### **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

### FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 7, 2024

# SERES THERAPEUTICS, INC. (Exact name of Registrant as Specified in Its Charter)

Delaware (State or other jurisdiction of incorporation)

001-37465

27-4326290 (IRS Employer Identification No.)

101 Cambridgepark Drive Cambridge, MA
(Address of principal executive offices)

02140 (Zip Code)

Registrant's telepho	one number, including area code: (	017) 945-9626
(Former Name	Not Applicable or Former Address, if Changed Since Last	Report)
	ended to simultaneously satisfy the fi	ling obligation of the registrant under any of the
Written communications pursuant to Rule 425 under the	e Securities Act (17 CFR 230.425)	
Soliciting material pursuant to Rule 14a-12 under the E	xchange Act (17 CFR 240.14a-12)	
Pre-commencement communications pursuant to Rule	14d-2(b) under the Exchange Act (17	CFR 240.14d-2(b))
Pre-commencement communications pursuant to Rule	13e-4(c) under the Exchange Act (17	CFR 240.13e-4(c))
urities registered pursuant to Section 12(b) of the Act:		
Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001 per share	MCRB	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)
		405 of the Securities Act of 1933 (§ 230.405 of this
rging growth company		
	(Former Name)  ck the appropriate box below if the Form 8-K filing is into twing provisions:  Written communications pursuant to Rule 425 under the Soliciting material pursuant to Rule 14a-12 under the E Pre-commencement communications pursuant to Rule Pre-commencement communications pursuant to Rule urities registered pursuant to Section 12(b) of the Act:  Title of each class  Common stock, par value \$0.001 per share  cate by check mark whether the registrant is an emerging ofter) or Rule 12b-2 of the Securities Exchange Act of 193 reging growth company   emerging growth company   emerging growth company, indicate by check mark if the securities are	ck the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the fiving provisions:  Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)  Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)  Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 urities registered pursuant to Section 12(b) of the Act:  Title of each class  Trading Symbol(s)  Common stock, par value \$0.001 per share  MCRB  Acted by check mark whether the registrant is an emerging growth company as defined in Rule enter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

#### Item 2.02. Results of Operations and Financial Condition.

On November 13, 2024, Seres Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2024 and provided operational updates. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the "Current Report")

#### Item 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On November 7, 2024, the Company received a letter from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that, for the last 30 consecutive business days, the bid price for the Company's common stock, par value \$0.001 per share (the "Common Stock"), had closed below the \$1.00 per share minimum bid price requirement for continued inclusion on The Nasdaq Global Select Market pursuant to Nasdaq Listing Rule \$450(a)(1) (the "Bid Price Requirement").

The letter has no immediate effect on the listing of the Common Stock on The Nasdaq Global Select Market, and the Common Stock will continue to trade on The Nasdaq Global Select Market under the symbol "MCRB," subject to the Company's compliance with the other continued listing requirements of The Nasdaq Global Select Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has been provided an initial compliance period of 180 calendar days from receipt of the letter, or until May 6, 2025, to regain compliance with the Bid Price Requirement. To regain compliance, the closing bid price for the Common Stock must be at least \$1.00 per share for a minimum of 10 consecutive business days prior to May 6, 2025. There can be no assurance that the Company will be able to regain compliance or that Nasdaq will extend the compliance period.

If the Company does not regain compliance with the Bid Price Requirement by May 6, 2025, the Company may be eligible for an additional 180 calendar day compliance period. To qualify, the Company must submit an application to transfer the listing of the Common Stock to The Nasdaq Capital Market, which requires the Company to meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, other than the Bid Price Requirement. The Company would also need to pay an application fee to Nasdaq and to provide written notice of its intention to cure the deficiency during the additional compliance period. As part of its review process, Nasdaq will make a determination of whether it believes the Company will be able to cure this deficiency.

If the Company does not regain compliance within the applicable compliance period(s), the Company expects that Nasdaq will provide written notification to the Company that the Common Stock will be subject to delisting. At that time, the Company may appeal the delisting determination to a Nasdaq Listing Qualifications Panel.

