			
Research and development expenses	$ 64,600	$ 117,597	$ 109,651
General and administrative expenses	53,183	77,500	70,263
Manufacturing services	3,532	—	—
Total operating expenses	121,315	195,097	179,914
Loss from operations	(121,315)	(195,097)	(179,914)
Other (expense) income:			
Gain on sale of VOWST Business	5,684	—	—
Interest income	3,967	7,301	3,058
Interest expense	—	(2,468)	(6,020)
Other (expense) income, net	(14,107)	134	(705)
Total other (expense) income, net	(4,456)	4,967	(3,667)
Net loss from continuing operations	$ (125,771)	$ (190,130)	$ (183,581)
Net income (loss) from discontinued operations, net of tax	$ 125,907	$ 76,406	$ (66,576)
Net income (loss)	$ 136	$ (113,724)	$ (250,157)
Net loss from continuing operations per share attributable to common stockholders, basic and diluted	$ (0.81)	$ (1.49)	$ (1.70)
Net income (loss) from discontinued operations per share attributable to common stockholders, basic and diluted	$ 0.81	$ 0.60	$ (0.62)
Net loss per share attributable to common stockholders, basic and diluted	$ 0.00	$ (0.89)	$ (2.31)
Weighted average common shares outstanding, basic and diluted	155,400,760	128,003,294	108,077,043
Other comprehensive income:			
Unrealized gain on investments, net of tax of $0	—	10	49
Currency translation adjustment	—	2	(1)
Total other comprehensive income	—	12	48
Comprehensive income (loss)	$ 136	$ (113,712)	$ (250,109)

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Source: Seres Therapeutics, Inc.