Seres Therapeutics Reports Third Quarter 2026 Financial Results and Announces Plans for Advancing Development of SER-155 To Prevent Immune Checkpoint Inhibitor-Related Enterocolitis (irEC)

November 4, 2026

Prevention approach aims to keep patients on immune checkpoint inhibitor (ICI) therapy and avoid immunosuppressive irEC treatments, representing an additional broad therapeutic opportunity for SER-155

Seres expects to submit plans for the next irEC study design to the FDA in Q1 2027

Study builds on encouraging investigator-sponsored trial (IST) results, in which 12 of 15 participants (80%) with moderate-to-severe irEC achieved an immunosuppressive-free clinical response of diarrhea following treatment with SER-155

CAMBRIDGE, Mass., Nov. 04, 2026 (GLOBE NEWSWIRE) -- Seres Therapeutics, Inc. (Nasdaq: MCRB), (Seres or the Company), a leading live biotherapeutics company, today reported third quarter 2026 financial results and announced it is progressing plans for a next study evaluating SER-155 for the prevention of immune checkpoint inhibitor-related enterocolitis (irEC) in patients initiating immune checkpoint inhibitor (ICI) cancer therapy, which is expected to include a dose optimization component. The Company anticipates submitting the study design to the FDA in the first quarter of 2027.

The planned study builds on previously announced positive topline results from an investigator-sponsored trial (IST) conducted at Memorial Sloan Kettering Cancer Center (MSK) in patients with moderate-to-severe irEC, in which 80% of participants achieved an immunosuppressive-free clinical response at Day 15, following treatment with SER-155. SER-155 was well tolerated, with no drug-related serious adverse events observed. irEC is a frequent and debilitating adverse reaction associated with widely used ICI cancer therapy that often requires patients to halt life-saving ICI treatment and begin systemic immunosuppressive corticosteroids. irEC is listed as an adverse reaction in the labels of all approved ICIs, including PD-1 inhibitors (Keytruda®, Opdivo®, Zynyz®), PD-L1 inhibitors (Imfinzi®, Bavencio®), CTLA-4 inhibitors (Yervoy®, Imjudo®), and LAG-3 inhibitor (Opdualag) - all of which were therapies received by patients in the IST.

"The irEC IST provided promising evidence that orally administered SER-155 improved epithelial barrier integrity and reduced gastrointestinal inflammation without systemic immunosuppression and was well-tolerated in patients with ICI-induced enterocolitis, " said Richard Kender, Executive Chairman and Interim Chief Executive Officer of Seres. "Based on those results, and in consultation with key opinion leaders in the field, we determined that developing SER-155 to prevent irEC could address a significant unmet clinical need in patients being treated with ICIs for their cancer. We believe SER-155 may enable ICI patients, of whom there are currently estimated to be approximately 300,000 in the U.S. alone, to remain on their therapy by reducing the occurrence of irEC, which often requires the halting of life-saving cancer treatment. We also think this development approach offers a time and capital efficient path to clinical data and positions SER-155 to potentially address a broad ICI-treated population and look forward to submitting our planned study design to the FDA in the first quarter of 2027. We are pleased to have two oncology-focused programs for SER-155, one with the goal of preventing irEC, and the other, in allogeneic hematopoietic stem cell transplant (allo-HCT), aimed at reducing the risk of bloodstream infections, a leading cause of mortality in these patients. We continue to seek capital through partnerships and other sources to advance our programs in irEC and in allo-HCT, which is Phase 2 ready, pending funding."

