

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2025

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number: 001-37465

**Seres Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)  
**101 Cambridgepark Drive**  
**Cambridge, MA**  
(Address of principal executive offices)

**27-4326290**  
(I.R.S. Employer  
Identification No.)

**02140**  
(Zip Code)

**(617) 945-9626**

(Registrant's telephone number, including area code)

Not Applicable  
(Former name, former address and former fiscal year, if changed since last report)

Securities 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	MCRB	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of May 2, 2025, the registrant had 8,732,422 shares of common stock, \$0.001 par value per share, outstanding.

Seres Therapeutics, Inc.

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## FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or the Quarterly Report, contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this Quarterly Report, including without limitation statements regarding our future results of operations and financial position including projected cash runway, requirement for additional funding, business strategy, including potential strategic partnership efforts, ability to recognize the benefits of the Transaction (as defined herein), including the Second Installment Payment (as defined herein) and Transaction Consideration (as defined herein), prospective products, the timing and results of our clinical studies and data readouts, product approvals, communications with, feedback from, or submissions to the FDA, research and development costs, timing and likelihood of success, our ability to continue as a going concern, our ability to maintain compliance with any applicable Nasdaq listing requirements, or the timing of any of the foregoing, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements 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.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this report and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the risks, uncertainties and assumptions described under the sections in this report titled “Summary Risk Factors,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Quarterly Report.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

You should read this Quarterly Report and the documents that we reference in this Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

## TRADEMARKS, SERVICE MARKS AND TRADENAMES

We have proprietary rights to trademarks used in this Quarterly Report, which are important to our business and many of which are registered under applicable intellectual property laws. Solely for convenience, the trademarks, service marks, logos and trade names referred to in this Quarterly Report are without the ® and ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights to these trademarks, service marks and trade names. This Quarterly Report contains additional trademarks, service marks and trade names of others, which are the property of their respective owners. All trademarks, service marks and trade names appearing in this Quarterly Report are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies’ trademarks, service marks, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

## SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part II, Item 1A. “Risk Factors” in this Quarterly Report. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include the following:

- We will need additional funding in order to advance development of our product candidates (including to complete the planned Phase 2 study of SER-155 in allo-HSCT) and commercialize our product candidates, if approved. If we are unable to raise capital or secure a partnership, we could be forced to delay, reduce or eliminate our product development programs or any potential future commercialization efforts.
- We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern.

- We are a clinical-stage company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- The total amount of the Second Installment Payment (as defined herein) and Milestone Payments (as defined herein) we may receive from the Transaction (as defined herein), and the amounts payable or due under the Profit Sharing Payments (as defined herein), are subject to various risks and uncertainties.
- We may not be able to realize the anticipated benefits of the Transaction (as defined herein), and we may face new challenges as a smaller, less diversified company.
- Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We are early in our development efforts of our product candidates and may not be successful in our efforts to use our reverse translational platform to build a pipeline of product candidates and develop additional marketable drugs.
- Our product candidates are based on live biotherapeutics, which is a novel approach to therapeutic intervention.
- Clinical drug development involves a risky, lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and any potential future commercialization of our product candidates.
- Delays or difficulties in the enrollment of patients in clinical trials, could result in our receipt of necessary regulatory approvals being delayed or prevented.
- Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or any collaborators will not be able to commercialize our product candidates or will not be able to do so as soon as anticipated, and our ability to generate revenue will be materially impaired. Additionally, failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.
- We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.
- Even if any of our product candidates receive marketing approval, such product candidates may fail to achieve the degree of market acceptance by physicians, patients, hospitals, third-party payors and others in the medical community necessary for commercial success.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- If we are unable to adequately protect our proprietary technology or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- Our recent reverse stock split may not result in the market price per share of our common stock to either exceed or remain in excess of the \$1.00 minimum bid price as required by Nasdaq, or have any of its other anticipated impacts, and we may be unable to satisfy or maintain other Nasdaq continued listing rules.

**PART I – FINANCIAL INFORMATION**

**Item 1. Condensed Consolidated Financial Statements (unaudited)**

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

	March 31, 2025	December 31, 2024
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 58,849	\$ 30,793
Accounts receivable due from SPN - related party	2,761	2,068
Prepaid expenses and other current assets (1)	4,468	5,813
Total current assets	66,078	38,674
Property and equipment, net	10,547	11,534
Operating lease assets	78,858	80,903
Restricted cash	8,668	8,668
Other non-current assets	31	31
Total assets	<u>\$ 164,182</u>	<u>\$ 139,810</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,168	\$ 4,079
Accrued expenses and other current liabilities	6,220	10,719
Accrued liabilities due to SPN - related party	13,886	17,750
Operating lease liabilities	9,049	8,674
Total current liabilities	31,323	41,222
Operating lease liabilities, net of current portion	80,499	82,966
Other long-term liabilities	1,895	1,838
Total liabilities	<u>113,717</u>	<u>126,026</u>
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at March 31, 2025 and December 31, 2024; no shares issued and outstanding at March 31, 2025 and December 31, 2024	—	—
Common stock, \$0.001 par value; 360,000,000 shares authorized at March 31, 2025 and December 31, 2024; 8,732,187 and 8,650,227 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	9	9
Additional paid-in capital	995,873	991,874
Accumulated other comprehensive loss	—	—
Accumulated deficit	(945,417)	(978,099)
Total stockholders' equity	<u>50,465</u>	<u>13,784</u>
Total liabilities and stockholders' equity	<u>\$ 164,182</u>	<u>\$ 139,810</u>

<sup>(1)</sup> Includes \$1,622 as of March 31, 2025 and \$2,683 as of December 31, 2024 of unbilled receivable from SPN (related party) related to certain costs of the transition services performed by the Company. See Note 3, *Discontinued Operations and TSA*, for further details.

*The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.*

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

	Three Months Ended March 31,	
	2025	2024
Operating expenses:		
Research and development expenses	\$ 11,821	\$ 19,494
General and administrative expenses	11,888	14,944
Manufacturing services	3,527	—
Total operating expenses	<u>27,236</u>	<u>34,438</u>
Loss from operations	<u>(27,236)</u>	<u>(34,438)</u>
Other income (expense):		
Gain on sale of VOWST Business	52,181	—
Interest income	618	1,648
Interest expense	—	(618)
Other income (2)	7,119	505
Total other income, net	<u>59,918</u>	<u>1,535</u>
Net income (loss) from continuing operations	<u>\$ 32,682</u>	<u>\$ (32,903)</u>
Net (loss) from discontinued operations, net of tax	<u>\$ —</u>	<u>\$ (7,230)</u>
Net income (loss) and comprehensive income (loss)	<u>\$ 32,682</u>	<u>\$ (40,133)</u>
Net income (loss) from continuing operations per share attributable to common stockholders - basic	\$ 3.76	\$ (4.50)
Net (loss) from discontinued operations per share attributable to common stockholders - basic	\$ —	\$ (0.99)
Net income (loss) per share attributable to common stockholders - basic	\$ 3.76	\$ (5.49)
Net income (loss) from continuing operations per share attributable to common stockholders - diluted	\$ 3.75	\$ (4.50)
Net (loss) from discontinued operations per share attributable to common stockholders - diluted	\$ —	\$ (0.99)
Net income (loss) per share attributable to common stockholders - diluted	\$ 3.75	\$ (5.49)
Weighted average common shares outstanding - basic	8,703,221	7,305,026
Weighted average common shares outstanding - diluted	8,714,701	7,305,026

<sup>[2]</sup> Includes \$6,309 for the three months ended March 31, 2025 related to reimbursement received from SPN (related party) for transition services provided by the Company.

*The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.*

**SERES THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
(unaudited, in thousands, except share data)

	<u>Common Stock</u>		Additional Paid-in Capital	Accumulated Other Comprehen- sive Loss (Income)	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Par Value				
<b>Balance at December 31, 2024</b>	8,650,227	\$ 9	\$ 991,874	\$ —	\$ (978,099)	\$ 13,784
Issuance of common stock upon vesting of RSUs and PSUs, net of tax withholdings	12,966	—	—	—	—	—
Issuance of common stock under ESPP	14,188	—	184	—	—	184
Issuance of common stock from at the market equity offering, net of issuance costs of \$26	54,806	—	996	—	—	996
Stock-based compensation expense	—	—	2,819	—	—	2,819
Net income	—	—	—	—	32,682	32,682
<b>Balance at March 31, 2025</b>	8,732,187	\$ 9	\$ 995,873	\$ —	\$ (945,417)	\$ 50,465

	<u>Common Stock</u>		Additional Paid-in Capital	Accumulated Other Comprehen- sive Loss (Income)	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Par Value				
<b>Balance at December 31, 2023</b>	6,752,073	\$ 7	\$ 933,372	\$ —	\$ (978,235)	\$ (44,856)
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—
Issuance of common stock upon vesting of RSUs and PSUs, net of tax withholdings	30,440	—	—	—	—	—
Issuance of common stock under ESPP	21,198	—	353	—	—	353
Issuance of common stock from at the market equity offering, net of issuance costs of \$548	768,331	1	18,408	—	—	18,409
Stock-based compensation expense	—	—	6,489	—	—	6,489
Net loss	—	—	—	—	(40,133)	(40,133)
<b>Balance at March 31, 2024</b>	7,572,042	\$ 8	\$ 958,622	\$ —	\$ (1,018,368)	\$ (59,738)

*The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.*

**SERES THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(unaudited, in thousands)

	Three Months Ended March 31,	
	2025	2024
<b>Cash flows from operating activities:</b>		
Net income (loss)	\$ 32,682	\$ (40,133)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation expense	2,819	6,489
Depreciation and amortization expense	1,076	1,559
Non-cash operating lease cost	2,045	2,393
Amortization of debt issuance costs	—	465
Loss on disposal of fixed assets	—	293
Impairment of long-lived assets	—	3,267
Change in fair value of warrant liabilities	—	(416)
Changes in operating assets and liabilities:		
Accounts receivable due from SPN - related party	(693)	—
Prepaid expenses and other current and other non-current assets	1,345	4,406
Collaboration receivable - related party	—	1,256
Inventories	—	(12,326)
Deferred income - related party	—	379
Accounts payable	(1,966)	1,594
Accrued liabilities due to SPN - related party	(3,864)	—
Operating lease liabilities	(2,092)	(218)
Accrued expenses and other current and long-term liabilities	(4,442)	(4,244)
Net cash provided by (used in) operating activities	<u>26,910</u>	<u>(35,236)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(34)	(62)
Net cash used in investing activities	<u>(34)</u>	<u>(62)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from at the market equity offering, net of issuance costs	996	18,409
Issuance of common stock under ESPP	184	353
Net cash provided by financing activities	<u>1,180</u>	<u>18,762</u>
<b>Net increase (decrease) in cash, cash equivalents, and restricted cash</b>	<b>28,056</b>	<b>(16,536)</b>
Cash, cash equivalents and restricted cash at beginning of period	39,461	136,150
Cash, cash equivalents and restricted cash at end of period	<u>\$ 67,517</u>	<u>\$ 119,614</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ —	\$ 3,580
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Property and equipment purchases included in accounts payable and accrued expenses	\$ 55	\$ —

*The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.*

**SERES THERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(Amounts in thousands, except share and per share data)**  
**(Unaudited)**

**1. Nature of the Business and Basis of Presentation**

Seres Therapeutics, Inc. (the “Company”) was incorporated under the laws of the State of Delaware in October 2010 under the name Newco LS21, Inc. In October 2011, the Company changed its name to Seres Health, Inc., and in May 2015, the Company changed its name to Seres Therapeutics, Inc. The Company is a clinical-stage company focused on improving patient outcomes in medically vulnerable populations through novel live biotherapeutics. The Company led the successful development and approval of VOWST (previously referred to as SER-109), the first FDA-approved orally administered microbiome therapeutic, which was sold to Nestlé Health Science (as defined below) in September 2024. The Company is progressing the development of SER-155, an investigational, oral, live biotherapeutic designed to decolonize gastrointestinal (“GI”) pathogens, improve GI epithelial barrier integrity, and induce immune homeostasis to prevent bacterial bloodstream infections (“BSIs”), including those that can harbor antimicrobial resistance (“AMR”), as well as other pathogen-associated negative clinical outcomes in patients undergoing allogeneic hematopoietic stem cell transplantation (“allo-HSCT”). The Company also continues to develop another proprietary live biotherapeutic composition, SER-147, designed to prevent bacterial bloodstream and spontaneous bacterial peritonitis infections in patients with metabolic disease, including chronic liver disease. 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 the Company's placebo-controlled Phase 1b study of SER-155 in allo-HSCT, Cohort 2 results demonstrated that SER-155 was associated with a 77% relative risk reduction in bacterial BSIs and a significant reduction in systemic antibiotic exposure as well as a lower incidence of febrile neutropenia, as compared to placebo through day 100 post hematopoietic stem cell transplantation (“HSCT”). SER-155 was generally well tolerated, with no observed treatment-related serious adverse events. In addition to allo-HSCT, the Company is exploring the potential of SER-155 and other cultivated live biotherapeutic candidates in other medically vulnerable patient populations, including autologous-HSCT patients, cancer patients with neutropenia, chimeric antigen receptors therapy recipients, individuals with chronic liver disease, solid organ transplant recipients, as well as patients in the intensive care unit and long-term acute care facilities.

The Company has built and deploys a reverse translational platform and knowledge base for the discovery and development of live biotherapeutics, and maintains extensive proprietary know-how that may be used to support future research and development efforts. This platform incorporates high-resolution analysis of human clinical data to identify microbiome biomarkers associated with disease and non-disease states; preclinical screening using human cell-based assays and in vitro/ex vivo and in vivo disease models customized for live biotherapeutics; and microbiological capabilities and a strain library that spans broad biological and functional breadth to both identify specific microbes and microbial metabolites that are associated with disease and to design consortia of bacteria with specific pharmacological properties. In addition, the Company owns a valuable intellectual property estate related to the development and manufacture of live biotherapeutics.

