Seres Therapeutics Reports Third Quarter 2024 Financial Results and Provides Business Updates

November 13, 2024

SER-155 Phase 1b placebo-controlled clinical results demonstrated significant reduction in both bacterial bloodstream infections and systemic antibiotic exposure, as well as lower incidence of febrile neutropenia, as compared to placebo, through day 100 post allo-HSCT

Financial position strengthened following completion of VOWST™ sale; based on existing cash, projected 2025 deal economics and current operating plans, Seres expects to fund operations into Q4 2025

Seeking SER-155 strategic partnership to accelerate next study in allo-HSCT and expand to multiple target populations

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

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

"This quarter has been transformational for Seres, highlighted by our positive SER-155 placebo-controlled clinical results, and the sale of VOWST, which resulted in the Company becoming a more streamlined, focused organization, and which will support advancement into a potential SER-155 registration study," said Eric Shaff, President and Chief Executive Officer of Seres. "Our SER-155 data provides strong evidence highlighting its potential to significantly reduce the risk of bacterial bloodstream infections (BSIs), a leading cause of mortality and morbidity in patients undergoing allogeneic hemopoietic stem cell transplants (allo-HSCT), as well as other medically vulnerable populations. Based on these highly encouraging results, including a relative risk reduction of 77% in BSIs in the active arm as compared to placebo, we have requested Breakthrough Therapy designation and Qualified Infectious Disease Product (QIDP) designation, and anticipate feedback from the FDA by the end of this year. Additionally, we are planning for the next clinical study in allo-HSCT, which we believe could be a single registration study for efficacy. We intend to engage with the agency in the first quarter of 2025 to discuss our clinical study results and future study design."

Mr. Shaff elaborated, "With SER-155 as our primary focus and anchor program, and additional live biotherapeutic candidates, we have the opportunity to expand beyond allo-HSCT to other patient populations, including autologous-HSCT (auto-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, thereby potentially creating multiple significant commercial opportunities. Our market research indicates that a product providing similar efficacy to what we observed in our SER-155 studies would be transformational in the management of allo-HSCT patients, and rapidly become standard practice. To most effectively advance development in allo-HSCT and additional patient populations, we are seeking a partner who shares our vision and who would provide financial support and other capabilities to enable us to maximize SER-155's broad potential. We have engaged MTS Health Partners to facilitate the process."

Corporate 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 October 2024, the Company requested Breakthrough Therapy designation and Qualified Infectious Disease Product (QIDP) designation for SER-155, and expects to receive feedback from the U.S. Food and Drug Administration (FDA or the agency) by the end of 2024. The receipt of these designations could provide important benefits, with the potential to expedite development and review through mechanisms such as frequent engagement with the agency and Priority Review. Additionally, Seres plans to discuss with the FDA the potential for a single clinical study of SER-155 to serve as the efficacy basis for product approval, due to the substantial unmet need in allo-HSCT.

- In addition to allo-HSCT, Seres 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. SER-155 in allo-HSCT alone represents a significant commercial opportunity based on our market research which indicates broad adoption by clinicians for a product providing similar efficacy to what we have observed in our SER-155 studies. Additionally, the majority of allo-HSCT patients are treated in a specific subset of oncology centers across the globe, permitting efficient commercialization efforts, if approved. With the expanded targeted patient populations, SER-155 could represent multiple blockbuster opportunities.

- Seres is actively seeking a partner to provide financial resources and other capabilities to support the Company's goal to maximize the SER-155 product opportunity, while pursuing a capital-efficient development approach. Seres fully owns worldwide rights for the commercialization of SER-155 and its other pipeline programs.

- In September 2024, Seres announced that it had completed the sale of its VOWST business to Société des Produits Nestlé S.A (SPN, and with certain of its affiliates, collectively, Nestlé Health Science). Seres received gross proceeds of approximately $175M, including payment of an up-front, prepaid milestone and equity investment, less approximately $20M in settlement of net obligations payable to Nestlé Health Science. Seres expects to receive installment payments of $50M in January 2025 and $25M (less up to approximately $1.5M in employment-related payments to Nestlé Health Science) 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 $275M based on VOWST worldwide net sales.

- Seres continues to develop another proprietary live biotherapeutic composition, SER-147, designed to prevent bacterial bloodstream, antimicrobial resistant (AMR) and spontaneous bacterial peritonitis (SBP) infections in patients with metabolic disease, including chronic liver disease. The Company is advancing IND enabling activities in SER-147.

Financial Results
In the September 30, 2024 financial statements, the Company has classified the VOWST business as discontinued operations in the condensed 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 condensed consolidated statements of operations for both periods presented.

- Seres reported a net loss from continuing operations of $51 million for the third quarter of 2024, as compared to $41 million for the same period in 2023. The higher loss is primarily the result of a loss of $23.4 million associated with the extinguishment of the Oaktree debt, which was retired at completion of the VOWST sale in September 2024, and a reduction in interest income of $2 million, offset by lower operating expenses of $15.4 million.

- Research and development (R&D) expenses (in continuing operations) for the third quarter of 2024 were $16.5 million, compared with $25.2 million for the same period in 2023. The decrease in R&D expenses was primarily driven by lower personnel costs as a result of the restructuring plan announced in November 2023, and cost reduction efforts resulting in lower operating costs such as contractors and consultants.

- General and administrative (G&A) expenses (in continuing operations) for the third quarter of 2024 were $12.7 million, compared with $19.4 million for the same period in 2023. The decrease in G&A expenses was primarily driven by lower personnel costs as a result of the restructuring plan, and reduced headcount-related operating costs such as IT, along with lower professional fees.

- Net income from discontinued operations, net of tax, was $139.8 million for the third quarter of 2024, as compared to a net loss of $6.8 million for the same period in 2023. The difference is 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.