The Company intends to monitor the closing bid price of the Common Stock and may, if appropriate, consider taking actions to regain compliance with the Bid Price Requirement, including, subject to approval of the Company's Board of Directors and its stockholders, implementing a reverse stock split.

There can be no assurance that the Company will be able to regain compliance with the Bid Price Requirement or will otherwise be in compliance with other applicable Nasdaq listing rules within the applicable compliance period(s), that the Company will be able to successfully implement a reverse stock split, or, if the Company receives a delisting determination and decides to appeal the delisting determination, that such appeal would be successful.

#### Item 7.01. Regulation FD Disclosure.

On November 13, 2024, the Company posted an updated corporate presentation in the "Investors and News" portion of its website at www.serestherapeutics.com. A copy of the slide presentation is attached as Exhibit 99.2 to this Current Report and incorporated herein by reference.

The information in Items 2.02 and 7.01 of this Current Report, including Exhibits 99.1 and 99.2 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

#### Forward-Looking Statements Disclaimer

This Current Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report on Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including statements regarding the Company's intent or ability to transfer the listing of its common stock to The Nasdaq Capital Market, regain compliance with any applicable Nasdaq listing requirements, implement a reverse stock split, or the timing of any of the foregoing. These forward-looking statements are based on the Company's 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 the Company's 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 factors discussed under the caption "fixisk 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 Current Report. Any such forward-looking statements represent management's estimates as of the date of this Current Report. 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 Current Report.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following Exhibits 99.1 and 99.2 relate to Items 2.02 and 7.01, respectively, and shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Seres Therapeutics, Inc. Press Release issued November 13, 2024
99.2	Seres Therapeutics, Inc. Corporate Presentation as of November 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SERES THERAPEUTICS, INC.

Date: November 13, 2024

By: // Thomas J. DesRosier

Name: Thomas J. DesRosier

Title: Chief Legal Officer and Executive Vice President



## SERES THERAPEUTICS REPORTS THIRD QUARTER 2024 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATES

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.—November 13, 2024 — 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 Combatting 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 stat

# SERES THERAPEUTICS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited, in thousands, except share and per share data)

	Se	ptember 30, 2024	De	cember 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	Ť	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
	_			

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.

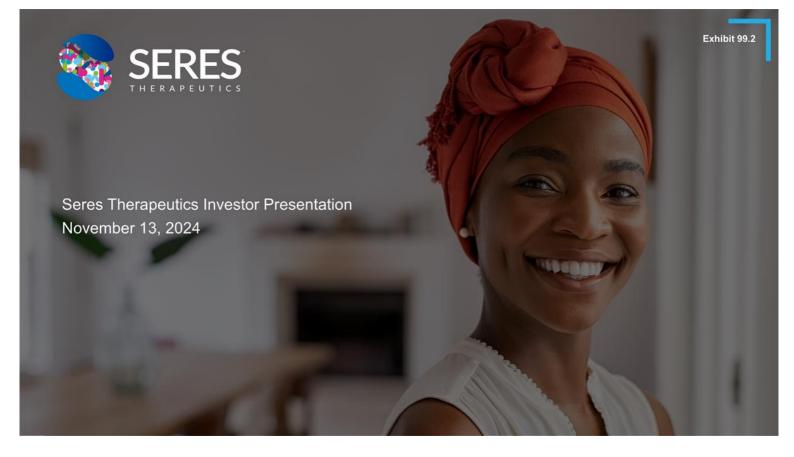
Includes related party amount of \$35,783 at December 31, 2023.

# 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 Septembe				
		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	15	52,648,238	12	28,289,871	1	50,097,482	1	27,297,667
Weighted average common shares outstanding, diluted	15	52,648,238	12	28,289,871	1	50,097,482	_1	27,297,667
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)

# Investor and Media Contact: IR@serestherapeutics.com

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



## **Disclaimers**

#### **Forward Looking Statements**

This communication contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this communication 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 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 communication. Any such forward-looking statements represent management's estimates as of the date of this communication. 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 communication.