At a special meeting of stockholders held on September 26, 2024, the Company's stockholders approved, and on September 30, 2024 (the “Closing Date”), the Company completed, the sale (the “Transaction”) of its VOWST microbiome therapeutic business (the “VOWST Business”), including inventory and equipment, certain patents and patent applications, know-how, trade secrets, trademarks, domain names, marketing authorizations and related rights, documents, materials, business records and data and contracts that are used or held for use primarily in the development, commercialization and manufacturing of the microbiome product sold under the brand name VOWST as provided for in accordance with the terms of the Purchase Agreement (the “Product”), to Société des Produits Nestlé S.A. (“SPN”), a wholly-owned subsidiary of Nestlé S.A., and its designated affiliates (collectively, “Nestlé Health Science”) pursuant to the Asset Purchase Agreement, dated as of August 5, 2024 (the “Purchase Agreement”), by and among the Company and SPN, and a wholly-owned subsidiary of Nestlé S.A. As consideration for the Transaction, SPN paid or agreed to pay, as applicable, the following Transaction Consideration:

- (i) a cash payment, which was paid upon completion of the Transaction (“Closing”), of \$100,000, less approximately \$17,857 owed by the Company to an affiliate of SPN as of March 31, 2024 under the prior license agreement between the Company and the SPN affiliate, less approximately CHF 2,000 in satisfaction of fees due under the Bacthera Manufacturing Agreement (defined below);
- (ii) cash installment payments of \$50,000, which was received on January 15, 2025 and \$25,000 due on July 1, 2025 (the “Installment Payments”) (to be reduced by approximately \$1,500 related to certain employment obligations assumed by SPN, as described below), conditioned on the Company's material compliance with obligations under the Transition Services Agreement (the “TSA”) (as described below) entered into at Closing between the Company and Nestlé Enterprises S.A., an affiliate of SPN, or NESA;

- (iii) prepayment of the \$60,000 milestone payment tied to the achievement of worldwide annual net sales of the Product of \$150,000 (the “First Sales Milestone”), which was paid in cash at Closing (the “Prepaid Milestone”), which Prepaid Milestone will accrue interest at a fixed rate of 10% per annum until the First Sales Milestone is achieved and 5% per annum thereafter until the earlier of (x) the date on which the Prepaid Milestone, plus accrued interest thereon, has been repaid in full by set-off and (y) the last day of the Milestone Period (as defined below); and
- (iv) future milestone payments of (x) \$125,000 tied to the achievement of worldwide annual net sales of the Product of \$400,000 and (y) \$150,000 tied to the achievement of worldwide annual net sales of the Product of \$750,000, during the period from Closing until December 31 of the calendar year in which the tenth anniversary of Closing occurs (the “Milestone Period”) (together, the “Future Milestone Payments” and, together with the Prepaid Milestone, the “Milestone Payments”).

As they are earned, the Milestone Payments will be satisfied as follows: (i) first, by set-off against all accrued interest on the Prepaid Milestone until the amount of such accrued interest has been paid in full, (ii) second, by set-off against the outstanding balance of the Prepaid Milestone until the Prepaid Milestone has been repaid in full and (iii) thereafter, in cash. If any amount of the Prepaid Milestone (and any accrued interest thereon) remains outstanding as of following the last day of the Milestone Period (defined below), the balance thereof (together with any interest accrued thereon) will be forgiven and the right of set-off of SPN with respect thereto will be deemed forfeited. The Installment Payment due on July 1, 2025 (the “Second Installment Payment”) will be reduced by approximately \$1,500 related to certain employment obligations assumed by SPN with respect to the period ended as of the Closing Date.

The Company and SPN share 50/50 in the net profit or net loss (the “Profit Sharing Payments”) achieved during the period from the date of Closing until December 31, 2025 (the “Profit Sharing Period”), with the net profit or net loss calculated as (i) the net sales of VOWST in the United States and Canada, plus (ii) other income received in connection with the grant of a license or sublicense with respect to VOWST in the United States and Canada as described in the Purchase Agreement, minus (iii) allowable expenses directly attributable or reasonably allocable to certain development activities, commercialization activities, medical affairs activities, manufacturing activities or other relevant activities, as described in the Purchase Agreement. During the Profit Sharing Period, the Company will reimburse SPN for (i) certain payments under the exclusive license agreement between the Company and Memorial Sloan Kettering Cancer Center, (ii) certain costs incurred in connection with an ongoing post-marketing safety study of VOWST and (iii) 80.1% of all rent and other costs due to the landlord under the lease for the Company’s Waltham facility.

At Closing, in exchange for a payment to be made by SPN to Bacthera AG, the Long Term Manufacturing Agreement, dated November 8, 2021 between the Company and Bacthera AG (the “Bacthera Manufacturing Agreement”) was terminated and each of Bacthera and Seres released one another from any and all losses, liabilities or other obligations arising thereunder with respect to the period ending at the Closing Date, including without limitation any milestone payments required to be paid to Bacthera thereunder.

On the Closing Date, the Company and SPN entered into a securities purchase agreement (the “Securities Purchase Agreement”) pursuant to which SPN purchased 714,285 shares (the “Shares”) of common stock at Closing, at a purchase price per share of \$21.00, for an aggregate purchase price of \$15,000. Under the terms of the Securities Purchase Agreement, SPN agreed not to sell or transfer the Shares for a period of six months after Closing, subject to certain customary exceptions. The Company agreed to register the resale of the Shares by SPN within 90 days of Closing. On October 1, 2024, the Company filed a registration statement to register the Shares, which became effective on October 11, 2024. In addition, under the terms of the Securities Purchase Agreement, for as long as SPN, together with its affiliates, beneficially owns at least 10% of the Company’s outstanding shares of common stock, the Company has agreed to take such action within its control to include one individual designated by SPN in the slate of nominees recommended by the Company’s board of directors (or the applicable committee of the board of directors) to the Company’s stockholders for election to the board of directors at the applicable stockholder meeting. SPN designated Hans-Juergen Woerle, M.D., Ph.D. and on February 4, 2025, the Company’s board of directors appointed Dr. Woerle to the board as a Class III director, with a term expiring at the Company’s 2027 annual meeting of stockholders. The Securities Purchase Agreement contains customary representations and warranties and closing conditions.

On the Closing Date, the Company entered into a TSA with NESAs, which provides for services to be performed by the Company in order to facilitate a transition of the business associated with the VOWST Business to NESAs and its affiliates. The scope of the transition services includes the provision of certain manufacturing services and certain administrative functions related to the VOWST Business and operations, including the maintenance of certain manufacturing services and the related facility in which such services are currently conducted. The Company will provide the manufacturing services until December 31, 2025, which period may be extended by up to six months (solely to ensure the manufacturing facility is in a state of compliance with the biologics license application for VOWST and readiness for potential regulatory inspection), and other services for the duration specified in the schedule to the TSA for each service. NESAs has agreed to pay the Company for certain fixed costs, including a monthly fixed fee and a variable per batch fee for preserved raw material suspension (“PRMS”) manufacturing, and will reimburse the Company for certain costs of the transition services performed by the Company under the TSA, including labor. The know-how and other intellectual property generated in connection with the performance of the TSA will be owned by NESAs with the Company having a non-exclusive license to such know-how and other intellectual property under the Cross-License Agreement. During the term of the TSA, upon

NESA's request, the Company will transfer the specifications for materials and documentation necessary to enable PRMS manufacturing services to a third party service provider designated by NESA. In the event of a material failure by the Company to deliver PRMS under the TSA, NESA will have step-in rights to negotiate to enter into a direct lease with the landlord of the manufacturing facility with respect to the portion of such facility used in connection with the VOWST Business or to cause such services to be performed, with any reasonable out-of-pocket costs and expenses incurred in connection therewith reimbursed by the Company.

At the Closing Date, the Company entered into a cross-license agreement with SPN under which the Company granted to SPN a perpetual, worldwide, non-exclusive, fully paid-up license under certain Company patents that have been issued or will issue in the future and current know-how controlled by the Company that is not transferred to SPN pursuant to the Purchase Agreement. In the field of the treatment of *Clostridioides difficile* infections ("CDI") and recurrent CDI and associated complications (collectively, the "CDI Field") the license to SPN under such Company patents and know-how will be exclusive to SPN for five years after Closing and co-exclusive between SPN and the Company following that five year period. The license from the Company to SPN is to issued Company patents that currently or in the future cover the Product or improvements thereof, and know-how that is used or reasonably useful in connection with the exploitation of the VOWST Business. The Company also granted SPN an exclusive, perpetual, worldwide, fully paid-up license under issued Company patents that currently or in the future cover the Product and improvements thereof and know-how that is used or reasonably useful in connection with the exploitation of the Product to exploit SER-262 in the CDI Field. SPN granted to the Company a perpetual, worldwide, non-exclusive license under the patents and know-how that are transferred to SPN pursuant to the Purchase Agreement or developed under the TSA, for the Company's products for use outside of the CDI Field, and after five years from Closing for Company products containing designed, cultivated, bacterial consortia not manufactured using human stool (excluding SER-262) in the CDI Field. From and after Closing, certain license agreements between the Company, SPN, and/or their respective affiliates terminated and are of no further force or effect, except as contemplated by the Purchase Agreement. For example, on September 30, 2024, in connection with the Transaction, the 2016 License Agreement (the "2016 License Agreement") with Nestec, Ltd., as succeeded by SPN (together with NHSc Rx License GmbH, their affiliates, and their subsidiaries "Nestlé"), and the 2021 License Agreement (the "2021 License Agreement") with NHSc Pharma Partners, succeeded by NHSc Rx License GmbH (together with Société des Produits Nestlé S.A, their affiliates, and their subsidiaries "Nestlé") were terminated upon mutual agreement of the parties, with provisions related to record retention, confidentiality obligations, indemnification obligations, intellectual property ownership, and any outstanding payment obligations surviving the termination of each of the 2016 License Agreement and 2021 License Agreement, respectively.

On the Closing Date, the parties entered into assignment and assumption of lease agreements (the "Assignment and Assumption Agreements"). Under the Assignment and Assumption Agreements, the Company assigned to SPN the Company's rights in, to and under certain real property leases, and SPN assumed the liabilities related thereto.

On the Closing Date, the parties entered into an employee support agreement (the "Employee Support Agreement"). Under the Employee Support Agreement, among other things and subject to the terms and conditions therein, certain employees of the Company related to the VOWST Business who accepted employment with SPN or one of its designated affiliates provided the services they provided to the Company prior to the Transaction to SPN, as well as other services as SPN may reasonably request, from Closing until the day prior to the beginning of SPN's or its designated affiliate's next pay period following the Closing. SPN reimbursed the Company's out of pocket costs in connection with such employees' services, including certain compensation and benefits paid or provided to such employees pursuant to the terms of the Employee Support Agreement. All such employees have transferred to SPN as of December 31, 2024.

In connection with the Transaction, the Company fully retired its senior secured debt facility with Oaktree Capital Management. The Company intends to use the remaining proceeds to support the further advancement of SER-155 and the Company's other wholly-owned cultivated live biotherapeutic candidates for medically vulnerable patient populations with potential to address large commercial opportunities.

### **Going Concern**

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

The accompanying condensed consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. As of March 31, 2025, the Company had an accumulated deficit of \$945,417 and cash and cash equivalents of \$58,849.

The Company's product candidates are in development, and will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to potential commercialization. There can be no

assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, or maintained, that any product candidate developed will obtain necessary government regulatory approval, or that any approved product will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales.

Primarily as a result of the costs associated with continuing the research and development efforts for other product candidates and preclinical programs, the Company incurred a loss from operations of \$27,236 for the three months ended March 31, 2025. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future. Based on the Company's currently available cash resources, current and forecasted level of operations, and forecasted cash flows for the 12-month period subsequent to the date of issuance of these condensed consolidated financial statements, the Company will require additional funding to support its ongoing operations and meet its obligations as they come due. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent upon its ability to obtain the necessary financing to meet its obligations and repay its liabilities arising from normal business operations when they come due, and to generate profitable operations in the future. Management plans to provide for the Company's capital requirements through financing or other strategic transactions, including potential business development transactions, and selling shares under the Company's at the market equity offering. There can be no assurance that the Company will be able to raise additional capital to fund operations with terms acceptable to the Company, or at all. Because certain elements of management's plans to mitigate the conditions that raised substantial doubt about the Company's ability to continue as a going concern are outside of the Company's control, including the ability to raise capital through an equity or other financing, those elements cannot be considered probable according to Accounting Standards Codification ("ASC") 205-40, *Going Concern* ("ASC 205-40"), and therefore cannot be considered in the evaluation of mitigating factors. As a result, management has concluded that substantial doubt exists about the Company's ability to continue as a going concern for 12 months from the date these condensed consolidated financial statements are issued. The accompanying condensed consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty.

### ***Unaudited Interim Financial Information***

The accompanying unaudited condensed consolidated financial statements as of March 31, 2025 and for the three months ended March 31, 2025 and 2024 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2024 included in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2024, which was filed with the SEC on March 5, 2024 (the "Annual Report").

The unaudited condensed consolidated interim financial statements have been prepared on the same basis as the audited consolidated financial statements. The condensed consolidated balance sheet at December 31, 2024 was derived from audited annual financial statements, but does not contain all of the footnote disclosures from the annual financial statements. In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments which are necessary for a fair statement of the Company's financial position, results of operations, and cash flows for the periods presented. Such adjustments are of a normal and recurring nature. The results of operations for the three months ended March 31, 2025 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2025.

In late September 2024, the Company's VOWST Business met all the conditions to be classified as held for sale and, because the Company considers the disposal of the VOWST Business to be a strategic shift that will have a major effect on its operations and financial results, represented a discontinued operation. All assets and liabilities associated with the Company's VOWST Business were therefore classified as assets and liabilities of discontinued operations in the Company's condensed consolidated balance sheets for the historical periods presented prior to the sale of the VOWST Business. Further, all historical operating results for the Company's VOWST Business are reflected within discontinued operations in the condensed consolidated statements of operations for all periods presented. For additional information, see Note 3, *Discontinued Operations and TSA*.

Our condensed consolidated financial statements include our accounts and the accounts of our wholly owned subsidiaries. All intercompany transactions have been eliminated in consolidation. The condensed consolidated financial statements have been prepared in conformity with U.S. GAAP.

