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

August 13, 2024

SER-155 Phase 1b placebo-controlled Cohort 2 clinical readout on track for September

VOWST asset sale to provide $175M cash infusion, less approximately $20M in settlement of net obligations between the Parties, at close

Transaction proceeds to fully retire debt and support advancement of wholly-owned cultivated live biotherapeutic pipeline to improve patient outcomes in medically vulnerable populations

Based on existing cash, deal economics and operating plans, Seres expects to fund operations into Q4 2025

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

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

"Our recently announced VOWST asset sale will, pending approval by stockholders and upon closing, significantly strengthen Seres' balance sheet and advance our goal to improve patient outcomes in medically vulnerable patient populations through the use of our wholly-owned cultivated live biotherapeutics," said Eric Shaff, President and Chief Executive Officer of Seres. "We intend to leverage our clinical, CMC, and regulatory successes by applying our therapeutic approach to new patient groups that face heightened risks of serious bacterial infections, which frequently lead to extensive and costly treatments and, unfortunately too often, death."

Mr. Shaff continued, "Our lead SER-155 program remains on track for a clinical data readout from the placebo-controlled study Cohort 2 in patients receiving allogeneic hematopoietic stem cell transplant (allo-HSCT) in September. This dataset has the potential to highlight the extensive clinical value and commercial opportunities of both our SER-155 program and our biotherapeutic approach more generally. Multiple patient groups are known to experience a disrupted gastrointestinal (GI) microbiome and a high risk of life-threatening enteric-derived bacterial infections as well as blood stream infections arising from translocated bacteria. Our development efforts are targeting multiple medically vulnerable patient groups, including potentially those with chronic liver disease, cancer neutropenia and solid organ transplants. In the longer term, we plan to develop our biotherapeutics to treat GI-related immune diseases such as inflammatory bowel disease."

Corporate Highlights

- In April, the Company announced the completed enrollment of Cohort 2 of the SER-155 Phase 1b study, which included 45 participants. Cohort 2 study data are anticipated in September and will include safety, drug pharmacology and efficacy-related measures, including the rates of bacterial infections and febrile neutropenia, through day 100 following allo-HSCT—a period in which patients frequently experience serious infections. SER-155 is designed to prevent GI-derived infections and resulting bloodstream infections, enhance epithelial barrier integrity and induce immune tolerance responses to reduce the incidence of graft-versus-host-disease (GvHD). The Company previously announced SER-155 Phase 1b Cohort 1 clinical data that showed SER-155 was well-tolerated, resulted in successful drug bacteria engraftment and a substantial reduction in pathogen domination in the GI microbiome compared to a reference cohort of patients. SER-155 received FDA Fast Track Designation. The Company's cultivated biotherapeutics are manufactured from single strain bacteria isolates through fermentation methods that allow for efficient, scalable processes.
- On August 6, the Company announced that it signed an agreement with Société des Produits Nestlé S.A ("SPN"), a wholly-owned subsidiary of Nestlé S.A., for the sale of its VOWST business to SPN (the "Purchase Agreement"). Under the terms of the Purchase Agreement, upon the deal close, Seres will receive capital infusions, including an upfront payment, a prepaid milestone payment and an equity investment. In addition, Seres is due to receive installment payments in 2025, contingent upon the Company's material compliance with transition obligations, as well as potential future milestone payments based on VOWST net sales targets. The completion of the transaction, which is subject to Seres' stockholder approval and other customary conditions, is expected to occur within 90 days following the signing of the Purchase Agreement. Seres continues to support VOWST commercial supply, and production capacity remains strong. Following the expected close of the asset sale transaction, Seres will provide transition services through the first quarter of 2025 and manufacturing support through the end of 2025, subject to SPN's limited ability to extend, and will continue to share 50/50 in the profits or losses of the business through the fourth quarter of 2025.
- Seres intends to evaluate SER-155 and other cultivated live biotherapeutic candidates in additional medically vulnerable patient populations, including chronic liver disease, cancer neutropenia, and solid organ transplants. Future development plans will be informed by pending SER-155 Cohort 2 results, and the Company plans to share more information regarding

its SER-155 development plans later in 2024.
- Seres is also developing another proprietary live biotherapeutic composition, SER-147, designed to prevent GI-derived infections and resulting bloodstream infections and to improve clinical outcomes in patients with metabolic disease, including those with chronic liver disease and at high risk of bacterial infections. We anticipate IND readiness for SER-147 in the second half of 2025.