## Transforming patient outcomes using proprietary consortia of live biotherapeutics

### Strong foundation

- Validated platform with VOWST® clinical and regulatory success
- Asset sale strengthens balance sheet, expected to extend runway into Q4
- Wholly-owned cultivated pipeline: SER-155, SER-147, beyond

### Favorable Phase 1b clinical data in SER-155 allo-HSCT

- 77% relative risk reduction for bloodstream infections
- Significant reduction in systemic antibacterial exposure
- Lower incidence of febrile neutropenia
- Well tolerated safety profile; no treatmentrelated SAEs

#### **Blockbuster opportunity**

- Accelerate SER-155 development in allo-HSCT
- Potential to initiate multiple clinical studies in the next 12-18 months
- · Potential to evaluate SER-155 in additional populations at high risk of serious bacterial infections (e.g., autologous HSCT, blood cancers, CAR-T)

#### **Expansive potential**

- Current focus of preventing life-threatening infections
- SER-147 designed to prevent infections in chronic liver disease
- · Longer-term potential to treat immune-related diseases (including IBD)

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



# Validated platform: Seres pioneered the development and FDA approval of VOWST as the first-ever oral live microbiome therapeutic



FDA approved (April 2023) to prevent the recurrence of *C. difficile* infection in adults

DRAMATIC CLINICAL BENEFIT – Preventing infection recurrence

**Approximately** 

88%

sustained clinical response rate (C. diff. recurrence, at up to 8 weeks)



# VOWST asset sale completed September 30, 2024: transformational for Seres – provides resources to support SER-155 advancement







- VOWST asset purchase agreement provided infusion of capital and supports SER-155 development
- Asset sale extends operational runway into Q4 2025
- · Retires debt and other obligations

#### **KEY FINANCIAL TERMS**

**\$100M** upfront payment to Seres, less ~\$20M in net obligations due to an affiliate of SPN\*

\$15M equity investment by SPN at closing

\$60M prepaid sales-based milestone at closing

**\$75M** in deferred payments due in 2025 (less ~\$1.5M in employment-related payments)

**\$275M** in potential future sales-based milestone payments (subject to reductions for interest on prepaid milestone payment)

Transaction results in a more streamlined, focused Seres organization and lower cash burn rate

\*SPN: Société des Produits Nestlé S.A.



# Near-term focus on SER-155 as anchor biotherapeutic program



- · Reduces risk of recurrent C. diff infections
- · Well tolerated safety profile

Program	Lead Indication & Development Stage	Therapeutic Objectives	Potential Additional Indications
SER-155	Allogeneic HSCT: Phase 1b Cohort 2 (placebo controlled) data announced Sept. '24	Reduce incidence of serious bacterial infections (e.g., BSIs), febrile neutropenia, and GvHD	<ul><li>Autologous HSCT</li><li>Blood cancers</li><li>CAR-T</li></ul>
SER-147	Chronic liver disease: IND-enabling activities	Reduce incidence of serious bacterial infections (e.g., SBP, BSIs) and related complications	Solid organ transplant     ICU patients     Long-term care patients

Engaging with FDA to explore potential for SER-155 to have single registrational study for efficacy, following successful precedent from VOWST

BSI: bloodstream infection; SBP: spontaneous bacterial peritonitis



## Potential to treat a range of vulnerable patient populations

### **Target population characteristics**



GI microbiome functional disruption



Antibiotic



Time in hospital/care settings



Immune suppression



Neutropenia



Lost epithelial or mucosal barrier integrity

### Potential to prevent bacterial infections and immune-related disease

## Prevent life-threatening infections (current focus)

- · Blood cancers (including HSCT, CAR-T)
- Solid organ transplant
- · ICU & long-term care patients
- · Chronic liver disease