On April 21, 2025, we effected a 1-for-20 reverse stock split of our common stock. All share and per share amounts in the financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse stock split. The reverse stock split had no impact on the number of authorized shares or the par value of preferred and common stock. Therefore, the Company reclassified an amount equal to the reduction in the number of shares of common stock at par value to additional paid-in capital. No fractional shares were issued in connection with the reverse split, and stockholders who would otherwise

be entitled to receive a fractional share instead received a cash payment equal to the fraction of a share of common stock in lieu of such fractional share. Proportionate adjustments were made to the number of shares authorized under the Company's equity incentive plans, the number of shares subject to any award or purchase right under the Company's equity incentive plans, and the exercise price or purchase price with respect to any stock option award or purchase right under the Company's equity incentive plans. See Note 7, *Stockholders' Equity*, for further information.

### **Reclassifications**

Certain amounts in prior periods have been reclassified to reflect the impact of the discontinued operations treatment of the VOWST Business in order to conform to the current period presentation.

## **2. Summary of Significant Accounting Policies**

The significant accounting policies and estimates used in preparation of the unaudited condensed consolidated financial statements are described in the Company's audited financial statements as of and for the year ended December 31, 2024, and the notes thereto, which are included in the Annual Report. There have been no material changes to the Company's significant accounting policies during the three months ended March 31, 2025.

### **Use of Estimates**

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements and the reported amount of expenses during the reporting periods. In the unaudited condensed consolidated financial statements, the Company uses estimates and assumptions related to the accrual of research and development expenses. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from those estimates.

### **Restricted Cash**

The Company held restricted cash of \$8,668 as of March 31, 2025 and December 31, 2024, which represents cash held for the benefit of the landlords for certain of the Company's leases. The Company has classified the restricted cash as long-term on its condensed consolidated balance sheets as the terms of the underlying leases are greater than one year.

Cash, cash equivalents and restricted cash were comprised of the following (in thousands):

	March 31, 2025	December 31, 2024
Cash and cash equivalents	\$ 58,849	\$ 30,793
Restricted cash, non-current	8,668	8,668
Total cash, cash equivalents and restricted cash	<u>\$ 67,517</u>	<u>\$ 39,461</u>

### **Recently Issued Accounting Pronouncements**

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* which requires public entities to disclose specific categories in the effective tax rate reconciliation as well as expanded disclosures on income taxes paid by jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact related to the adoption of ASU 2023-09 on its financial statement disclosures.

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses (Topic 220)*, which requires disclosure in the notes to financial statements about specific types of expenses included in the expense captions presented on the face of the statement of operations. The requirements of the ASU are effective for annual periods beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with early adoption permitted. The requirements will be applied prospectively with the option for retrospective application. The Company is currently evaluating the impact related to the adoption of ASU 2024-03 on its financial statement disclosures.

## **3. Discontinued Operations and TSA**

On September 30, 2024, the Company completed the sale of its VOWST Business to SPN. The Company has determined the sale of the VOWST Business represents a strategic shift that will have a major effect on its business and therefore met the criteria for classification as discontinued operations on September 30, 2024. Accordingly, the VOWST Business is reported as discontinued operations in accordance with ASC 205-20, *Discontinued Operations*. The related assets and liabilities of the VOWST Business were classified as assets and liabilities of discontinued operations in the condensed consolidated balance sheets for the historical periods presented prior to the sale of the VOWST Business and the results of operations from the VOWST Business were classified as discontinued operations in the condensed consolidated statements of operations. Applicable amounts in prior years have been recast to

conform to this discontinued operations presentation. The Company recognized a gain on the sale of the VOWST Business upon closing.

The Company has also entered into a Transition Services Agreement with NESAs, an affiliate of SPN, in connection with the Transaction, through which the Company will provide certain manufacturing services until December 31, 2025, and other transition services, for the duration specified in the schedule to the TSA for each service. For the three months ended March 31, 2025, the Company recognized \$6,309 of TSA reimbursement income in other income in the Company's condensed consolidated statements of operations and comprehensive income (loss). For the three months ended March 31, 2025, the Company has incurred \$3,527 of expenses related to manufacturing services and \$2,248 of TSA labor and passthrough expenses to support the transition services, including finance and accounting, information technology, human resources, operations, and other services.

For the three months ended March 31, 2025, \$7,403 has been billed to NESAs related to transition services performed by the Company, and the Company received \$56,709 from NESAs during the period, which includes the first installment payment of \$50,000 received in January 2025 that was conditioned on the Company's material compliance with obligations under the TSA. The \$50,000 installment payment was recognized in Gain on sale of VOWST Business within continuing operations in the Company's condensed consolidated statements of operations and comprehensive income (loss) for the three months ended March 31, 2025 as the gain was realizable. As of March 31, 2025, the Company has \$2,761 in accounts receivable due from SPN - related party and \$1,622 unbilled receivable included in prepaid expenses and other current asset in the Company's condensed consolidated balance sheets.

The Company has estimated costs associated with certain accrued liabilities due to SPN - related party as a loss contingency in accordance with ASC 450, *Contingencies*. These contingent liabilities are presented as Accrued Liabilities due to SPN - related party from continuing operations on the condensed consolidated balance sheet as of March 31, 2025 and December 31, 2024 and consist of the following (in thousands):

	March 31, 2025	December 31, 2024
Profit Sharing Payments	\$ 8,008	\$ 11,230
Royalties associated with the MSK Agreement	2,788	2,786
VOWST post-marketing safety surveillance study	526	771
80.1% of lease cost of Waltham facility	1,128	1,501
Employment-related costs for conveying employees	1,436	1,462
Total accrued liabilities due to SPN - related party	<u>\$ 13,886</u>	<u>\$ 17,750</u>

The contingent liabilities accrued on the Company's condensed consolidated balance sheet are remeasured at each reporting period based on i) cash payments made by the Company to reduce the accrued liabilities due to SPN - related party and ii) revised estimates of the total remaining liabilities due to SPN - related party. For the three months ended March 31, 2025, the Company recognized a gain on sale of VOWST Business of \$2,181 as a result of the change in accrued liabilities due to SPN - related party.

The Company has excluded from its condensed consolidated balance sheets the effects of i) future fixed installment payments to be received by the Company after it performs services and is determined by SPN to be in material compliance with the terms and conditions of the TSA and ii) certain milestone payments received by the Company after the Product has achieved net sales-based milestones. These contingent receivables will be recognized as a gain contingency, in accordance with ASC 450, *Contingencies*, in continuing operations in the period when the contingencies are resolved.

The cash flows related to discontinued operations have not been segregated and are included in the condensed consolidated statements of cash flows. There were no cash flows related to discontinued operations for the three months ended March 31, 2025. For the three months ended March 31, 2024, capital expenditures related to the VOWST Business were \$59. Depreciation expense related to the VOWST Business for the same period was \$328. Non-cash operating lease costs related to the VOWST Business for the three months ended March 31, 2024 were \$476, while the share based compensation expense for the same period was \$703. There were no other material operating or investing non-cash items related to the VOWST Business for either period presented in the condensed consolidated statements of cash flows for the three months ended March 31, 2025 and 2024.

#### 4. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	March 31, 2025	December 31, 2024
Laboratory equipment	\$ 24,548	\$ 24,468
Computer equipment	3,924	3,924
Furniture and office equipment	4,524	4,523
Leasehold improvements	30,953	30,954
Construction in progress	870	861
	<u>64,819</u>	<u>64,730</u>
Less: Accumulated depreciation and amortization	(54,272)	(53,196)
	<u>\$ 10,547</u>	<u>\$ 11,534</u>

Depreciation and amortization expense was \$1,076 and \$1,559 for the three months ended March 31, 2025 and 2024, respectively. The expense for the three months ended March 31, 2024 includes amounts related to both continuing and discontinued operations. The Company did not dispose of any assets during the three months ended March 31, 2025. During the three months ended March 31, 2024, the Company disposed of certain assets with a cost basis of \$594. In addition, during the three months ended March 31, 2024, the Company recorded an impairment loss of \$1,536 related to leasehold improvements at one of the Company's locations for which impairment indicators were determined to exist as of March 31, 2024. See Note 6, *Leases*, for further details.

#### 5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	March 31, 2025	December 31, 2024
Clinical and development costs	\$ 507	\$ 422
Manufacturing and quality costs	188	478
Payroll and employee-related costs	2,892	7,656
Facility and other	2,633	2,163
	<u>\$ 6,220</u>	<u>\$ 10,719</u>

#### 6. Leases

The Company leases real estate, primarily laboratory, office and manufacturing space. The Company's leases have remaining terms ranging from approximately one to eight years. Certain leases include one or more options to renew, exercisable at the Company's sole discretion, with renewal terms that can extend the lease from approximately one year to ten years. The Company evaluated the renewal options in its leases to determine if it was reasonably certain that the renewal option would be exercised, given the Company's current business structure, uncertainty of future growth, and the associated impact to real estate, the Company concluded that it is not reasonably certain that any renewal options would be exercised. Therefore, the operating lease assets and operating lease liabilities only contemplate the initial lease terms. All the Company's leases qualify as operating leases.

In January 2024, the Company entered into a sublease agreement with an unrelated third party to sublease a portion of its office and laboratory space in Cambridge, Massachusetts. The term of the sublease agreement commenced in March 2024 and ends on January 13, 2030. The Company will receive lease payments over the sublease term totaling \$10,400. The sublessee is obligated to pay all real estate taxes and costs related to the subleased premises, including cost of operations, maintenance, repair, replacement and property management. Sublease income is recorded as Other income in the Company's condensed consolidated statements of operations and comprehensive income (loss).

During the three months ended March 31, 2024, the Company identified an indicator of impairment of its donor collection facility in Cambridge, Massachusetts, as the facility is no longer being used by the Company as a result of operational efficiencies implemented related to the production process and is being marketed for sublease. The Company determined that this represents a significant adverse change in the extent in which the long-lived asset was being used. The Company determined that the location contains multiple asset groups for the purpose of the long-lived asset impairment assessment. The Company concluded that the carrying value of each asset group was not recoverable as it exceeded the future net undiscounted cash flows that are expected to be generated from the assets within the asset group. In the first quarter of 2024, the Company recognized an impairment loss of \$3,267, consisting of \$1,731 on the operating lease right-of-use asset and \$1,536 on the leasehold improvements. \$2,727 of the total impairment loss is included in

research and development expenses and the remaining \$540 is included in general and administrative expenses in the accompanying condensed consolidated statements of operations and comprehensive income (loss).

The following table summarizes the presentation in the Company's condensed consolidated balance sheets of its operating leases (in thousands):

	March 31, 2025	December 31, 2024
<b>Assets:</b>		
Operating lease assets	\$ 78,858	\$ 80,903
<b>Liabilities:</b>		
Operating lease liabilities	\$ 9,049	\$ 8,674
Operating lease liabilities, net of current portion	80,499	82,966
Total operating lease liabilities	<u>\$ 89,548</u>	<u>\$ 91,640</u>

The following table summarizes the effect of lease costs in the Company's condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended March 31,	
	2025	2024
Operating lease costs	\$ 4,831	\$ 5,771
Short-term lease costs	—	374
Variable lease costs	1,242	1,967
Sublease income	(823)	(376)
Total lease costs	<u>\$ 5,250</u>	<u>\$ 7,736</u>

During the three months ended March 31, 2025 and 2024, the Company made cash payments for operating leases of \$4,878 and \$3,596, respectively. The lease cost and lease payment amounts above include amounts related to discontinued operations for the three months ended March 31, 2024.

As of March 31, 2025, future payments of operating lease liabilities are as follows (in thousands):

	As of March 31, 2025
2025 (remaining 9 months)	\$ 14,563
2026	19,983
2027	20,582
2028	20,863
2029	20,132
2030 and thereafter	36,850
Total future minimum lease payments	\$ 132,973
Less: interest	(43,425)
Present value of operating lease liabilities	<u>\$ 89,548</u>

As of March 31, 2025, the weighted average remaining lease term was 6.73 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 13%. As of March 31, 2024, the weighted average remaining lease term was 7.70 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 13%.

## 7. Common Stock and Stock-Based Awards

On April 10, 2025, at the Company's 2025 annual meeting of stockholders (the "2025 Annual Meeting"), stockholders approved an amendment to the Company's Restated Certificate of Incorporation in order to effect a reverse stock split of all outstanding shares of the Company's common stock. On April 21, 2025, the Company effected a 1-for-20 reverse stock split of its common stock. The reverse stock split had no impact on the number of authorized shares or the par value of preferred and common stock. As of the effective time of the reverse stock split, the number of shares of common stock issuable upon exercise, vesting or settlement of outstanding awards, the exercise price of all outstanding options and any stock price vesting goals with respect to any outstanding awards under the Company's equity plans (including the 2025 Plan, as defined below) was proportionately adjusted (and rounded down to the nearest whole share in the case of shares and up to the nearest whole cent in the case of exercise prices, as applicable) based on the 1-for-20 ratio. In addition, the number of shares available for future issuance and any share-based award

limits under the Company's equity plans were proportionately reduced based on the 1-for-20 ratio. Trading of the Company's common stock on The Nasdaq Global Select Market commenced on a split-adjusted basis on April 22, 2025.

Additionally, at the 2025 Annual Meeting, stockholders approved the Seres Therapeutics, Inc. 2025 Incentive Award Plan (the "2025 Plan") as an amendment and restatement of the Seres Therapeutics, Inc. 2015 Incentive Award Plan (the "2015 Plan"). The amendment, among other things, authorized the issuance of 2,230,243 shares of the Company's common stock for awards under the 2025 Plan, which includes 1,750,493 shares previously authorized for issuance under the 2015 Plan plus an increase of 479,750 shares (in each case, which amounts reflect the 1-for-20 reverse stock split), and extended the term of the 2025 Plan to March 3, 2035, the tenth anniversary of the approval of the 2025 Plan by the Company's board of directors.