Recent Highlights

SER-155 for the prevention of irEC

- Seres intends to advance SER-155 into a next study evaluating prophylactic oral administration in patients initiating ICI therapy, with a dose optimization component, dependent on funding. The study is being designed in consultation with leading oncologists and irEC experts. As part of the development program, Seres plans to engage with the FDA to discuss study design and potential endpoints, which could include incidence of irEC (all grades), ICI administration, and safety. In addition, Seres looks forward to receiving FDA feedback on plans to optimize prophylactic dosing for the study, which could include a healthy volunteer study component or a dosing lead-in element, the results of which are expected to inform the prophylactic dosing course, before initiating dosing in the broader ICI population. As in the completed IST, the Company anticipates enrolling patients across a wide range of ICI types.
- The prevention approach is designed to reduce incidence of irEC, keep patients on ICI therapy and avoid immunosuppressive irEC treatments. irEC is among the most frequent and severe immune-related adverse reactions in patients receiving ICIs, and affects up to 50% of ICI recipients, with rates varying by ICI type and regimen. Current standard of care for moderate or worse irEC (Grade 2 or above) requires halting life-saving ICI therapy and initiating a systemic immunosuppressive corticosteroid, a biologic, or both, which carry their own toxicities and may compromise the anti-cancer effect of ICI therapy.

- The planned next study builds on encouraging topline results from the open-label IST (NCT06801067) conducted at MSK evaluating SER-155 as a potential treatment in irEC, which Seres reported in July. The study enrolled 15 participants with moderate-to-severe (Grade 2-3) irEC (which represents approximately 25% of all ICI recipients) who were naïve to immunosuppressive therapy; 12 of 15 (80%) of participants treated with SER-155 achieved an immunosuppressive-free clinical response at Day 15, the primary efficacy endpoint, defined as at least a one-grade improvement in diarrhea symptoms without immunosuppressive therapy. Five of 15 participants (33%) achieved immunosuppressive-free complete clinical remission at Day 15. SER-155 was generally well tolerated through Day 43, with no serious adverse events assessed as related to SER-155.
- In the IST, translational biomarkers of gastrointestinal inflammation and mucosal epithelial barrier integrity both improved following SER-155 treatment, with statistically significant reductions by Day 43.
- ICIs represent one of the largest and fastest-growing segments of the oncology market, with the worldwide market valued at well over $50 billion in 2025. In the U.S. alone, it is estimated that 300,000 patients are currently on ICIs, representing a large potential target patient population for SER-155 as a preventative treatment for irEC, and a potential multi-billion-dollar commercial opportunity, as the Company believes that both patients and clinicians will be motivated to adopt a prophylactic approach that could permit patients to remain on their ICI therapy.
- Seres expects to submit the proposed next study design to the FDA in the first quarter of 2027 and engage with the agency thereafter.
- Seres and MSK will present a poster entitled “High Immunosuppressive-Free Response Rate of irEC with SER-155, an Investigational Oral Live Biotherapeutic, as First-Line Therapy, in a Phase 1b Study” at the Society for Immunotherapy of Cancer (SITC) 2026 Annual Meeting in Phoenix, AZ on November 7, 2026. This poster will highlight the promising results of the IST.

Broader pipeline and portfolio

- SER-155 remains Phase 2 ready for the prevention of bloodstream infections in adults undergoing allo-HCT for the treatment of blood cancer, pending funding. SER-155 has received Breakthrough Therapy and Fast Track designations for this indication. Efforts continue to secure funding to advance clinical development for this program.
- On November 3, Seres announced that results from its Phase 1b clinical study of SER-155 in adults undergoing allo-HCT were published in *Nature Medicine,* marking an important milestone for the program and providing recognition of the innovative science being advanced by the Company. The publication reported that SER-155 was generally well tolerated and was associated with a 77% relative risk reduction in BSIs compared with placebo.
- Seres continues to progress development of SER-428, an investigational oral liquid formulation based on a subset of SER-155 strains supported by a grant from CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator), for dosing in patients who cannot take oral capsules, including critically ill patients who receive nutrition and medications via feeding tube. Seres is designing a Phase 1b open-label trial, in collaboration with Daniel E. Freedberg, M.D., M.S., of Columbia University, and in consultation with CARB-X, to evaluate SER-428 in patients with sepsis who are receiving antibiotics in the Medical Intensive Care Unit (MICU) and are at high risk of additional infection. Further clinical development of SER-428 will be progressed pending funding from grants or other sources.
- The Company continues to advance IND-enabling activities for SER-603, in development for inflammatory bowel disease (IBD), and is engaging potential collaborators to support the clinical advancement of this program as a mono and/or combination therapy.