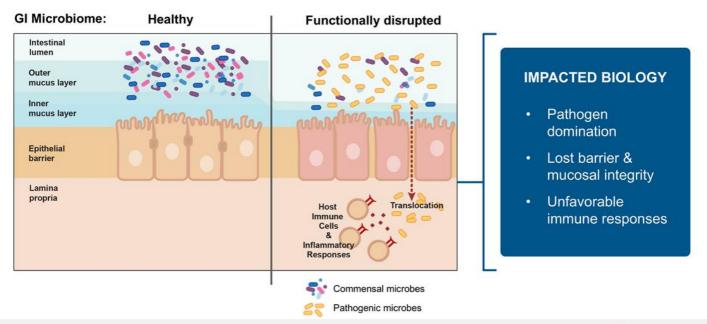
### Treat immune-related diseases

- · Inflammatory bowel disease
- Graft vs. host disease (GvHD)
- Checkpoint colitis
- Radiation enteritis



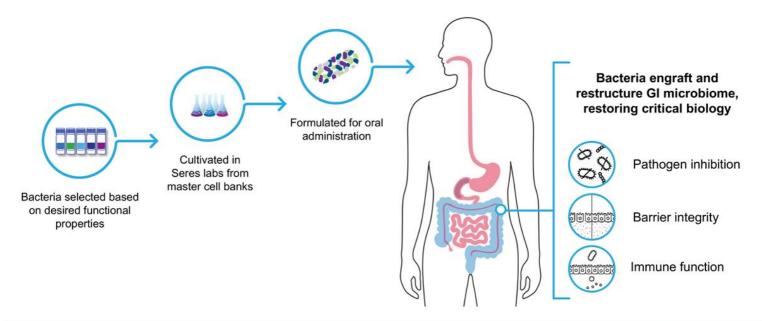
HSCT: hematopoietic stem cell transplant; CAR-T: chimeric antigen receptor T-cell therapy

# GI microbiome functional disruption leads to disease susceptibility





# Seres' biotherapeutics designed to restore functionality and health





# Seres' biotherapeutics and pipeline candidates are expected to have well tolerated safety profile, reducing development risk

- ✓ Based on GI bacteria naturally found in healthy humans, and not associated with disease
- √ VOWST product profile includes well tolerated safety without drug-related serious adverse events
- ✓ Well tolerated safety profile in multiple clinical trials and patient
  populations, including medically vulnerable allo-HSCT recipients

Safety profile has potential to mitigate a primary cause of drug development failure

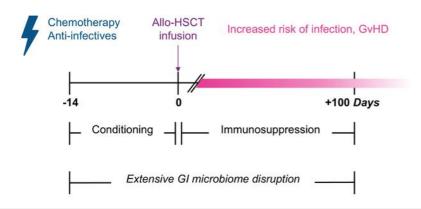
SERES THERAPEUTICS

## Allo-HSCT regimen can result in potentially life-threatening complications



- · Investigational live oral biotherapeutic cultivated from clonal master cell banks
- Designed to prevent GI-derived bacterial bloodstream infections (BSIs) and other pathogen-associated complications

## Allo-HSCT treatment regimen



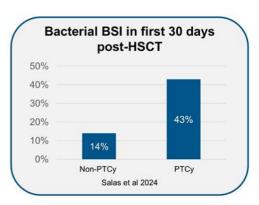
- Only ~60% survival 3 years posttransplant
- · Significant immune compromise
- ~10% transplant mortality for adults in first 100 days post-transplant
- Infections are leading cause of death in first 100 days post-transplant for adults
- Other leading causes of death are disease relapse and organ failure



# Bloodstream infections (BSI) are a leading cause of death and an escalating problem post-transplant

### Incidence

- 32-55% BSI incidence reported in the literature
- BSI risk escalating due to recent adoption of post-transplant cyclophosphamide (PTCy) for GvHD prophylaxis
- ~50% of infections believed to be gutseeded
- 50-80% febrile neutropenia incidence



### **Impact**

- Infection is leading cause of death in first 100 days post-HSCT for adults
- ~7.5% mortality rate from bloodstream infections
- Complications including infection associated with longer hospital stay and ICU utilization, driving substantial cost increase



# SER-155 Phase 1b study evaluated safety, pharmacology, and efficacy in adult allo-HSCT recipients



Open-label (n=15 enrolled)

#### COHORT 2

Placebo-controlled 1:1 (n=45 enrolled)