On September 30, 2024, the Company entered into the Securities Purchase Agreement with SPN, pursuant to which SPN purchased 714,285 shares at the Closing at a purchase price per share of \$21.00, for an aggregate purchase price of \$15,000. Under the terms of the Securities Purchase Agreement, SPN has agreed not to sell or transfer the shares for a period of six months after Closing, subject to certain customary exceptions. The Company agreed to register the resale of the Shares by SPN within 90 days of Closing. On October 1, 2024, the Company filed a registration statement to register the Shares, which became effective on October 11, 2024. In addition, under the terms of the Securities Purchase Agreement, for as long as SPN, together with its affiliates, beneficially owns at least 10% of the Company's outstanding shares of common stock, the Company has agreed to take such action within its control to include one individual designated by SPN in the slate of nominees recommended by the Company's board of directors (or the applicable committee of the board) to the Company's stockholders for election to the board at the applicable stockholder meeting. The Securities Purchase Agreement contains customary representations and warranties and closing conditions. The aggregate fair value of \$13,516 for the common stock issued to SPN was recorded in equity, with the remaining \$1,484 cash received from SPN under the Securities Purchase Agreement allocated to the consideration transferred for the VOWST Business.

On May 21, 2021, the Company entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") to sell shares of the Company's common stock, with aggregate gross sales proceeds of up to \$150,000, from time to time, through an "at the market" equity offering program ("ATM") under which Cowen acts as sales agent. During the three months ended March 31, 2025, the Company sold 54,806 shares of common stock under the Sales Agreement, at an average price of approximately \$18.60 per share, raising aggregate net proceeds of approximately \$996 after deducting an aggregate commission of approximately 3% and other issuance costs. During the three months ended March 31, 2024, the Company sold 768,331 shares of common stock under the Sales Agreement, at an average price of approximately \$24.60 per share, raising aggregate net proceeds of approximately \$18,409 after deducting an aggregate commission of approximately 3% and other issuance costs.

### Stock Options

The following table summarizes the Company's stock option activity since December 31, 2024:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2024	886,123	\$ 129.29	6.59	\$ 87
Granted	477,431	\$ 15.65		
Exercised	—	\$ —		
Forfeited	(119,070)	\$ 95.46		
Outstanding as of March 31, 2025	<u>1,244,484</u>	\$ 88.93	7.37	\$ —
Vested or expected to vest as of March 31, 2025	<u>1,244,484</u>	\$ 88.93	7.37	\$ —
Options exercisable as of March 31, 2025	<u>495,252</u>	\$ 186.07	4.77	\$ —

The weighted average grant date fair value of stock options granted during the three months ended March 31, 2025 and 2024 was \$13.74 and \$19.03 per share, respectively.

During the three months ended March 31, 2024, the Company granted stock options to certain executives for the purchase of an aggregate of 127,500 shares of common stock. These awards will vest only to the extent that the 30-day trailing simple average public market closing price of the Company's common stock reaches certain price thresholds. These awards have an exercise price of \$22.00 and vest and become exercisable when the market conditions are satisfied or, if later, on the first anniversary of the grant date. These awards expire 10 years from the date of grant. The fair value of these market-based stock options was estimated using a Monte Carlo valuation method. During the three months ended March 31, 2025 and 2024, the Company recognized \$73 and \$142 of compensation expense related to these awards, respectively.

### **Restricted Stock Units**

The Company has granted restricted stock units with service-based vesting conditions (“RSUs”) and restricted stock units with performance-based vesting conditions (“PSUs”). RSUs and PSUs represent the right to receive shares of common stock upon meeting specified vesting requirements. Restricted stock units may not be sold or transferred by the holder and vest according to the vesting conditions of each award. The following table summarizes the Company’s RSU and PSU activity since December 31, 2024:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted stock units as of December 31, 2024	81,459	\$ 55.36
Granted	11,250	\$ 14.37
Vested	(12,966)	\$ 59.63
Forfeited	(3,266)	\$ 68.28
Unvested restricted stock units as of March 31, 2025	<u>76,477</u>	<u>\$ 48.05</u>

During the three months ended March 31, 2025 and 2024, the Company granted 11,250 and 64,058 RSUs, respectively. During the three months ended March 31, 2025 and 2024, the Company did not grant any PSUs. RSUs generally vest over four years, with 25% vesting after one year, and the remaining 75% vesting quarterly over the next 3 years, subject to continued service to the Company through the applicable vesting date. PSUs vest according to the performance requirements of the awards, generally when the Company has determined that the specified performance targets have been achieved.

During the three months ended March 31, 2023, the Company granted PSUs to employees for the purchase of an aggregate of 66,135 shares of common stock with a grant date fair value of \$110.00. These PSUs begin to vest ratably only upon achievement of specified performance targets, which were achieved in April 2023. Accordingly, the Company recorded \$260 in compensation expense during the three months ended March 31, 2024, with respect to these PSUs. The remaining compensation expense associated with these PSUs was fully recognized as of December 31, 2024.

### **Stock-based Compensation Expense**

The Company recorded stock-based compensation expense in the following expense categories of its condensed consolidated statements of operations and comprehensive income (loss) (in thousands):

	Three Months Ended March 31,	
	2025	2024
Research and development expenses	\$ 1,330	\$ 3,610
General and administrative expenses	1,489	2,879
	<u>\$ 2,819</u>	<u>\$ 6,489</u>

For the three months ended March 31, 2024, the table above includes stock-based compensation amounts related to discontinued operations.

## **8. Net Income (Loss) per Share**

Basic and diluted net income (loss) per share attributable to common stockholders was calculated as follows (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2025	2024
<b>Basic Earnings Per Share:</b>		
Numerator:		
Net income (loss) from continuing operations attributable to common stockholders	\$ 32,682	\$ (32,903)
Net loss from discontinuing operations attributable to common stockholders	\$ —	\$ (7,230)
Net income (loss) attributable to common stockholders - basic	\$ 32,682	\$ (40,133)
Denominator:		
Weighted-average shares outstanding - basic	8,703,221	7,305,026
Net income (loss) from continuing operations per share attributable to common stockholders - basic	\$ 3.76	\$ (4.50)
Net loss from discontinued operations per share attributable to common stockholders - basic	\$ —	\$ (0.99)
Net income (loss) per share attributable to common stockholders - basic	\$ 3.76	\$ (5.49)
<b>Diluted Earnings Per Share:</b>		
Numerator:		
Net income (loss) from continuing operations attributable to common stockholders	\$ 32,682	\$ (32,903)
Net loss from discontinuing operations attributable to common stockholders	\$ —	\$ (7,230)
Net income (loss) attributable to common stockholders - diluted	\$ 32,682	\$ (40,133)
Denominator:		
Weighted-average shares outstanding - basic	8,703,221	7,305,026
Dilutive impact from:		
Stock options to purchase common stock	—	—
Unvested restricted stock units	10,364	—
Shares issuable under employee stock purchase plan	1,116	—
Weighted-average shares outstanding - diluted	8,714,701	7,305,026
Net income (loss) per share applicable to common stockholders - diluted	\$ 3.75	\$ (4.50)
Net loss from discontinuing operations attributable to common stockholders - diluted	\$ —	\$ (0.99)
Net income (loss) attributable to common stockholders - diluted	\$ 3.75	\$ (5.49)
Anti-dilutive potential common stock equivalents excluded from the calculation of net income (loss) per share:		
Stock options to purchase common stock	1,244,484	957,735
Unvested restricted stock units	76,477	207,403
Shares issuable under employee stock purchase plan	4,229	3,774
Warrants to purchase common stock	32,379	58,871

The Company's potential dilutive securities include stock options, unvested restricted common stock and shares issuable under the 2015 Employee Stock Purchase Plan. The effect of dilutive securities was calculated using the treasury stock method. The anti-dilutive potential common stock equivalents for the three months ended March 31, 2025 were excluded from the computation of diluted net income per share attributable to common stockholders because those stock options to purchase common stock and restricted stock units had an anti-dilutive impact due to the assumed proceeds per share using the treasury stock method being greater than the average fair value of the Company's common shares for those periods. For that same period, the warrants to purchase common stock were excluded because the exercise price of the Tranche A Warrants is greater than the average fair value of the Company's common shares. The anti-dilutive potential common stock equivalents for the three months ended March 31, 2024 were excluded from the computation of diluted net loss per share attributable to common stockholders because those stock options to purchase common stock, restricted stock units, and shares issuable under employee stock purchase plan had an anti-dilutive impact as the Company reported a net loss attributable to common stockholders for those periods.

The Company utilizes the control number concept in the computation of diluted earnings per share to determine whether potential common stock equivalents are dilutive. The control number used is income (loss) from continuing operations. The control number concept requires that the same number of potentially dilutive securities applied in computing diluted earnings per share from continuing operations be applied to all other categories of income or loss, regardless of their anti-dilutive effect on such categories.

Since the Company had a net loss from continuing operations for all periods in which discontinued operations is presented, no dilutive effect has been recognized in the calculation of income from discontinued operations per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same for the three months ended March 31, 2024.

## **9. Commitments and Contingencies**

### ***Leases***

Refer to Note 6, Leases, for discussion of the commitments associated with the Company's lease portfolio.

### ***Indemnification Agreements***

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of March 31, 2025 or December 31, 2024.

### ***Legal Contingencies***

The Company accrues a liability for legal contingencies when it believes that it is both probable that a liability has been incurred and that the Company can reasonably estimate the amount of the loss. The Company reviews these accruals and adjusts them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and the views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in the Company's accrued liabilities would be recorded in the period in which such determination is made.

In addition, in accordance with the relevant authoritative guidance, for any matters in which the likelihood of material loss is at least reasonably possible, the Company will provide disclosure of the possible loss or range of loss. If a reasonable estimate cannot be made, however, the Company will provide disclosure to that effect. The Company expenses legal costs as they are incurred.

The Company did not accrue any liabilities related to legal contingencies in its consolidated financial statements as of March 31, 2025 or December 31, 2024.

## **10. Income taxes**

The Company did not provide for any income taxes in its condensed consolidated statement of operations and comprehensive income (loss) for the three months ended March 31, 2025 and 2024. While the Company has net income for the three months ended March 31, 2025, the Company is projecting book and tax losses for the full year ended December 31, 2025, for which it is more likely than not that the Company will not realize a benefit. Based on its evaluation of the positive and negative evidence bearing upon its ability to realize its deferred tax assets, the Company determined that it is more likely than not that it will not realize such benefits. Accordingly, the Company has recorded a full valuation allowance against its deferred tax assets as of March 31, 2025 and December 31, 2024, and has not recorded any income taxes for the three months ended March 31, 2025 and 2024. Management reevaluates the positive and negative evidence at each reporting period.

## **11. Related Party Transactions**

As described in Note 1, *Nature of the Business and Basis of Presentation* and Note 3, *Discontinued Operations and TSA*, in September 2024, the Company sold the VOWST Business, including inventory and equipment, certain patents and patent applications, know-how, trade secrets, trademarks, domain names, marketing authorizations and related rights, documents, materials, business records and data and contracts that are used or held for use primarily in the development, commercialization and manufacturing of VOWST, to SPN, and SPN assumed certain liabilities from the Company. As consideration for the Transaction, the Company received an upfront cash payment of \$139,788, which consists of \$100,000, less \$17,857 owed by the Company to an affiliate of SPN under the prior license agreement between the Company and the SPN affiliate, less approximately \$2,355 in satisfaction of fees due under the

Bacthera Manufacturing Agreement; plus a prepayment of the \$60,000 milestone payment tied to the achievement of worldwide annual net sales of VOWST of \$150,000; plus an equity investment of \$15,000 based on the Securities Purchase Agreement pursuant to which SPN purchased 714,285 shares of common stock at a purchase price of \$21.00 per share.

As of March 31, 2025, there was \$13,886 included in Accrued Liabilities due to SPN - related party on the Company's condensed consolidated balance sheet, which represents amounts due to SPN pursuant to the Purchase Agreement, which are further described in Note 3, *Discontinued Operations and TSA*. During the three months ended March 31, 2025, the Company paid \$1,309 to SPN related to the Purchase Agreement.

As described in Note 3, *Discontinued Operations and TSA*, the Company entered into the TSA with NESAs, an affiliate of SPN, in connection with the Transaction, through which the Company will provide certain manufacturing services until December 31, 2025, and other transition services, for the duration specified in the schedule to the TSA for each service. For the three months ended March 31, 2025, the Company recognized \$6,309 of TSA reimbursement income in other income in the Company's condensed consolidated statements of operations and comprehensive income (loss). For the three months ended March 31, 2025, the Company has incurred \$3,527 of expenses related to manufacturing services and \$2,248 of TSA labor and passthrough expenses to support the transition services, including finance and accounting, information technology, human resources, operations, and other services.

During the three months ended March 31, 2025, \$7,403 has been billed to NESAs related to transition services performed by the Company, and the Company received payments of \$56,709 related to transition services performed, which includes the first installment payment of \$50,000 received in January 2025 that was conditioned on the Company's material compliance with obligations under the TSA. As of March 31, 2025, the Company has \$2,761 in accounts receivable due from SPN - related party and \$1,622 unbilled receivable included in prepaid expenses and other current assets in the Company's condensed consolidated balance sheets.

## 12. Segment Reporting

Our Chief Executive Officer ("CEO"), who is the Chief Operating Decision Maker ("CODM"), manages and allocates resources to the operations of our company on a total company basis by assessing the overall level of resources available and how to best deploy these resources across functions and research and development projects that are in line with our long-term company-wide strategic goals. The CODM uses the Company's consolidated net income (loss) to monitor actual results versus the budget in assessing segment performance and the allocation of resources. The measure of segment assets is reported on the consolidated balance sheets as total assets.

The Company's reportable segment net income (loss) for the three months ended March 31, 2025 and 2024, consisted of the following (in thousands):

	Three Months Ended March 31,	
	2025	2024
Significant segment expenses:		
Live biotherapeutics platform	\$ 5,123	\$ 9,164
SER-155	577	2,400
R&D personnel-related (including stock-based compensation)	6,118	7,845
G&A personnel-related (including stock-based compensation)	4,173	6,641
Professional fees	3,180	2,628
Facility-related and other	4,535	5,675
Gain on sale of VOWST Business	(52,181)	-
Other segment expense (income) (1)	(4,207)	(1,450)
Net income (loss) from continuing operations	32,682	(32,903)
Net (loss) from discontinued operations, net of tax (2)	-	(7,230)
Net income (loss)	<u>\$ 32,682</u>	<u>\$ (40,133)</u>

<sup>[1]</sup> Other segment (expense) income includes research and development expenses on early stage programs, manufacturing services expenses, interest income and other (expense) income, net.