Corporate Updates

- In October, Seres received the second of the two $12.5 million payments related to the buy-out of potential future VOWST net sales-based milestones from Nestlé Health Science (Nestlé).
- On July 31, Seres entered into an agreement to terminate the lease for its facility at 200 Sidney Street in Cambridge, MA. The early termination materially eliminates the Company's obligations under the lease as of December 31, 2026, and results in reduced ongoing facility-related cash costs beginning in 2027.

Third Quarter 2026 Financial Results

- Net loss was $16.3 million for the third quarter of 2026, compared to net income of $8.2 million for the same period in 2025. The difference is primarily due to a $25 million installment payment received in the third quarter of 2025 related to

the sale of the VOWST business to Nestlé, recognized as a Gain on Sale.

- Research and development expenses were $5.6 million for the third quarter of 2026, compared with $12.6 million for the same period in 2025, reflecting lower facilities costs, transition services agreement (TSA) costs, personnel-related expenses and SER-155 costs driven by lower activities in these areas and cost reduction efforts.
- General and administrative expenses were $5.4 million for the third quarter of 2026, compared with $9.5 million for the same period in 2025, due to lower personnel-related expenses, facilities costs, and IT costs, including those related to IT services provided under the TSA.
- In the third quarter of 2026, the Company recorded a $5.7 million non-cash impairment of assets charge related to the early termination of its lease at 200 Sidney Street.

Cash and Cash Runway

As of September 30, 2026, Seres had $17.5 million in cash and cash equivalents. Based on Seres' currently available cash resources, including the $12.5 million payment received from Nestlé in October, and considering future operating plans, the Company expects to fund operations through the first quarter of 2027. This projection excludes proceeds from any potential future partnerships or other sources of capital.