### **SER-155**

**SER-155** 

Placebo

results reported May 2023

results announced Sept. 2024

#### **Primary Endpoints:**

- · Safety and tolerability
- SER-155 bacterial strain engraftment

#### Key Secondary Endpoints through HSCT Day 100:

- Incidence of bloodstream infections (BSI), GI infections, and acute GvHD ≥ Grade 2
- · Incidence and duration of febrile neutropenia
- · Bacterial pathogen abundance

Received US FDA Fast Track Designation in December 2023; Filed for Breakthrough Therapy and Qualified Infectious Disease Product (QIDP) designations



## Patient Safety: Cohort 2 SER-155 was generally well tolerated with no treatment-related SAEs

Treatment-emergent adverse events (TEAEs)

- · All but one subject in the placebo arm experienced at least 1 TEAE
- Most common for SER-155 treated subjects (≥50% and with Δ≥5% greater than placebo): diarrhea (86% vs. 74% placebo), nausea (62% vs. 53% placebo)
- 1/40 (3%) subject experienced a TEAE leading to treatment discontinuation (active = 0; placebo = 1)
- 3/40 (8%) subjects experienced a TEAE leading to study discontinuation (active = 1; placebo = 2)

Serious adverse events (SAEs)

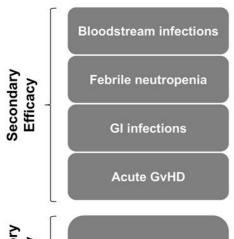
- 19/40 (48%) subjects experienced an SAE: 11/21 (52%) SER-155-treated subjects vs. 8/19 (42%) placebo-treated subjects; none considered related to SER-155 (no SUSARs)
  - o Most common SAE SOC: infections & infestations (24% active vs. 37% placebo)
  - 3 deaths prior to Day 100 (active = 1; placebo = 2), 1 death after Day 100 (active), none considered related to SER-155

Adverse events of special interest (AESIs)

- AESIs (bloodstream infections, GI infection, invasive infection): 14/40 (35%) subjects
- Rates of AESIs were lower in SER-155 arm vs placebo arm (29% vs 42% respectively)
- No SER-155 species were identified in culture from any subject



# Efficacy: SER-155 administration favorable with significant\* reduction in both bacterial BSIs and systemic antibiotic exposure; lower febrile neutropenia



**Significant decrease** in bacterial bloodstream infections in SER-155-treated subjects vs. placebo

**Numerically lower incidence rate** of febrile neutropenia in SER-155-treated subjects vs. placebo

**All GI infections were CDI**\*\*; 4 subjects in SER-155-treated (20%) and 2 subjects in placebo (14.3%) developed GI infections from HSCT Day 0-100

**No subjects in either arm** developed ≥ Grade 3 acute GvHD; 2 subjects in each arm developed Grade 2 acute GvHD

Exploratory

Efficacy

antimycotic exposure

**Significantly lower** mean cumulative exposure (days) to systemic antibacterials / antimycotics for SER-155-treated subjects vs. placebo

**Significantly lower** cumulative exposure rate to systemic antibacterials / antimycotics for SER-155-treated subjects vs. placebo

\*\* CDI: C. difficile infection



<sup>\*</sup> no multiplicity adjustments were applied

## Bloodstream infections from HSCT Day 0 to Day 100: Lower incidence in SER-155 treated subjects vs. placebo

Bloodstream infections from Day 0 to Day 100 (# patients)	SER-155 n=20 n (%)	Placebo n=14 n (%)
Subjects with confirmed BSI	2 (10.0%)	6 (42.9%)
95% confidence interval	(1.2, 31.7)	(17.7, 71.1)

mITT-1 population

dds ratio	0.15
95% confidence interval	(0.01, 1.13)
p-value	0.0423

Organisms in SER-155 patients: Finegoldia magna; E. coli/Strep mitis Organisms in placebo patients: E.coli; Enterococcus faecium/staph haemolyticus/Candida krusei; Staph aureus; Staph haemolyticus; Pseudomonas aeruginosa; E coli