<sup>[2]</sup> See Note 3, *Discontinued Operations and TSA*, for further details.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, such as statements regarding our plans, objectives, expectations, intentions and projections, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report, our actual results could differ materially from the results described in, or implied by, these forward-looking statements.*

### Overview

We are a clinical-stage company focused on improving patient outcomes in medically vulnerable populations through novel live biotherapeutics. We led the successful development and approval of VOWST, the first FDA-approved orally administered microbiome therapeutic, which was sold to Société des Produits Nestlé S.A., or SPN, and with certain of its affiliates, collectively, Nestlé Health Science, in September 2024. We are progressing the development of SER-155, an investigational, oral, live biotherapeutic designed to decolonize gastrointestinal, or GI, pathogens, improve GI epithelial barrier integrity, and induce immune homeostasis to prevent bacterial bloodstream infections, or BSIs, including those that can harbor antimicrobial resistance, or AMR, as well as other pathogen-associated negative clinical outcomes in patients undergoing allogeneic hematopoietic stem cell transplantation, or allo-HSCT. We also continue to develop another proprietary live biotherapeutic composition, SER-147, designed to prevent bacterial bloodstream and spontaneous bacterial peritonitis, or SBP, infections in patients with metabolic disease, including chronic liver disease, or CLD. SER-155 and our other pipeline programs are designed to target multiple disease-relevant pathways and are manufactured from standard clonal cell banks via single-strain cultivation, rather than from the donor-sourced production process used for VOWST.

In our placebo-controlled Phase 1b study of SER-155 in allo-HSCT, Cohort 2 results demonstrated that SER-155 was associated with a 77% relative risk reduction in bacterial BSIs and a significant reduction in systemic antibiotic exposure as well as a lower incidence of febrile neutropenia, as compared to placebo through day 100 post HSCT. SER-155 was generally well tolerated, with no observed treatment-related serious adverse events. In December 2024, the FDA granted Breakthrough Therapy designation to SER-155 for the reduction of BSIs in patients 18 years and older undergoing allo-HSCT. In January 2025, we reported exploratory translational biomarker data from the SER-155 Phase 1b study which provided evidence supporting the intended therapeutic mechanisms, including promotion of intestinal epithelial barrier integrity to reduce the potential of bacterial translocation into the bloodstream, and reduction of systemic inflammatory responses. In the first quarter of 2025, we received feedback from the FDA regarding the development strategy for SER-155 in patients undergoing allo-HSCT. The FDA provided input on certain elements of the next study, including a recommendation for a Phase 2 study, feedback on the primary endpoint, and confirmation of their expectations for the manufacture and control of SER-155. Based on FDA feedback and strategic considerations, we are designing the next SER-155 allo-HSCT study as a standalone Phase 2 study that provides a time and capital-efficient path to obtaining clinical results and, if successful, supports a subsequent Phase 3 study for product registration. The Phase 2 study is expected to target 248 participants and incorporate an adaptive design and an interim data analysis when approximately half of the enrolled participants have reached the primary endpoint timepoint. We expect to obtain interim clinical results within twelve months following study initiation, which we believe will facilitate timely engagement with the FDA on the design of a Phase 3 study and inform development in adjacent medically vulnerable patient populations. We plan to submit the Phase 2 protocol to the FDA in the coming weeks. We are actively seeking a partner to provide financial resources and other capabilities to support our goal to maximize the SER-155 opportunity.

Our live biotherapeutic candidates are consortia of bacteria designed to optimize specific, targeted pharmacological properties, and are formulated for oral delivery. We maintain a differentiated live biotherapeutics drug discovery and development platform that includes good manufacturing practices, or GMP, manufacturing capabilities for this novel drug modality. We are designing live biotherapeutic candidates optimized to prevent the colonization and overgrowth of pathogens in the gastrointestinal tract and modulate host function to increase epithelium integrity and to induce immune homeostasis and tolerance. We believe clinical and nonclinical data across our programs support the development of live biotherapeutics to target the prevention and treatment of a broad swath of infections, and in inflammatory and immune diseases. We believe that the scientific and clinical data from the development of VOWST (our then product candidate SER-109 program) and the data from the SER-155 Phase 1b study validate this novel therapeutic approach in the context of infection. We believe this approach may be replicable across different bacterial pathogens to develop live biotherapeutics with the potential to protect a range of medically compromised patients from infections, including pathogens that harbor AMR.

Our partnership discussions are focused on supporting SER-155 clinical advancement to reduce the risk of BSIs, including life-threatening and antimicrobial resistant infections, in medically vulnerable patient populations. We believe that SER-155 and other cultivated live biotherapeutic candidates could be developed in additional patient populations beyond allo-HSCT, including autologous-HSCT patients, cancer patients with neutropenia, chimeric antigen receptors therapy recipients, or CAR-T, individuals with chronic liver disease, or CLD, solid organ transplant recipients, as well as patients in the intensive care unit and long-term acute care facilities.

Additional efforts in the early-stage portfolio are focused on inflammatory bowel disease, or IBD, with programmatic objectives supported through a partnership with the Crohn's and Colitis Foundation, or CCF. These efforts aim to (i) confirm the functional phenotype and inflammatory state of patient subpopulations observed in our prior ulcerative colitis, or UC, clinical trials, and (ii) prioritize inflammatory targets and evaluate the potential to utilize biomarker-based patient selection and stratification for future studies. In addition, we continue to leverage microbiome pharmacokinetic and pharmacodynamic data from across our clinical and preclinical portfolios, using our reverse translational development platform to prioritize future drug targets and to identify opportunities for monotherapy treatment and in combination with existing therapies across various indications, including inflammatory and immune diseases, cancer, and metabolic diseases.

We have built and deploy a reverse translational platform and knowledge base, which we call our MbTx Platform, for the discovery and development of live biotherapeutics, and maintain extensive proprietary know-how that may be used to support future research and development efforts. This platform incorporates high-resolution analysis of human clinical data to identify microbiome biomarkers associated with disease and non-disease states; preclinical screening using human cell-based assays and in vitro/ex vivo and in vivo disease models customized for live biotherapeutics; and microbiological capabilities and a strain library that spans broad biological and functional breadth. This platform and knowledge base enables identification of specific microbes, microbial genes, and microbial metabolites/peptides associated with disease and the design of therapeutic consortia of bacteria for specific pharmacological properties to restructure the gut microbiome and modulate functional pathways associated with disease. In addition, we own a valuable intellectual property estate related to the development and manufacture of live biotherapeutics.

Since our inception in October 2010, we have devoted substantially all of our resources to developing our programs, platforms, and technologies, building our intellectual property portfolio, developing our supply chain, business planning, raising capital and providing general and administrative support for these operations.

Our product candidates are in early-stage clinical or preclinical development. Our ability to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Since our inception, we have incurred significant operating losses. Our loss from operations was \$27.2 million for the three months ended March 31, 2025. As of March 31, 2025, we had an accumulated deficit of \$945.4 million.

While we plan to focus our investment on progressing the development of SER-155 and advancing our other wholly-owned live biotherapeutic candidates in the near-term, our expenses may increase in connection with these future activities. See “Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—*We are a clinical-stage company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.*”

In addition, if we obtain marketing approval for any of our product candidates, we expect to incur costs related to product manufacturing and commercialization, including marketing, sales and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company.

As a result, we will need additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of collaborations with third parties, public or private equity or debt financings or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of factors such as the impacts of pandemics, such as COVID-19, and increases in inflation rates, interest rates and tariffs. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. Our inability to raise capital or secure a partnership would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability, and we may never do so.

As of March 31, 2025, we had cash and cash equivalents totaling \$58.8 million. Based on our currently available cash resources, including the capital obtained from the Transaction, and the expected receipt of the Second Installment Payment, which is subject to material compliance with the TSA, and considering our future operating plans and our ongoing obligations related to the Transaction, we anticipate that we will require additional funding in the first quarter of 2026. In accordance with applicable accounting standards, we evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within 12 months after the date of the issuance of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. In performing this analysis, we excluded certain elements of our operating plan that cannot be considered probable of occurring. Under the applicable accounting standards, the receipt of contingent payments from the Transaction and any future equity issuances cannot be considered probable, as these events are outside our control. Accordingly, management has concluded that substantial doubt exists about our ability to continue as a going concern for 12 months from the date the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, are issued. See “Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital —*We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern.*”

#### ***Sale of our VOWST Business to SPN***

VOWST (previously referred to as SER-109) was approved by the FDA on April 26, 2023, to prevent recurrence of CDI in individuals 18 years of age or older following antibacterial treatment for recurrent CDI. We launched VOWST in the United States with our then collaborator, Nestlé Health Science, in June 2023. On August 5, 2024, we entered into an Asset Purchase Agreement, or Purchase Agreement, with Société des Produits Nestlé S.A., or SPN, a wholly-owned subsidiary of Nestlé S.A., pursuant to which, after approval by our stockholders at a special meeting of stockholders held on September 26, 2024, we sold our VOWST microbiome therapeutic business, or the VOWST Business, to SPN and its designated affiliates on September 30, 2024, or the Transaction. Following the completion of the Transaction, or the Closing, our headcount decreased by approximately 100 employees, principally due to the transition of manufacturing and quality team members from Seres to Nestlé Health Science, positioning us to efficiently progress SER-155 and our other wholly-owned cultivated live biotherapeutic candidates.

Under the terms of the Purchase Agreement, we sold the VOWST Business, including inventory and equipment, certain patents and patent applications, know-how, trade secrets, trademarks, domain names, marketing authorizations and related rights, documents, materials, business records and data and contracts that are used or held for use primarily in the development, commercialization and manufacturing of the microbiome product sold under the brand name VOWST, or the Product, to SPN, and SPN assumed certain liabilities from us. As consideration for the Transaction, SPN paid or agreed to pay us, as applicable, the following Transaction Consideration:

- (i) a cash payment, which was paid upon Closing, of \$100 million, less approximately \$17.9 million owed by us to an affiliate of SPN as of March 31, 2024 under the prior license agreement between us and the SPN affiliate, and less approximately CHF 2.0 million in satisfaction of fees due under an existing manufacturing agreement between us and Bacthera;
- (ii) cash installment payments of \$50 million, which was received on January 15, 2025, and \$25 million due on July 1, 2025, or the Second Installment Payment (to be reduced by approximately \$1.5 million related to certain employment obligations assumed by SPN, as described below), conditioned on our material compliance with obligations under the TSA (as defined below), which was entered into at Closing between us and Nestlé Enterprises S.A., an affiliate of SPN, or NESA;
- (iii) prepayment of the \$60 million milestone payment tied to the achievement of worldwide annual net sales of the Product of \$150 million, or the First Sales Milestone, which was paid in cash at Closing, or the Prepaid Milestone, which Prepaid Milestone will accrue interest at a fixed rate of 10% per annum until the First Sales Milestone is achieved and 5% per annum thereafter until the earlier of (x) the date on which the Prepaid Milestone, plus accrued interest thereon, has been repaid in full by set-off and (y) the last day of the Milestone Period (as defined below); and
- (iv) future milestone payments of (x) \$125 million tied to the achievement of worldwide annual net sales of the Product of \$400 million and (y) \$150 million tied to the achievement of worldwide annual net sales of the Product of \$750 million, during the period from Closing until December 31 of the calendar year in which the tenth anniversary of Closing occurs, or the Milestone Period, and together, the Future Milestone Payments and, together with the Prepaid Milestone, the Milestone Payments.

*See Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—The total amount of the Second Installment Payment and Milestone Payments we may receive from the Transaction, and the amounts payable or due under the Profit Sharing Payments, are subject to various risks and uncertainties.*

As they are earned, the Milestone Payments will be satisfied as follows: (1) first, by set-off against all accrued interest on the Prepaid Milestone until the amount of such accrued interest has been paid in full, (2) second, by set-off against the outstanding balance of the Prepaid Milestone until the Prepaid Milestone has been repaid in full and (3) thereafter, in cash. If any amount of the Prepaid Milestone (and any accrued interest thereon) remains outstanding as of following the last day of the Milestone Period (defined below), the balance thereof (together with any interest accrued thereon) will be forgiven and the right of set-off of SPN with respect thereto will be deemed forfeited. The Second Installment Payment due on July 1, 2025 will be reduced by approximately \$1.5 million related to certain employment obligations assumed by SPN with respect to the period ending as of the Closing Date.

We and SPN share 50/50 in the net profit or net loss achieved during the period from the Closing Date until December 31, 2025, or the Profit Sharing Period, with the net profit or net loss calculated as (i) the net sales of VOWST in the United States and Canada, plus (ii) other income received in connection with the grant of a license or sublicense with respect to VOWST in the United States and Canada as described in the Purchase Agreement, minus (iii) allowable expenses directly attributable or reasonably allocable to certain development activities, commercialization activities, medical affairs activities, manufacturing activities or other relevant activities, as described in the Purchase Agreement. During the Profit Sharing Period, we will reimburse SPN for (i) certain payments under the exclusive license agreement between us and Memorial Sloan Kettering Cancer Center, (ii) certain costs incurred in connection with an ongoing post-marketing safety study of VOWST and (iii) 80.1% of all rent and other costs due to the landlord under the lease for our Waltham facility.

We estimated the costs associated with these future payments and recorded them within accrued liabilities due to SPN - related party on our condensed consolidated balance sheets as of the Closing. The contingent liabilities are remeasured at each reporting period based on (i) cash payments made by the Company to reduce the accrued liabilities due to SPN - related party and (ii) revised estimates of the total remaining liabilities due to SPN - related party. As of March 31, 2025, the contingent liabilities included \$8.0 million associated with the Profit Sharing Payments, \$2.8 million associated with the MSK Agreement, \$1.1 million associated with our obligation to pay 80.1% of the costs associated with the lease of the Waltham facility through December 31, 2025, \$1.5 million associated with certain employment-related costs for conveying employees, and \$0.5 million associated with our ongoing post-marketing safety study of VOWST. We recorded a gain of \$2.2 million for the three months ended March 31, 2025 primarily as a result of SPN's actual first quarter of 2025 Profit Sharing as compared to the previous estimate.