VOWST Commercial Performance
Seres collaborator SPN and certain of its affiliates (collectively, "Nestlé Health Science") have continued to lead VOWST commercialization efforts. Since the VOWST product launch in June 2023, the breadth of utilization has steadily increased among healthcare providers. Second quarter 2024 net sales were approximately $14.4 million, reflecting an increase of approximately 43% compared to first quarter net sales of $10.1 million. Seres shares equally with Nestlé Health Science in the VOWST commercial profits or losses. Seres' share of the VOWST net loss for the second quarter of 2024 was $6.6 million, which was included in the Company's operating results within Collaboration (profit) loss sharing-related party.

Financial Results

- Seres reported a net loss of $32.9 million for the second quarter of 2024, as compared to net income of $46.6 million for the same period in 2023. The difference is primarily the result of a $125 million milestone payment received from Nestlé in the second quarter of 2023, upon the FDA approval of VOWST, offset by operating expense reductions.
- Research and development (R&D) expenses for the second quarter of 2024 were $17.9 million, compared with $46.8 million for the same period in 2023. The decrease in R&D expenses was primarily driven by VOWST commercial manufacturing costs no longer being recognized in the Seres profit and loss (P&L) following the product approval in April 2023, but instead being capitalized and recognized on the Company's balance sheet, as well as lower personnel and other costs as a result of the restructuring plan announced in November 2023.
- General and administrative (G&A) expenses for the second quarter of 2024 were $16.1 million, compared with $28.1 million for the same period in 2023. The decrease in G&A expenses was primarily driven by a reduction in professional fees and lower personnel costs as a result of the restructuring plan.

Cash Runway
Seres plans to use the capital obtained from the VOWST asset sale transaction to fully retire its senior secured debt facility with Oaktree Capital Management. Additionally, the Bacthera manufacturing contract will be terminated upon close of the transaction, and Seres will have no further obligations to Bacthera.

Various VOWST-related capabilities, including product manufacturing, will transition to Nestlé Health Science as part of the asset sale. As a result, Seres expects that more than a third of its employees will transfer to Nestlé Health Science following the close of the transaction. Moving forward, Seres will be a streamlined and more focused organization, and the Company's cash burn rate is expected to be reduced.

As of June 30, 2024, Seres had $71.2 million in cash and cash equivalents. Based on existing cash and operating plans, expected cash to be received upon the close of the VOWST sale and related installment payments due in 2025, and ongoing transaction-related obligations, the Company expects to fund operations into the fourth quarter of 2025. Absent the VOWST sale, the Company expects to fund operations into the fourth quarter of 2024.

Conference Call Information
Seres' management will host a conference call today, August 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 4877586. To join the live webcast, please visit the "Investors and News" section of the Seres website at www.seresherapeutics.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.

INDICATION AND IMPORTANT SAFETY INFORMATION FOR VOWST
INDICATION
VOWST (fecal microbiota spores, live-brpk) is indicated to prevent the recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI).

Limitation of Use: VOWST is not indicated for treatment of CDI.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Transmissible infectious agents: Because VOWST is manufactured from human fecal matter, it may carry a risk of transmitting infectious agents. Report any infection that is suspected to have been transmitted by VOWST to Aimmune Therapeutics, Inc. at 1-833-246-2566.

Potential presence of food allergens: VOWST may contain food allergens. The potential to cause adverse reactions due to food allergens is unknown.

ADVERSE REACTIONS

The most common adverse reactions (reported in ≥5% of participants) were abdominal distension (31.1%), fatigue (22.2%), constipation (14.4%), chills (11.1%) and diarrhea (10.0%).

To report SUSPECTED ADVERSE REACTIONS, contact Aimmune Therapeutics at 1-833-AIM-2KNO (1-833-246-2566), or the FDA at 1-800-FDA-1088, or visit www.fda.gov/MedWatch.