- CI: 95% 2-sided Clopper-Pearson confidence interval of incidence is applied
   Odds ratio: for incidence between treatment groups (SER-155 and placebo) with 95% 2-sided confidence interval and the corresponding p-value calculated based on the Fisher's Exact test



## Cumulative exposure to systemic antibacterials / antimycotics through HSCT Day 100: Lower incidence in SER-155 treated subjects vs. placebo

Cumulative Antibacterial or Antimycotic Exposure (HSCT Days)	SER-155 n=20 n (SD)	Placebo n=14 n (SD)
Mean (SD)	9.2 (5.44)	21.1 (20.31)
Median	9.0	14.0
Min, Max	0, 19	0, 74

Mean Difference (95% CI)	-11.9 (-23.85, -0.04)
p-value	0.0494

mITT-1 population

Cumulative exposure is the sum of all days a subject received systemic antibacterials and/or antimycotics between HSCT Day 0 through Day 100; counting once per day regardless of number of agents taken 95% confidence interval and p-value based on independent samples t-test of the difference in mean days between SER-155 and placebo



## Cumulative exposure rate to systemic antibacterials / antimycotics through HSCT Day 100: Lower incidence in SER-155 treated subjects vs. placebo

Cumulative Antibacterial or Antimycotic Exposure Rate	SER-155 n=20 Rate (SD)	Placebo n=14 Rate (SD)
Mean (SD)	0.090 (0.0530)	0.305 (0.2898)
Median	0.089	0.244
Min, Max	0.00, 0.18	0.00, 0.90

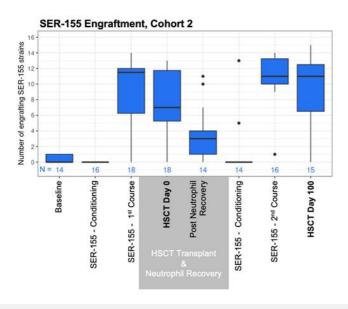
Mean Difference (95% CI)	-0.2 (-0.38, -0.05)
p-value	0.0163

mITT-1 population



Cumulative exposure rate is calculated as the sum of all days a subject received systemic antibacterials and/or antimycotics on or after HSCT Day 0 (counting once per day, regardless of number of antibacterial/antimycotic medications taken in a day) through HSCT Day 100 over the total number of days a subject was on the study from HSCT Day 0 to the earliest of EOS, or HSCT Day 100 95% confidence interval and p-value are based on independent samples t-test of the difference in mean days or mean rate of cumulative exposure between SER-155 and Placebo

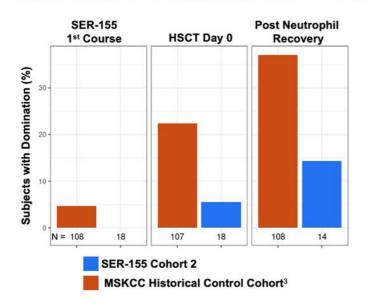
# SER-155 Strain Engraftment: Primary objective achieved - drug bacteria strain engraftment was robust and as expected



- The majority of SER-155 strains were present at start of HSCT conditioning and durable through chemotherapy exposure
- Engraftment decreased but was detectable postneutrophil recovery, suggesting sustained engraftment, even under unfavorable GI conditions (e.g., antibiotic exposure), and through period of greatest BSI susceptibility
- The second course of SER-155 was effective at increasing strain engraftment following transplant & neutrophil recovery, with engraftment durable out to day 100 following transplant
- Cohort 1 and Cohort 2 engraftment magnitude and kinetics had high congruence



# Pathogen Domination: Prevalence in SER-155 Cohort 2 was substantially lower relative to Historical Control Cohort



- SER-155 was designed to reduce pathogen domination that has been associated with risk of BSIs and other negative clinical outcomes<sup>1</sup>
- Observed pathogen domination events were low in the placebo and SER-155 arms with no significant differences observed
- Pathogen domination was substantially lower in SER-155 Cohort 2 compared to Historical Control Cohort<sup>2</sup>