At Closing, in exchange for a payment to be made by SPN to Bacthera AG, the Long Term Manufacturing Agreement, dated November 8, 2021, between the Company and Bacthera AG, or the Bacthera Manufacturing Agreement, was terminated and each of Bacthera and Seres released one another from any and losses, liabilities or other obligations arising thereunder with respect to the period ending as of the Closing Date, including without limitation any milestone payments required to be paid to Bacthera thereunder.

In connection with the Closing, we and SPN entered into a securities purchase agreement, or the Securities Purchase Agreement, pursuant to which SPN purchased 714,285 shares of our common stock, or the Shares, at Closing, at a purchase price per share of \$21.00, for an aggregate purchase price of \$15 million. Under the terms of the Securities Purchase Agreement, SPN agreed not to sell or transfer the Shares for a period of six months after Closing, subject to certain customary exceptions. We agreed to register the resale of the Shares by SPN within 90 days of Closing. On October 1, 2024, we filed a registration statement to register the Shares, which became effective on October 11, 2024. In addition, under the terms of the Securities Purchase Agreement, for as long as SPN, together with its affiliates, beneficially owns at least 10% of our outstanding shares of common stock, we agreed to take such action within our control to include one individual designated by SPN in the slate of nominees recommended by our board of directors (or the applicable committee of the board of directors) to our stockholders for election to the board of directors at the applicable stockholder meeting. SPN designated Hans-Juergen Woerle, M.D., Ph.D., and on February 4, 2025, our board of directors appointed Dr. Woerle to the board as a Class III director, with a term expiring at our 2027 annual meeting of stockholders. The Securities Purchase Agreement contains customary representations and warranties and closing conditions.

In connection with the Closing, we entered into a Transition Services Agreement, or the TSA, with NESAs, which provides for services to be performed by us in order to facilitate a transition of the business associated with the VOWST Business to NESAs and its affiliates. The scope of the transition services includes the provision of certain manufacturing services and certain administrative functions related to the VOWST Business and operations, including the maintenance of certain manufacturing services and the related facility in which such services are currently conducted. We will provide the manufacturing services until December 31, 2025, which period may be extended by up to six months (solely to ensure the manufacturing facility is in a state of compliance with the biologics license application for VOWST and readiness for potential regulatory inspection), and other services, for the duration specified in the schedule to the TSA for each service. NESAs has agreed to pay us for certain fixed costs, including a monthly fixed fee and a variable per batch fee for preserved raw material suspension manufacturing, or PRMS, and will reimburse us for certain costs of the transition services performed by us under the TSA. The know-how and other intellectual property generated in connection with the performance of the TSA will be owned by NESAs with us having a non-exclusive license to such know-how and other intellectual property under the Cross-License Agreement. During the term of the TSA, upon NESAs's request, we will transfer the specifications for materials and documentation necessary to enable PRMS manufacturing services to a third party service provider designated by NESAs. In the event of a material failure by us to deliver PRMS under the TSA, NESAs will have step-in rights to negotiate to enter into a direct lease with the landlord of the manufacturing facility with respect to the portion of such facility used in connection with the VOWST Business or to cause such services to be performed, with any reasonable out-of-pocket costs and expenses incurred in connection therewith reimbursed by us.

In connection with the Closing, we entered into a cross-license agreement with SPN under which, we granted to SPN a perpetual, worldwide, non-exclusive, fully paid-up license under certain Seres patents that have been issued or will issue in the future and current know-how controlled by us that is not transferred to SPN pursuant to the Purchase Agreement. In the field of the treatment of *Clostridioides difficile* infections, or CDI, and rCDI and associated complications, or collectively, the CDI Field, the license to SPN under such Seres patents and know-how is exclusive to SPN for five years after the Closing and co-exclusive between SPN and Seres following that five year period. The license from Seres to SPN is to issued Seres patents that currently or in the future cover the Product or improvements thereof and know-how that is used or reasonably useful in connection with the exploitation of the VOWST Business. See "Intellectual Property" below.

In connection with the Closing, the parties entered into assignment and assumption of lease agreements, or the Assignment and Assumption Agreements. Under the Assignment and Assumption Agreements, we assigned to SPN or its designated affiliates, our rights in, to and under certain real property leases, and SPN or its designated affiliates assumed the liabilities related thereto.

In connection with the Closing, the parties entered into an employee support agreement, or the Employee Support Agreement. Under the Employee Support Agreement, among other things and subject to the terms and conditions therein, certain of our employees

related to the VOWST Business who accepted employment with SPN or one of its designated affiliates provided the services they provided to us prior to the Transaction to SPN, as well as other services as SPN may reasonably request, from Closing until the day prior to the beginning of SPN's or its designated affiliate's next pay period following the Closing. SPN will reimburse our out of pocket costs in connection with such employees' services, including certain compensation and benefits paid or provided to such employees pursuant to the terms of the Employee Support Agreement. All such employees have transferred to SPN as of December 31, 2024.

### ***Infection Risk Reduction***

We believe that the scientific and clinical data from our SER-109 program validate our novel approach of using live biotherapeutics to decolonize GI pathogens and improve GI epithelial barrier integrity, resulting in reduced rate of infections in medically compromised patients. Data from the SER-109 ECOSPOR III and ECOSPOR IV Phase 3 trial published in the *New England Journal of Medicine* (Feuerstadt et al., 2022) and *Journal of the American Medical Association* (Sims et al., 2023) suggest that live biotherapeutics have the potential to restructure the gut microbiome and shift the gut metabolic landscape. Additional data show that SER-109 rapidly reduced the abundance of bacteria associated with common antibiotic resistance genes, or ARGs, and reduced ARG abundance in the gut (Straub et al., 2023). Collectively, we believe these data suggest the potential for live biotherapeutics to prevent the colonization and overgrowth of pathogens that can establish in the gut and ultimately to reduce infections. We believe that reducing pathogen colonization in the GI tract and improving GI epithelial barrier integrity to reduce the risk of infection may be replicable in a range of medically compromised patients, protecting them from infections and resulting downstream clinical sequelae. We believe this approach may also enable us to reduce AMR, which the World Health Organization declared as a top ten global public health threat facing humanity, and with estimates that yearly deaths may reach 10 million by 2050, putting mortality due to AMR on par with deaths due to cancer.

#### ***SER-155***

We are developing SER-155, an investigational, oral, live biotherapeutic designed to decolonize GI pathogens, improve GI epithelial barrier integrity, and induce immune homeostasis to prevent bacterial BSIs, including those that can harbor AMR, as well as other pathogen associated negative clinical outcomes in patients undergoing allo-HSCT. SER-155 contains 16 bacterial strains selected using our reverse translation discovery and development platform technologies to optimize SER-155's functional profile. The design incorporates biomarker data from human clinical data and screening data from nonclinical human cell-based assays and in vivo disease models. The bacteria consortia is designed to optimize: (i) the prevention of the growth of various *Enterococcaceae* and *Enterobacteriaceae* species known to potentially dominate the GI tract and lead to downstream negative clinical outcomes in medically compromised patients and that can harbor antibacterial resistance, (ii) the production of multiple bacterial metabolites that can promote mucosal and epithelial barrier integrity with the goal of reducing the likelihood of harmful bacteria translocating from the gut to the bloodstream through a compromised epithelium, and (iii) the production of multiple bacterial metabolites that can modulate immune pathways to induce immune tolerance with a potential impact on graft versus host disease, or GvHD.

The rationale for this program is based in part on published clinical evidence from our collaborators at Memorial Sloan Kettering Cancer Center showing that allo-HSCT patients with decreased diversity of commensal microbes and pathogen domination in the gastrointestinal tract were significantly more likely to die due to infection and/or lethal GvHD (Peled et al., 2020). There are an estimated 40,000 allo-HSCT procedures annually worldwide, and infection is one of the most common causes of mortality in these patients. The Center for International Blood & Marrow Transplant Research, or CIBMTR, reports that 19-28% of deaths in allo-HSCT patients over 18 years of age within 100 days post-transplant are caused by infections and 5-14% by GvHD. In December 2023, we received Fast Track Designation for SER-155 to reduce the risk of infection and GvHD in allo-HSCT patients. In December 2024, the FDA granted Breakthrough Therapy designation to SER-155 for the reduction of BSIs in patients 18 years and older undergoing allo-HSCT.

#### ***SER-155 Phase 1b Study***

SER-155 has been evaluated in a Phase 1b study in patients undergoing allo-HSCT. The SER-155 Phase 1b study included two cohorts. Cohort 1 was designed to assess safety and drug pharmacology, specifically the drug strain engraftment in the gastrointestinal tract. Cohort 1 included 13 subjects who received any dosing of the SER-155 regimen, with 11 subjects subsequently receiving an allo-HSCT. Results from this cohort, announced in May 2023, showed SER-155 was generally well tolerated and resulted in successful drug strain engraftment and a reduction in pathogen domination in the GI microbiome relative to a historical control cohort.

Study Cohort 2 utilized a randomized, double-blinded 1:1 placebo-controlled design to further evaluate safety and drug strain engraftment, as well as key secondary and exploratory endpoints such as the incidence of bacterial bloodstream infections and related medical consequences such as febrile neutropenia and antibiotic use. Cohort 2 included 45 patients in the intention-to-treat (ITT) population. Of the ITT population, 20 received SER-155 and 14 received placebo, each of whom subsequently received an allo-HSCT, with data available for clinical evaluation through day 100, the study's prespecified primary observation point. Exploratory hypothesis testing was conducted at the two-sided  $\alpha=0.05$  level. Ninety-five percent (95%) 2-sided confidence intervals (CIs) were determined, where specified. No adjustment for multiplicity was done. A subset of patient samples was available for drug pharmacology analysis.

The median age in Cohort 2 was 63, and most subjects had acute myeloid leukemia, acute lymphocytic leukemia, myelodysplastic syndrome or myeloproliferative neoplasia as their primary disease and received reduced-intensity conditioning pre-transplant. Most patients received peripheral blood stem cells from a matched unrelated donor. A majority received post-transplant cyclophosphamide as part of their graft-versus-host disease (GvHD) prophylaxis.

Results from Cohort 2, announced in September 2024, were consistent with the observations from Cohort 1. SER-155 was generally well tolerated, and no treatment-emergent serious adverse events related to drug were observed. SER-155 bacterial strains engrafted into the gastrointestinal tract of patients following the administration of SER-155.

The incidence of BSIs was significantly lower in the SER-155 arm compared with the placebo arm (2/20 (10%) vs. 6/14 (42.9%), respectively; [Odds Ratio: 0.15; 95% CI: 0.01, 1.13, p=0.0423]), which represents a relative risk reduction of approximately 77% and an absolute risk reduction of approximately 33%. In addition, while antibiotic starts were similar in each arm, patients administered SER-155 were treated with antibiotics for a significantly shorter duration compared to patients in the placebo arm (9.2 days vs. 21.1 days, respectively, with a mean difference of -11.9 days [95% CI: -23.85, -0.04; p=0.0494]). The incidence of febrile neutropenia was lower in patients administered SER-155 compared to placebo (65% vs. 78.6%, respectively; [Odds Ratio: 0.51; 95% CI: 0.07, 2.99; p=0.4674]). Six cases of gastrointestinal infections (*C. difficile* infections) were observed in the study, with four cases (20%) in the SER-155 arm and two cases (14.3%) in the placebo arm.

Recent changes in the allo-HSCT standard of care and the increasing use of post-transplant cyclophosphamide as part of prophylactic therapy for GvHD have reduced rates of GvHD overall in this patient population. The rates of GvHD in the study were low, with two cases of grade 2 GvHD observed in each arm, and no cases of grade 3 or 4 GvHD were observed.

In Cohort 2, the ability to detect pathogen domination (i.e., relative abundance in the GI  $\geq 30\%$ ) in the placebo arm, and differences between the study arms, was constrained due to the limited number of placebo stool samples (placebo patients submitted fewer stool samples) and an imbalance in the number of available stool samples between the arms. Observed pathogen domination events were low in the placebo and SER-155 arms with no significant differences identified. In a comparison of the prevalence of pathogen domination versus a larger allo-HSCT historical control cohort, pathogen domination in SER-155 subjects was substantially lower, providing further evidence of SER-155 activity.

We believe the available study data from Cohort 1 suggest that SER-155 administration results in significantly lower incidence rates of gastrointestinal dominations with pathogens of clinical concern, such as *Enterococcaceae*, *Enterobacteriaceae*, *Streptococcaceae*, and *Staphylococcaceae*. We further believe the resulting Cohort 2 data, together with the Cohort 1 SER-155 Phase 1b study results provide encouraging evidence to support further development of SER-155 to potentially reduce GI associated bloodstream and AMR infections as well as increase immune tolerance in individuals undergoing allo-HSCT for cancers and other serious conditions.

#### Proposed SER-155 Phase 2 Study

In the first quarter of 2025, we received feedback from the FDA regarding the development strategy for SER-155 in patients undergoing allo-HSCT. The FDA provided input on certain elements of the next study, including a recommendation for a Phase 2 study, feedback on the primary endpoint, and confirmation of their expectations for the manufacture and control of SER-155. Based on FDA feedback and strategic considerations, we are designing the next SER-155 allo-HSCT study as a standalone Phase 2 study that provides a time and capital-efficient path to obtaining clinical results and, if successful, supports a subsequent Phase 3 study for product registration. The Phase 2 study is expected to target 248 participants and incorporate an adaptive design and an interim data analysis when approximately half of the enrolled participants have reached the primary endpoint timepoint. We expect to obtain interim clinical results within twelve months following study initiation, which we believe will facilitate timely engagement with the FDA on the design of a Phase 3 study and inform development in adjacent medically vulnerable patient populations. We plan to submit the Phase 2 protocol to the FDA in the coming weeks. We are actively seeking a partner to provide financial resources and other capabilities to support our goal to maximize the SER-155 opportunity.