About Seres Therapeutics

Seres Therapeutics, Inc. (Nasdaq: MCRB) is a clinical-stage biotechnology company developing novel live biotherapeutics products in oncology that address causes of mortality and discontinuation of life-saving cancer treatment, and in inflammatory and immune (I&I) diseases, by modulating host function to protect and improve mucosal epithelial barrier integrity, induce immune homeostasis and tolerance, and prevent the colonization and overgrowth of pathogens in the gastrointestinal (GI) tract. The Company previously led the development and FDA approval of VOWST™, the first orally administered microbiome therapeutic, which was subsequently divested to Nestlé Health Science. SER-155, an investigational cultivated multi-strain biotherapeutic, which has received Breakthrough Therapy and Fast Track designations, is being advanced for the prevention of bloodstream infections in patients undergoing allogeneic hematopoietic stem cell transplant (allo-HCT), and is Phase 2 ready, pending receipt of funding. SER-155 is also being developed to prevent immune checkpoint inhibitor-related enterocolitis (irEC), with the aim of enabling patients to continue their ICI cancer therapy and avoid the need for immunosuppressive steroid treatment. Following promising results from an investigator-sponsored trial, Seres plans to submit the design of a study for the prevention of irEC in patients initiating ICI therapy to the FDA. The Company is advancing IND-enabling studies for SER-603, which is in development for inflammatory bowel disease. Mechanistically, Seres' biotherapeutics target the mucosal epithelial barrier-immune interface and are optimized to modulate host function to increase mucosal epithelium integrity, induce immune homeostasis, and prevent the colonization and overgrowth of harmful bacteria in the GI tract. 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, without limitation, statements about: SER-155 and its intended uses and benefits in irEC; our clinical development plans for SER-155, SER-603 and SER-428, including the design and timing of the next planned study of SER-155 for the prevention of irEC; potential accessibility for patients; planned submissions to and/or engagement with regulatory authorities, including the anticipated timing of FDA feedback; the timing and results of clinical studies and data readouts; the anticipated content and timing of upcoming presentations and conferences; current or future product candidates and their potential impacts and outcomes; the size of potential patient populations and markets and the potential commercial opportunity for SER-155; engagement with potential partners and financing sources; our ability to access capital to advance our programs; IND-enabling activities; our cash runway; the anticipated effects of our lease termination, including expected reductions in facility-related costs; our planned strategic focus; the 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 cost reduction actions may not achieve their intended benefits, including an extended cash runway; (5) our limited operating history; (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; (13) impact of our recent management transitions and appointments and our ability to retain key personnel; and (14) disruptions at the FDA or other government agencies. These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2026, to be filed with the Securities and Exchange Commission (SEC), as well as 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, except as required by law, 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, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 17,528	$ 45,766
Accounts receivable due from SPN - related party	12,500	360
Accounts receivable	183	157
Prepaid expenses and other current assets	4,212	3,093
Total current assets	34,423	49,376
Property and equipment, net	2,999	7,635
Operating lease assets	27,662	72,483
Restricted cash	773	8,668
Other non-current assets	31	31
Total assets	$ 65,888	$ 138,193
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,461	$ 1,682
Accrued expenses and other current liabilities	3,504	3,972
Accrued liabilities due to SPN - related party	3,278	3,278
Operating lease liabilities	12,650	10,390
Total current liabilities	20,893	19,322
Operating lease liabilities, net of current portion	23,122	72,576
Other long-term liabilities	514	2,077
Total liabilities	44,529	93,975
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2026 and December 31, 2025; no shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Common stock, $0.001 par value; 360,000,000 shares authorized at September 30, 2026 and December 31, 2025; 10,049,501 and 9,556,466 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	10	10
Additional paid-in capital	1,025,370	1,016,611
Accumulated deficit	(1,004,021)	(972,403)
Total stockholders' equity	21,359	44,218
Total liabilities and stockholders' equity	$ 65,888	$ 138,193

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
Grant revenue	593	351	1,687	351
Total revenue	593	351	1,687	351
Operating expenses:				
Research and development expenses	5,592	12,616	27,928	37,376
General and administrative expenses	5,448	9,476	20,579	31,617
Impairment of long-lived assets	5,705	—	11,512	—
Manufacturing services	—	736	—	5,952
Total operating expenses	16,745	22,828	60,019	74,945
Loss from operations	(16,152)	(22,477)	(58,332)	(74,594)
Other income (expense):				
Gain on sale of VOWST Business	—	27,222	25,000	79,588
Interest income	146	618	652	1,782
Other income (expense) (1)	(280)	2,841	1,062	14,255

Total other income (expense), net	(134)	30,681	26,714	95,625
Net (loss) income and comprehensive (loss) income	$ (16,286)	$ 8,204	$ (31,618)	$ 21,031
Net (loss) income per share attributable to common stockholders - basic	$ (1.63)	$ 0.94	$ (3.24)	$ 2.41
Net (loss) income per share attributable to common stockholders - diluted	$ (1.63)	$ 0.94	$ (3.24)	$ 2.40
Weighted average common shares outstanding - basic	9,982,031	8,758,692	9,764,763	8,735,418
Weighted average common shares outstanding - diluted	9,982,031	8,771,519	9,764,763	8,744,797

[1] Includes $0, $0, $2,028, and $11,827 for the three and nine months ended September 30, 2026 and 2025 related to reimbursement received from SPN (related party) for transition services provided by the Company.

Investor and Media Contact:
IR@serestherapeutics.com

Carlo Tanzi, Ph.D.
Kendall Investor Relations
ctanzi@kendallir.com

Source: Seres Therapeutics, Inc.