Note: In Cohort 2, the ability to detect pathogen domination (i.e., relative abundance in the GI ≥30%) in the placebo arm, and differences between the study arms, was constrained due to the limited number of placebo stool samples and an imbalance in the number of available stool samples between the arms

1. Peled et al, NELIM 2022, Stein-Thoerings, Stein-Thoerings, Kusakabe et al, BBMT 2022

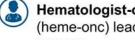
2. Subjects that are sampled at similar time points as SER-155 Phase 1b subjects; microbiome data produced using same protocols as SER-155 Phase 1b subjects

## Hematologist-oncologist leads care team and sets protocol for treating allo-**HSCT** patients

Diagnosis

Pre-transplant treatment

Hematopoietic stem cell transplant (HSCT)



Hematologist-oncologist (heme-onc) leads diagnosis process



Hematologist-oncologist makes treatment decisions and leads care team



**Pharmacist** 



Nursing



**Pathology** 



Hematologist-oncologist makes treatment decisions and leads expanded care team



Infectious disease



**Transplant support** 

· Blood tests

- · Bone marrow biopsy
- · Lumbar puncture
- · Chromosome and genetic analysis
- · Donor matching considerations begin
- · Induction chemotherapy
- · Consolidation and maintenance to maintain remission
- · Transplant for eligible patients
- · Conditioning regiments
- · Prophylactic regimens to prevent complications
- · Treating complications



Sources: Seres primary market research 2024; American Cancer Society; Mayo Clinic; EBMT Handbook: HSCT and Cellular Therapies 2019

Key procedures

Key providers

## Viral prophylaxis provides precedent in medically vulnerable patients

Prevymis - increasingly used for viral infection prophylaxis (e.g., allo-HSCT and solid organ transplant populations)



\$605M '23 WW sales

- · Reduces CMV infection in allo-HSCT recipients

· Lowers mortality rate

- Overall cost of allo-HSCT is high (~\$400K US year 1 allo-HSCT costs)
- Transplant-related complications (e.g., infections) raise cost by ~\$180K
- Infections result in longer hospital stays, readmissions, increased ICU utilization



## HCPs see SER-155 as a potentially transformative means to eliminate complications that get in the way of achieving transplant success

**Primary Value Driver for SER-155** 

Reducing the risk of HSCT-related complications, thus ensuring successful engraftment and long-term health of the patient

A relative risk reduction of 50% in BSIs is seen as "transformative" and would support broad inclusion in standard protocols for allo-HSCT patients



#### **Health Care Providers**

Streamlines the transplant process so they can spend more time treating the patient's underlying conditions and less time dealing with potential morbidities



#### **Patients**

One less thing to worry about for patients already dealing with a lot; additional financial and QoL benefits due to shortened hospital stays



#### **Healthcare System**

Reduced healthcare costs due to shorter hospital stays, fewer ICU visits, fewer antibiotic days and lower incidence of severe negative outcomes



The benefit would be massive because people die from these infections and so preventing them, the biggest benefit is mortality. The rest of the stuff with ICU admits and sepsis protocols and all...I think some of that also gets averted. That would be huge."



"This would probably be standard of care. It would be all eligible patients minus those who cannot tolerate it or are allergic."



Seres Therapeutics, Inc. © 2024

Source: Seres primary market research 2024

# SER-155 has blockbuster commercial potential, driven by poor standard of care and a robust SER-155 profile

- ✓ High unmet need to prevent frequent and serious infections
- √ ~40K annual transplants worldwide; 3% annual growth from aging population and transplant success rates
- ✓ Costly procedure (~\$400K US year 1 allo-HSCT per patient cost) with high incremental costs of infections (incremental ~\$180K/patient)
- ✓ SER-155 has potentially "transformational" profile with robust efficacy and safety
- Highly concentrated universe of procedures allows efficient commercial model with rapid education on new standard of care



## Accelerating SER-155 clinical development with positive Ph1b outcomes

Aim to accelerate SER-155 development in allo-HSCT

 Potential to follow successful precedent from VOWST development with single registrational study for efficacy