#### Exploratory biomarker data

In January 2025, we reported exploratory translational biomarker data from the SER-155 Phase 1b study which provided evidence supporting the intended therapeutic mechanisms, including promotion of intestinal epithelial barrier integrity to reduce the potential of bacterial translocation into the bloodstream, and reduction of systemic inflammatory responses. Results from this exploratory biomarker analysis showed that SER-155 was associated with lower levels of fecal albumin and lower concentrations of various plasma biomarkers associated with systemic inflammation (i.e., IFN- $\gamma$ , TNF- $\alpha$ , IL-17, and IL-8) in the HSCT peri-transplant period, the period from the end of the first SER-155 treatment course through to neutrophil engraftment. The results support SER-155's intended mechanisms of action and reinforce the previously reported promising clinical study efficacy and safety data. These systemic inflammatory response observations further support the potential to develop our live biotherapeutics to address inflammatory and immune diseases, including ulcerative colitis and Crohn's disease.

In February 2025, clinical and biomarker results from our biotherapeutic programs were presented as a poster at the 2025 Tandem Transplantation & Cellular Therapy Meetings of the American Society for Transplantation and Cellular Therapy

(ASTCT) and Center for International Blood and Marrow Transplant Research (CIBMTR). SER-155 Phase 1b clinical study data were also featured in an oral presentation in the Best Abstracts in Infectious Diseases track at the Tandem meeting.

In April 2025, we presented SER-155 Phase 1b clinical and exploratory biomarker results at the 5th annual meeting of the European Society for Blood and Marrow Transplantation, or EBMT. Our presented poster was recognized by the EBMT scientific organizing committee and obtained the “Best Clinical Poster Award.”

In May 2025, we presented data at the Digestive Disease Week, or DDW conference highlighting preclinical and clinical data that enable identification of patients with a disease etiology linked to the gastrointestinal microbiome, and the identification of microbiome-based biomarkers that are predictive of response and suitable for patient selection and stratification in clinical trials. Our poster, entitled “Candidate Biomarkers of Microbiome Disruption for Patient Selection or Stratification in Clinical Trials of Microbiome Therapies in Ulcerative Colitis” received a Poster of Distinction award in the Microbiome and Microbial Therapies subgroup. We believe that the data generated suggest that live biotherapeutics could provide a novel modality that could benefit patients living with gut-related inflammatory and immune diseases that are not effectively addressed today. Furthermore, research indicates that specific patient subpopulations optimally suited for biotherapeutic-based treatments may be identifiable. We are exploring options, including potential partnerships, to advance the development of our biotherapeutics in inflammatory and immune diseases, including ulcerative colitis and Crohn’s disease.

#### *SER-147 and other pipeline programs*

We continue to develop another proprietary live biotherapeutic composition, SER-147, designed to prevent bacterial bloodstream and spontaneous bacterial peritonitis, or SBP, infections in patients with metabolic disease, including chronic liver disease, or CLD. SER-147 was designed and optimized using our reverse translational therapeutics development platform. CLD is a progressive condition marked by deterioration of liver function and is reaching epidemic proportions affecting nearly 1.7 billion people worldwide, causing substantial health burden on afflicted countries (GBD 2017 Cirrhosis Collaborators, 2020, Clinical Liver Disease, 2021). In the advanced stages of CLD, known as decompensated cirrhosis, patients exhibit significant immune dysfunction, microbiome disruption, and increased contact with the healthcare system, all of which drive increased susceptibility to bacterial infections (Bajaj et al., 2021, Albillos et al., 2022). The Company is conducting IND-enabling activities for SER-147.

#### ***Nasdaq Notice and Compliance***

On November 7, 2024, we received a letter from the Listing Qualifications Department of The Nasdaq Stock Market LLC, or Nasdaq, notifying us that, for the last 30 consecutive business days, the bid price for our 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 5450(a)(1), or the Bid Price Requirement.

On April 10, 2025, at our 2025 annual meeting of stockholders, our stockholders approved an amendment to our certificate of incorporation to effect a reverse stock split of all outstanding shares of our common stock. On April 21, 2025, we effected a 1-for-20 reverse stock split of our common stock. The reverse stock split had no impact on the number of authorized shares or the par value of preferred and common stock. Trading of our common stock on The Nasdaq Global Select Market commenced on a split-adjusted basis on April 22, 2025. On May 6, 2025, we were notified by the Nasdaq Listing Qualifications staff that the closing bid price of our common stock had been at \$1.00 per share or greater for 10 consecutive business days, from April 22, 2025 to May 5, 2025. Accordingly, we have regained compliance with the Bid Price Requirement and this matter is now closed.

All shares of our common stock, stock-based instruments, and per-share data included in this Quarterly Report on Form 10-Q have been retroactively adjusted as though the reverse stock split had been effected prior to all periods presented.

### **Intellectual Property**

#### ***Patent Portfolio***

We have an extensive patent portfolio directed to rationally designed ecologies of spores and microbes. The portfolio includes both company-owned patents and applications, and those that we have rights to as licensee. The patents and applications included in our portfolio cover both composition of matter and methods (e.g., method of treating). Our intellectual property rights related to SER-155 and SER-147 extend through 2043 (not including any potential term extension). We plan on continuing to broaden our patent portfolio. Currently, we have 21 active patent families, which includes 19 nationalized applications, one at the PCT stage, and one at the provisional stage. To date, we have obtained issuance of 32 U.S. patents (which includes three as licensee). Of the issued U.S. patents, 13 U.S. patents (including one as licensee) have been assigned to Nestlé Health Science as part of its purchase of VOWST.

In connection with the Transaction and pursuant to the Purchase Agreement, we transferred certain patents and trademarks affiliated with the VOWST Business to SPN at Closing. In addition, in connection with Closing, we entered into a cross-license

agreement, or the Cross-License Agreement, with SPN. Under the Cross-License Agreement, we granted to SPN a perpetual, worldwide, non-exclusive, fully paid-up license under certain Seres patents that have been issued or will issue in the future and current know-how controlled by us that was not transferred to SPN pursuant to the Purchase Agreement. In the field of the treatment of CDI and recurrent CDI and associated complications, or collectively, the CDI Field, the license to SPN under such Seres patents and know-how is exclusive to SPN for five years after the Closing and co-exclusive between SPN and Seres following that five year period. The license from Seres to SPN is to issued Company patents that currently or in the future cover the Product or improvements thereof and know-how that is used or reasonably useful in connection with the exploitation of the VOWST Business. We also granted SPN an exclusive, perpetual, worldwide, fully paid-up license under issued Seres patents that currently or in the future cover the Product and improvements thereof and know-how that is used or reasonably useful in connection with the exploitation of the Product to exploit SER-262 in the CDI Field. SPN granted to us a perpetual, worldwide, non-exclusive license under the patents and know-how that are transferred to SPN pursuant to the Purchase Agreement or developed under the TSA, for Seres' products for use outside of the CDI Field, and after five years from Closing for Seres products containing designed, cultivated, bacterial consortia not manufactured using human stool (excluding SER-262) in the CDI Field. From and after Closing, certain license agreements between us, SPN, and/or their respective affiliates terminated and are of no further force or effect, except as contemplated by the Purchase Agreement.

***Regulatory Exclusivity***

If we obtain marketing approval for any of our product candidates, we expect to receive reference product exclusivity against biosimilar products.

## Financial Operations Overview

### *Revenue*

To date we have not generated any revenues from the sale of products. Our revenues have been derived primarily from our agreements with our collaborators. See “–Liquidity and Capital Resources.”

### *Operating Expenses*

Our operating expenses since inception have consisted primarily of research and development activities and general and administrative costs. In connection with the TSA the Company entered into with NESAs following the sale of the VOWST Business during the third quarter of 2024, our operating expenses also consisted of certain passthrough costs incurred in performing duties under the TSA and manufacturing services related to the VOWST Business and operations.

#### *Research and Development Expenses*

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts, and the development of our product candidates and other obligations, which include:

- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct research, preclinical activities and clinical trials on our behalf as well as contract manufacturing organizations that manufacture drug products for use in our preclinical and clinical trials;
- salaries, benefits and other related costs, including stock-based compensation expense, for personnel in our research and development functions;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- the cost of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- costs related to compliance with regulatory requirements;
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs; and
- labor and passthrough costs, reimbursable by Nestlé, incurred in performing duties under the TSA.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors and our clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our unaudited condensed consolidated financial statements as prepaid or accrued research and development expenses.

Our primary focus of research and development since inception has been on our reverse translational platform and the subsequent development of our product candidates. Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs, such as fees paid to investigators, consultants, CROs in connection with our preclinical studies and clinical trials, lab supplies and consumables, and regulatory fees. We do not allocate employee-related costs and other indirect costs to specific research and development programs because these costs are deployed across multiple product programs under development.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We anticipate an overall decrease in research and development expenses in 2025 as compared to 2024, following the sale of VOWST Business, completion of the Phase 1b study of SER-155 in allo-HSCT, development activities other than the completion of the SER-155 Phase 1b study, and costs associated with preparing for the next study of SER-155 in allo-HSCT. Research and development expenses may increase in the future if and as we resume development of any clinical or preclinical programs. In 2025, research and development expenses continue to include labor and passthrough costs, reimbursable by Nestlé, incurred in performing obligations under the TSA.

#### *General and Administrative Expenses*

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, commercial, business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs. Beginning in the fourth quarter of 2024, general and administrative expenses also include labor and passthrough costs, reimbursable by Nestlé, incurred in performing duties under the TSA.

We expect that our general and administrative expenses will decrease in 2025 as compared to 2024, following the sale of VOWST Business, reduction of our workforce and overall cost containment efforts. General and administrative expenses may increase in the future as we continue to incur increased expenses associated with being a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing rules and the requirements of the SEC, director and officer insurance costs and investor and public relations costs. In 2025, general and administrative expenses continue to include labor and passthrough costs, reimbursable by Nestlé, incurred in performing obligations under the TSA.

#### *Manufacturing Services*

Under the TSA with NESAs, beginning in the fourth quarter of 2024, we provide certain manufacturing services and related functions of the VOWST Business and operations. Expenses associated with the manufacturing services include certain facility-related, labor, lab supplies and consumables, and other manufacturing costs that would have been capitalized into inventory prior to the sale of VOWST Business.

We will provide the manufacturing services until December 31, 2025, which period may be extended by up to six months. We expect manufacturing services expenses to increase in 2025 as compared to 2024, given the TSA obligations exist for the full year in 2025 as compared to one quarter in 2024.

#### **Other Income, Net**

##### *Interest Income*

Interest income consists of interest earned on our cash, cash equivalents and investments.

##### *Interest Expense*

Interest expense consists of interest incurred under a previous manufacturing agreement with Bacthera.

##### *Other Income, Net*

Other income, net primarily consists of:

- sublease income;
- amortization of premiums or accretion of discounts on investments;
- gains and losses on foreign currency transactions;
- changes in the fair values of our warrant liabilities associated with the Oaktree Term Loan;
- the amount Nestlé agrees to pay for costs associated with preserved raw material suspension ("PRMS") manufacturing; and reimbursement for certain labor and other passthrough costs of the transition services performed by the Company under the TSA; and
- gains or losses associated with the change in the Company's accrued liabilities due to SPN - related party.

#### **Discontinued Operations**

We completed the sale of the VOWST Business to SPN on September 30, 2024. The financial results of the VOWST Business have been classified as discontinued operations in the condensed consolidated statements of operations and the related assets and liabilities of the VOWST Business have been classified as assets and liabilities of discontinued operations in the condensed consolidated balance sheets. Unless otherwise noted, amounts and disclosures in this section relate to our continuing operations (except for the Liquidity and Capital Resources section).

#### **Income Taxes**

Since our inception in 2010, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. We did not provide for any income taxes in the three months ended March 31, 2025 or 2024.

## Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States. The preparation of these condensed consolidated financial statements requires the application of appropriate technical accounting rules and guidance, as well as the use of estimates. The application of these policies necessarily involves judgments regarding future events. These estimates and judgments, in and of themselves, could materially impact the condensed consolidated financial statements and disclosures based on varying assumptions. The accounting policies discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on March 13, 2025, or the Annual Report, are considered by management to be the most important to an understanding of the consolidated financial statements because of their significance to the portrayal of our financial condition and results of operations. There have been no material changes to that information disclosed in our Annual Report during the three months ended March 31, 2025.

### Results of Operations

#### *Comparison of Three Months Ended March 31, 2025 and 2024*

The following table summarizes our results of operations for the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31,		Change
	2025	2024	
Operating expenses:			
Research and development	\$ 11,821	\$ 19,494	(7,673)
General and administrative	11,888	14,944	(3,056)
Manufacturing services	3,527	—	3,527
Total operating expenses	<u>27,236</u>	<u>34,438</u>	<u>(7,202)</u>
Loss from continuing operations	<u>(27,236)</u>	<u>(34,438)</u>	<u>7,202</u>
Other (expense) income:			
Gain on sale of VOWST Business	52,181	—	52,181
Interest income	618	1,648	(1,030)
Interest expense	—	(618)	618
Other income	7,119	505	6,614
Total other income, net	<u>59,918</u>	<u>1,535</u>	<u>58,383</u>
Net income (loss) from continuing operations	<u>\$ 32,682</u>	<u>\$ (32,903)</u>	<u>\$ 65,585</u>

#### *Research and Development Expenses*

	Three Months Ended March 31,		Change
	2025	2024	
Live biotherapeutics platform	\$ 5,123	\$ 9,164	\$ (4,041)
SER-155	577	2,400	(1,823)
Early stage programs	3	85	(82)
Total direct research and development expenses	<u>5,703</u>	<u>11,649</u>	<u>(5,946)</u>
Personnel-related (including stock-based compensation)	<u>6,118</u>	<u>7,845</u>	<u>(1,727)</u>
Total research and development expenses	<u>\$ 11,821</u>	<u>\$ 19,494</u>	<u>\$ (7,673)</u>

Research and development expenses were \$11.8 million for the three months ended March 31, 2025 and \$19.5 million for the three months ended March 31, 2024. The decrease of \$7.7 million was primarily due to the following:

- a decrease in personnel-related costs of \$1.7 million primarily due to a decrease in salaries, bonus, employee benefits expenses, and stock-based compensation expense due to lower headcount;
- a decrease of \$4.0 million in expenses related to our live biotherapeutics platform and research and development operations due to a decrease of \$3.4 million of facilities and depreciation expense primarily related to the impairment charge that we recorded in the first quarter of 2024, as well as decreases of \$0.3 million of lab assays and \$0.3 million of clinical storage costs, and
- a decrease of \$1.8 million in expenses related to our SER-155 program due to lower clinical trial costs as the Phase 1b study has largely been completed.