DRUG INTERACTIONS

Do not administer antibacterials concurrently with VOWST.

Please see Full Prescribing Information and Patient Information

About SER-155
The SER-155 composition is designed to prevent GI-derived infections and resulting bloodstream infections, enhance epithelial barrier integrity, and induce immune tolerance responses, to reduce the incidence of GvHD. SER-155 is being evaluated in a Phase 1b placebo-controlled study in patients undergoing allo-HSCT. SER-155 is a consortium of bacterial species selected and optimized using Seres' reverse translation discovery and development platform technologies. The design incorporates biomarker data from human clinical data, nonclinical human cell-based assays and *in vivo* disease models. SER-155 has received FDA Fast Track Designation.

About Seres Therapeutics
Seres Therapeutics, Inc. (Nasdaq: MCRB) is a commercial-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. The Company is evaluating SER-155 in a Phase 1b study in patients receiving allo-HSCT. SER-155 is designed to prevent GI-derived infections and resulting bloodstream infections, enhance epithelial barrier integrity and induce immune tolerance responses to reduce the incidence of GvHD. The Company is also advancing additional cultivated oral microbiome therapeutic candidates for medically vulnerable populations, including those with chronic liver disease, cancer neutropenia and solid organ transplants. For more information, please visit www.serestherapeutics.com.

Important Additional Information About the Transaction and Where to Find It

This communication is being made in respect of the proposed transaction involving Seres Therapeutics, Inc., a Delaware corporation ("Seres") and Société des Produits Nestlé S.A., a société anonyme organized under the laws of Switzerland ("SPN"). Seres intends to file a proxy statement and other relevant documents with the Securities and Exchange Commission (the "SEC") in connection with a special meeting of Seres' stockholders for purposes of obtaining, stockholder approval of the proposed transaction. The definitive proxy statement will be sent or given to the stockholders of Seres and will contain important information about the proposed transaction and related matters. INVESTORS AND STOCKHOLDERS OF SERES ARE URGED TO READ THE DEFINITIVE PROXY STATEMENT AND OTHER RELEVANT MATERIALS CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT SERES AND THE PROPOSED TRANSACTION. Investors may obtain a free copy of these materials (when they are available) and other documents filed by Seres with the SEC at the SEC's website at www.sec.gov or from Seres at its website at ir.serestherapeutics.com.

Participants in the Solicitation

Seres and certain of its directors, executive officers and other members of management and employees may be deemed to be participants in soliciting proxies from its stockholders in connection with the proposed transaction. Information regarding the persons who may, under the rules of the SEC, be considered to be participants in the solicitation of Seres' stockholders in connection with the proposed transaction will be set forth in Seres' definitive proxy statement for its stockholder meeting at which the proposed transaction will be submitted for approval by Seres' stockholders. You may also find additional information about Seres' directors and executive officers in Seres' Annual Report on Form 10-K for the fiscal year ended December 31, 2023, which was filed with the SEC on March 5, 2024, Seres' Definitive Proxy Statement for its 2024 annual meeting of stockholders, which was filed with the SEC on March 5, 2024, and in subsequently filed Current Reports on Form 8-K and Quarterly Reports on Form 10-Q.