## Engage with FDA on advancement of SER-155 allo-HSCT program

- Filed for Breakthrough Therapy and Qualified Infections Disease Product designations
- · Expect to receive feedback by end of 2024

Intend to evaluate SER-155 in **additional patient populations** with high risk of serious bacterial infections

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



# Anticipated SER-155 expansion in biologically adjacent populations

Population	Transplants / diagnoses per year (US + EU)			
Autologous HSCT	~30K			
Blood cancers with high neutropenia rates (acute myeloid leukemia, multiple myeloma, B cell non-Hodgkin's lymphomas)	~190K			

Potential to initiate multiple clinical studies within the next 12-18 months with sufficient financing



## Advancing SER-147 to prevent infections in chronic liver disease patients

### Substantial unmet need

## 0.5M

2.1M



~50%

experience bacterial infections in a 6 month period

~20-25%

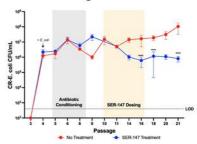
of infections are spontaneous bacterial peritonitis (SBP) and bloodstream infections likely to be gut-seeded

### Promising preclinical data

SER-147 is an investigational live oral biotherapeutic designed to reduce pathogens causing gut-seeded SBP and BSIs in liver disease patients

Declining E. coli titers

Example: 1-3 log reduction of *E. coli* in *in vitro* models, plus reduction of other pathogens



Sources: GBD 2017 Cirrhosis Collaborators, Lancet Gastroenterology & Hepatology 2020; United Nations world population data; Trebicka et al, J Hepatol 2020; Seres preclinical data from 2023 IDWeek



# Manufacturing platform delivers defined consortia in oral formulation using cost-effective production



**Strain isolation and characterization pipeline** to rapidly identify cGMP-suitable medium components

Highly intensive *strain bioprocessing* leveraging flexible, single-use manufacturing technology for cost-effective production

**Novel formulations** enabling consistent drug product composition, drug stability for distribution, and targeted drug delivery



**Quality systems** to ensure product quality and stability, extending prior regulatory successes, including developing product release specifications with the FDA



## Maximizing opportunity going forward

Additional Opportunities

**Prevent life-threatening infections** in additional populations **Treat immune-related diseases** (e.g., IBD, GvHD, checkpoint colitis, radiation enteritis)

**SER-147** 

**Chronic liver disease**: Progressing towards IND readiness **Indication expansion** (e.g., ICU and long-term care patients, organ transplant)

**SER-155** 

**Allo-HSCT**: Engaging with FDA to accelerate; filed for Breakthrough Therapy and Qualified Infectious Disease Product designations

Evaluate in additional populations with high risk of serious bacterial infections

**VOWST** 

rCDI: Proven clinical and regulatory success; asset sale to Nestlé; Seres to participate in future milestones



## Summary and path forward

## Developing a pipeline of novel live biotherapeutics in areas of high unmet need

- · SER-155 Phase 1b placebo-controlled clinical efficacy data further support Seres' strategy
- Pipeline aims to bring transformative medicines to a wider set of patients, led by SER-155 while advancing SER-147
- VOWST approval validates using live biotherapeutics to prevent life-threatening infections

### SER-155 Phase 1b placebo-controlled clinical results promising

- SER-155 administration associated with 77% relative risk reduction for bloodstream infections
- SER-155 administration associated with significant reduction in systemic antibiotic exposure and lower incidence of febrile neutropenia as compared to placebo through day 100 post HSCT
- SER-155 demonstrated generally well tolerated safety profile and confirmed drug bacteria strain engraftment
- Company is pursuing SER-155 strategic partnership to accelerate next study in allo-HSCT and expand to multiple target populations

### VOWST asset sale strengthens financial position

- \$66.8M in cash at end Q3 2024; cash runway projected into Q4 2025
- · Fully retired outstanding debt
- VOWST asset sale closed in September; received \$175M at closing less an ~\$20M settlement of net obligations, and \$75M (less ~\$1.5M in employment-related payments) in installment payments due in 2025 + \$275M potential future milestones