Cash Runway
Following completion of the VOWST sale, Seres is a more streamlined organization with no outstanding debt and a projected lower cash burn rate. Seres' headcount decreased by 100 to a team of approximately 100 employees following the VOWST sale, principally due to the transition of manufacturing and quality team members to Nestlé Health Science. The Company continues to evaluate and implement actions to reduce expenses and is evaluating a variety of approaches to support its capital strategy.

As of September 30, 2024, Seres had $66.8 million in cash and cash equivalents. Based on existing cash, projected installment payments to be received from Nestlé Health Science in 2025, transaction-related obligations and current operating plans, the Company expects to fund operations into the fourth quarter of 2025.

Conference Call Information
Seres' management will host a conference call today, November 13, 2024, 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 5051385. 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 FDA Fast Track designation for reducing the risk of infection and GvHD in patients undergoing HSCT. 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 demonstrated a significant reduction in bloodstream infections and related complications (as compared to placebo) in a clinical study in patients undergoing allogeneic hematopoietic stem cell transplantation (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, 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 statements about; the financial terms and future payments related to the VOWST sale; the timing and results of our clinical studies and data readouts; future product candidates, development plans and commercial opportunities; interactions with regulatory agencies; 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 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: (1) we have incurred significant losses, are not currently profitable and may never become profitable; (2) our need for additional funding; (3) our history of operating losses; (4) our novel approach to therapeutic intervention; (5) our reliance on third parties to conduct our clinical trials and manufacture our product candidates; (6) the competition we will face; (7) our ability to protect our intellectual property; (8) our ability to retain key personnel and to manage our growth; (9) the effect of the VOWST sale on our ability to retain and hire key personnel and maintain relationships with our customers, suppliers, advertisers, partners and others with whom we do business, or on our operating results and businesses generally; (10) the risks associated with the disruption of management's attention from ongoing business operations due to the obligation to provide transition services; (11) our failure to receive the installment payments or the milestone payments in the future; (12) the uncertainty of impact of the 50/50 profit and loss sharing arrangement on our reported results and liquidity; and (13) we may not be able to realize the anticipated benefits of the VOWST sale. 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 13, 2024, 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, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 66,824	$ 127,965
Prepaid expenses and other current assets	6,104	8,049
Current assets of discontinued operations	—	39,396
Total current assets	72,928	175,410
Property and equipment, net	12,566	17,614
Operating lease assets	82,910	90,417
Restricted cash	9,873	8,185
Restricted investments	—	1,401
Other non-current assets	465	2,187
Non-current assets of discontinued operations (1)	—	63,386
Total assets	$ 178,742	$ 358,600
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 8,254	$ 3,641
Accrued expenses and other current liabilities	17,716	22,509
Accrued liabilities due to SPN - related party	30,517	—
Operating lease liabilities	8,346	5,587
Current liabilities of discontinued operations (2)	—	66,922
Total current liabilities	64,833	98,659
Long term portion of note payable, net of discount	—	101,544
Operating lease liabilities, net of current portion	85,266	91,652
Accrued liabilities due to SPN, net of current portion - related party	2,941	—

Warrant liabilities	—	546
Other long-term liabilities	1,783	1,628
Non-current liabilities of discontinued operations	—	109,427
Total liabilities	154,823	403,456
Commitments and contingencies (Note 13)		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2024 and December 31, 2023; no shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value; 360,000,000 shares authorized at September 30, 2024 and 240,000,000 shares authorized at December 31, 2023; 170,200,253 and 135,041,467 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	170	135
Additional paid-in capital	986,211	933,244
Accumulated other comprehensive loss	—	—
Accumulated deficit	(962,462)	(978,235)
Total stockholders' equity (deficit)	23,919	(44,856)
Total liabilities and stockholders' equity (deficit)	$ 178,742	$ 358,600

[1] 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.

[2] Includes related party amount of $35,783 at December 31, 2023.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development expenses	16,460	25,154	$ 51,759	94,554
General and administrative expenses	12,710	19,432	$ 40,721	63,519
Total operating expenses	29,170	44,586	$ 92,480	158,073
Loss from operations	(29,170)	(44,586)	$ (92,480)	(158,073)
Other income (expense):				
Interest income	652	2,572	$ 3,530	5,330
Interest expense	—	—	$ —	(2,468)
Other (expense) income	(22,517)	999	$ (21,184)	(202)
Total other (expense) income, net	(21,865)	3,571	$ (17,654)	2,660
Net loss from continuing operations	$ (51,035)	$ (41,015)	$ (110,134)	$ (155,413)
Net income (loss) from discontinued operations, net of tax	$ 139,811	$ (6,839)	$ 125,907	$ 82,937
Net income (loss)	$ 88,776	$ (47,854)	$ 15,773	$ (72,476)
Net loss from continuing operations per share attributable to common stockholders, basic and diluted	$ (0.33)	$ (0.32)	$ (0.73)	$ (1.22)
Net income (loss) from discontinued operations per share attributable to common stockholders, basic and diluted	$ 0.92	$ (0.05)	$ 0.84	$ 0.65
Net income (loss) per share attributable to common stockholders, basic and diluted	$ 0.58	$ (0.37)	$ 0.11	$ (0.57)
Weighted average common shares outstanding, basic	152,648,238	128,289,871	150,097,482	127,297,667
Weighted average common shares outstanding, diluted	152,648,238	128,289,871	150,097,482	127,297,667
Other comprehensive income:				
Unrealized income on investments, net of tax of $0	—	—	—	10
Currency translation adjustment	—	1	—	2
Total other comprehensive income	—	1	—	12
Comprehensive income (loss)	$ 88,776	$ (47,853)	$ 15,773	$ (72,464)

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Source: Seres Therapeutics, Inc.