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, timing and completion of the sale of VOWST assets to Nestlé Health Science; the receipt of future payments and the use of proceeds of the transaction; the timing and results of our clinical studies and data readouts; future product candidates, development plans and commercial opportunities; operating plans and our future cash runway; our ability to 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) the restrictions in our debt agreement; (5) our novel approach to therapeutic intervention; (6) our reliance on third parties to conduct our clinical trials and manufacture our product candidates; (7) the competition we will face; our ability to protect our intellectual property; (8) our ability to retain key personnel and to manage our growth; (9) the occurrence of any event, change or other circumstance that could give rise to the termination of the Purchase Agreement; (10) our failure to obtain stockholder approval for the proposed transaction or to satisfy any of the other conditions to the completion of the proposed transaction; (11) the effect of the announcement of the proposed transaction 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; (12) the risks associated with the disruption of management's attention from ongoing business operations due to the proposed transaction and the obligation to provide transition services; (13) our failure to receive the installment payments or the milestone payments in the future; (14) the significant costs, fees and expenses related to the proposed transaction; (15) the uncertainty of impact of the 50/50 profit or loss sharing arrangement on our reported results and liquidity; (16) the risk that the proposed transaction will not be completed within the expected time period or at all; and (17) we may not be able to realize the anticipated benefits of the proposed transaction. 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 May 8, 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)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 71,232	$ 127,965
Collaboration receivable - related party	18,601	8,674
Inventories	52,997	29,647
Prepaid expenses and other current assets	6,435	9,124
Total current assets	149,265	175,410
Property and equipment, net	17,794	22,457
Operating lease assets	103,282	109,793
Restricted cash	9,873	8,185
Restricted investments	—	1,401
Other non-current assets (1)	41,517	41,354
Total assets	$ 321,731	$ 358,600
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 4,809	$ 3,641
Accrued expenses and other current liabilities (2)	86,356	80,611
Operating lease liabilities	9,195	6,677
Deferred income - related party	7,922	7,730
Total current liabilities	108,282	98,659
Long term portion of note payable, net of discount	102,494	101,544
Operating lease liabilities, net of current portion	100,936	105,715
Deferred revenue - related party	95,364	95,364
Warrant liabilities	—	546
Other long-term liabilities	1,729	1,628
Total liabilities	408,805	403,456
Commitments and contingencies (Note 15)		
Stockholders' deficit:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2024 and December 31, 2023; no shares issued and outstanding at June 30, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value; 360,000,000 shares authorized at June 30, 2024 and 240,000,000 shares authorized at December 31, 2023; 151,633,922 and 135,041,467 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	152	135
Additional paid-in capital	964,012	933,244
Accumulated other comprehensive loss	—	—
Accumulated deficit	(1,051,238)	(978,235)
Total stockholders' deficit	(87,074)	(44,856)
Total liabilities and stockholders' deficit	$ 321,731	$ 358,600

[1] Includes $38,877 as of June 30, 2024 and December 31, 2023, of milestones related to the construction of the Company's dedicated manufacturing suite at BacThera AG, or Bacthera. Such amounts will form part of the right-of-use asset upon lease commencement.
[2] Includes related party amounts of $43,075 and $28,053 at June 30, 2024 and December 31, 2023, respectively (see Note 17, *Related Party Transactions*).

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue:				
Collaboration revenue - related party	$ —	$ 126,473	$ —	$ 125,951
Total revenue	—	126,473	—	125,951

Operating expenses:				
Research and development expenses	17,875	46,792	$ 39,577	90,761
General and administrative expenses	16,059	28,051	$ 31,525	50,521
Collaboration (profit) loss sharing - related party	(2,589)	2,106	$ (171)	5,713
Total operating expenses	31,345	76,949	$ 70,931	146,995
(Loss) income from operations	(31,345)	49,524	$ (70,931)	(21,044)
Other income (expense):				
Interest income	1,230	1,726	$ 2,878	2,758
Interest expense	(3,447)	(3,187)	$ (8,110)	(5,135)
Other income (expense)	692	(1,511)	$ 3,160	(1,201)
Total other expense, net	(1,525)	(2,972)	$ (2,072)	(3,578)
Net (loss) income	$ (32,870)	$ 46,552	$ (73,003)	$ (24,622)
Net (loss) income per share attributable to common stockholders, basic	$ (0.22)	$ 0.36	$ (0.49)	$ (0.19)
Net (loss) income per share attributable to common stockholders, diluted	$ (0.22)	$ 0.36	$ (0.49)	$ (0.19)
Weighted average common shares outstanding, basic	151,514,597	127,713,486	148,808,089	126,793,342
Weighted average common shares outstanding, diluted	151,514,597	129,844,931	148,808,089	126,793,342
Other comprehensive (loss) income:				
Unrealized (loss) income on investments, net of tax of $0	—	(2)	—	10
Currency translation adjustment	—	(1)	—	1
Total other comprehensive (loss) income	—	(3)	—	11
Comprehensive loss (income)	$ (32,870)	$ 46,549	$ (73,003)	$ (24,611)

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Source: Seres Therapeutics, Inc.