## General and Administrative Expenses

	Three Months Ended March 31,		Change
	2025	2024	
Personnel related (including stock-based compensation)	\$ 4,173	\$ 6,641	\$ (2,468)
Professional fees	3,180	2,628	552
Facility-related and other	4,535	5,675	(1,140)
Total general and administrative expenses	<u>\$ 11,888</u>	<u>\$ 14,944</u>	<u>\$ (3,056)</u>

General and administrative expenses were \$11.9 million for three months ended March 31, 2025 compared to \$14.9 million for the three months ended March 31, 2024. The decrease of \$3.1 million was primarily due to the following:

- a decrease in personnel-related costs of \$2.5 million primarily due to a decrease in salaries, bonus, employee benefits expenses, and stock-based compensation expenses due to the decrease in headcount period over period; and
- a decrease in facility-related and other costs of \$1.1 million primarily related to headcount-based information technology costs that were reduced following the decrease in headcount, as well as impairment charges recorded in the first quarter of 2024 related to our idled donor collection facility in Cambridge, Massachusetts.

The decrease of \$3.6 million was partially offset by an increase in professional fees of \$0.6 million due to an increase in consulting fees, which were primarily related to information technology consultants engaged to assist with the TSA, which costs are reimbursable by Nestlé.

### Manufacturing Services

Beginning with the effectiveness of the TSA with Nestlé in the fourth quarter of 2024, manufacturing services resulted in \$3.5 million of expenses for the three months ended March 31, 2025. The expenses are associated with the PRMS manufacturing performed on behalf of Nestlé, including labor, materials, allocated facility-related, lab supplies and other manufacturing costs that would have been capitalized into inventory prior to the sale of VOWST Business.

### Other Income, Net

Other income, net was \$59.9 million and \$1.5 million for the three months ended March 31, 2025 and 2024. The increase in other income, net was primarily due to the \$50.0 million installment payment received from Nestlé in January 2025 that was conditioned on the Company's material compliance with obligations under the TSA, as well as \$6.3 million of reimbursement income associated with the performance of TSA services. The increases were partially offset by a decrease in interest income of \$1.0 million due to our lower cash balance.

## Liquidity and Capital Resources

Since our inception, we have generated revenue only from collaborations and have incurred recurring net losses. We anticipate that we will continue to incur losses for at least the next several years. We will need additional capital to fund our operations, which include our research and development and general and administrative expenses, which we may obtain from additional financings, public offerings, research funding, additional collaborations, contract and grant revenue or other sources.

On August 5, 2024, we entered into the Purchase Agreement with SPN, pursuant to which we agreed to sell our VOWST Business, including inventory and equipment, certain patents and patent applications, know-how, trade secrets, trademarks, domain names, marketing authorizations and related rights, documents, materials, business records and data and contracts that are used or held for use primarily in the development, commercialization and manufacturing of the Product to SPN and its designated affiliates, and SPN and its designated affiliates assumed certain liabilities from us. Our stockholders approved the Transaction at a special meeting of stockholders held on September 26, 2024, and the Transaction closed on September 30, 2024. As consideration for the Transaction, SPN agreed to pay us:

- (i) a cash payment, which was paid at Closing, of \$100 million, less approximately \$17.9 million owed by us to an affiliate of SPN as of March 31, 2024 under the prior license agreement between us and the SPN affiliate, less approximately CHF 2.0 million in satisfaction of fees due under an existing manufacturing agreement between us and Bacthera;
- (ii) cash installment payments of \$50 million, which was received on January 15, 2025, and \$25 million due on July 1, 2025, or the Second Installment Payment (to be reduced by approximately \$1.5 million related to certain employment obligations assumed by SPN, as described below), conditioned on our material compliance with obligations under the TSA entered into at Closing between us and NESA;
- (iii) prepayment of the \$60 million Prepaid Milestone tied to the achievement of the First Sales Milestone of worldwide annual net sales of the Product of \$150 million, which was paid in cash at Closing, which Prepaid Milestone will accrue interest

at a fixed rate of 10% per annum until the First Sales Milestone is achieved and 5% per annum thereafter until the earlier of (x) the date on which the Prepaid Milestone, plus accrued interest thereon, has been repaid in full by set-off and (y) the last day of the Milestone Period; and

- (iv) future Milestone Payments of (x) \$125 million tied to the achievement of worldwide annual net sales of the Product of \$400 million and (y) \$150 million tied to the achievement of worldwide annual net sales of the Product of \$750 million, during the Milestone Period from Closing until December 31 of the calendar year in which the tenth anniversary of Closing occurs.

As they are earned, the Milestone Payments will be satisfied as follows: (i) first, by set-off against all accrued interest on the Prepaid Milestone until the amount of such accrued interest has been paid in full, (ii) second, by set-off against the outstanding balance of the Prepaid Milestone until the Prepaid Milestone has been repaid in full and (iii) thereafter, in cash. If any amount of the Prepaid Milestone (and any accrued interest thereon) remains outstanding as of following the last day of the Milestone Period (defined below), the balance thereof (together with any interest accrued thereon) will be forgiven and the right of set-off of SPN with respect thereto will be deemed forfeited. The Second Installment Payment due on July 1, 2025 will be reduced by approximately \$1.5 million related to certain employment obligations assumed by SPN through the period prior to the Closing Date.

We and SPN share 50/50 in the net profit or net loss achieved during the Profit Sharing Period, with the net profit or net loss calculated as (i) the net sales of VOWST in the United States and Canada, plus (ii) other income received in connection with the grant of a license or sublicense with respect to VOWST in the United States and Canada as described in the Purchase Agreement, minus (iii) allowable expenses directly attributable or reasonably allocable to certain development activities, commercialization activities, medical affairs activities, manufacturing activities or other relevant activities, as described in the Purchase Agreement. During the Profit Sharing Period, we will reimburse SPN for (i) certain payments under the exclusive license agreement between us and Memorial Sloan Kettering Cancer Center, (ii) certain costs incurred in connection with an ongoing post-marketing safety study of VOWST and (iii) 80.1% of all rent and other costs due to the landlord under the lease for our Waltham facility.

As a condition to Closing, we and SPN entered into the Securities Purchase Agreement, pursuant to which SPN purchased 714,285 shares of Common Stock at Closing, at a purchase price per share of \$21.00, for an aggregate purchase price of \$15.0 million.

In May 2021, we entered into a Sales Agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, to sell shares of our common stock, with aggregate gross sales proceeds of up to \$150.0 million, from time to time, through an “at the market” equity offering program under which Cowen acts as sales agent. As of March 31, 2025, we have sold 1,503,956 shares of common stock under the Sales Agreement, at an average price of approximately \$32.65 per share, raising aggregate net proceeds of approximately \$47.1 million after deducting an aggregate commission of approximately 3% and other issuance costs.

As of March 31, 2025, we had cash and cash equivalents totaling \$58.8 million and an accumulated deficit of \$945.4 million. For the three months ended March 31, 2025, we incurred a loss from continuing operations of \$27.2 million. We expect that our operating losses and negative cash flows will continue for the foreseeable future.

Under applicable accounting standards, we have the responsibility to evaluate whether conditions or events raise substantial doubt about our ability to meet our future financial obligations as they become due within 12 months after the date the consolidated financial statements are issued. The ability to obtain the Second Installment Payment and sufficient additional equity, collaborations or other financing with terms favorable or acceptable to us cannot be considered probable, as these events are outside of our control. Based on our currently available cash resources, including the capital obtained from the Transaction, and the expected receipt of the Second Installment Payment, which is subject to material compliance with the TSA, and considering our future operating plans and our ongoing obligations related to the Transaction, we anticipate that we will require additional funding in the first quarter of 2026. Accordingly, management has concluded that these circumstances raise substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing. If potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. We will need to generate significant revenues to achieve profitability, and we may never do so. Because of the numerous risks and uncertainties associated with the development of our current and any future product candidates, the development of our platform and technology and because the extent to which we may enter into collaborations with third parties for development of any of our product candidates is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses required for completing the research and development of our product candidates.

## Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Three Months Ended March 31,	
	2025	2024
	(in thousands)	
Cash provided by (used in) operating activities	\$ 26,910	\$ (35,236)
Cash used in investing activities	(34)	(62)
Cash provided by financing activities	1,180	18,762
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ 28,056</u>	<u>\$ (16,536)</u>

### Operating Activities

During the three months ended March 31, 2025, cash provided by operating activities was \$26.9 million due to net income of \$32.7 million and non-cash charges of \$5.9 million, partially offset by changes in our operating assets and liabilities of \$11.0 million. Non-cash charges consisted of stock-based compensation expense of \$2.8 million, \$2.0 million related to the amortization of right-of-use assets, and \$1.1 million of depreciation and amortization. Changes in our operating assets and liabilities during the three months ended March 31, 2025 consisted of an increase in accounts receivable due from SPN of \$0.7 million, a decrease in accrued liabilities due to SPN of \$3.9 million, a decrease in operating lease liabilities of \$2.1 million, a decrease in accrued expenses and other current and long-term liabilities of \$4.4 million, and a decrease increase in accounts payable of \$2.0 million, partially offset by a decrease in prepaid expenses and other current and other non-current assets of \$1.3 million.

During the three months ended March 31, 2024, operating activities used \$35.2 million of cash, primarily due to a net loss of \$40.1 million and changes in our operating assets and liabilities of \$9.2 million, partially offset by non-cash charges of \$14.1 million. Non-cash charges consisted of stock-based compensation expense of \$6.5 million, \$2.4 million related to the amortization of right-of-use assets, \$1.6 million of depreciation and amortization, \$0.5 million of amortization of debt issuance costs, \$0.3 million loss on disposal of fixed assets, and \$3.3 million of impairment charges related to our long-lived assets. These were partially offset by a \$0.4 million increase in the fair value of warrants. Changes in our operating assets and liabilities during the three months ended March 31, 2024 consisted of a decrease in accrued expenses and other current and long-term liabilities of \$4.2 million, a decrease in operating lease liabilities of \$0.2 million, and an increase in inventories of \$12.3 million related to the capitalization of VOWST manufacturing costs during the period, partially offset by a decrease in prepaid expenses and other current and other non-current assets of \$4.4 million, a decrease in collaboration receivable - related party of \$1.3 million, an increase in deferred income - related party of \$0.4 million, and an increase in accounts payable of \$1.6 million.

### Investing Activities

During the three months ended March 31, 2025, net cash used in investing activities was \$0.1 million, consisting entirely of purchases of property and equipment.

During the three months ended March 31, 2024, net cash used in investing activities was \$0.1 million, consisting entirely of purchases of property and equipment.

### Financing Activities

During the three months ended March 31, 2025, net cash provided by financing activities was \$1.2 million, consisting of \$1.0 million from the issuance of common stock under our at the market equity program, net of issuance costs and \$0.2 million from the issuance of common stock under our 2015 Employee Stock Purchase Plan, or ESPP.

During the three months ended March 31, 2024, net cash provided by financing activities was \$18.8 million, consisting of \$18.4 million from the issuance of common stock under our at the market equity program, net of issuance costs and \$0.4 million in connection with the issuance of common stock under our 2015 Employee Stock Purchase Plan, or ESPP.

## ***Funding Requirements***

Our expenses may increase in connection with our ongoing clinical development activities and research and development activities. In addition, we expect to continue to incur additional costs associated with operating as a public company. We anticipate that our future expenses will increase if and as we:

- continue the clinical development of SER-155 in patients undergoing allo-HSCT and for other medically vulnerable populations;
- perform our obligations under the TSA;
- make strategic investments in manufacturing capabilities;
- maintain and augment our extensive proprietary live biotherapeutic drug development know-how that may be used to support future research and development efforts, including our intellectual property portfolio and intellectual property that we may opportunistically acquire;
- establish a sales and distribution infrastructure and scale-up manufacturing capabilities to commercialize any other products for which we may obtain regulatory approval;
- perform our obligations under any agreements with collaborators;
- seek to obtain regulatory approvals for our product candidates; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

Because of the numerous risks and uncertainties associated with the development of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements will depend on many factors, including:

- the total amount of the Second Installment Payment and Milestone Payments we may receive from the Transaction, and the amounts payable or due under the Profit Sharing Payments;
- the cost of manufacturing our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates and research activities;
- the costs, timing and revenue, if any, of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for our current or future product candidates and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Additionally, part of our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. Additionally, market volatility resulting from macroeconomic conditions, or other factors could also adversely impact our ability to access capital as and when needed. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as common stockholders. Any debt financing and preferred equity financing, if available, may involve agreements that include, covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Additional debt or preferred equity financing may also require the issuance of warrants, which could potentially dilute our stockholders' ownership interest.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, in addition to our existing collaboration agreements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity, debt financings, or collaborations when needed, we may be required to delay, limit, reduce or terminate our product development programs or any potential future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

As discussed in Note 1 of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, we have the responsibility to evaluate whether conditions or events raise substantial doubt about our ability to meet our future financial obligations as they become due within 12 months after the date the condensed consolidated financial statements are issued. The receipt of contingent payments from the Transaction, collaborations or future equity issuances cannot be considered probable, as these events are outside of our control. Accordingly, management has concluded that these circumstances raise substantial doubt about our ability to continue as a going concern. Based on our currently available cash resources, including the capital obtained from the Transaction, and the expected receipt of the Second Installment Payment, which is subject to material compliance with the TSA, and considering our future operating plans and our ongoing obligations related to the Transaction, we anticipate that we will require additional funding in the first quarter of 2026.

#### *Contractual Obligations and Commitments*

The disclosure of our contractual obligations and commitments was included in our Annual Report. There have been no material changes from the contractual commitments and obligations previously disclosed in our Annual Report.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

We are exposed to market risk from changes in interest rates and inflation. These market risks arise in the normal course of business. During the three months ended March 31, 2025, there have been no material changes to the information included under Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk, in our Annual Report on Form 10-K for the year ended December 31, 2024.

### **Item 4. Controls and Procedures.**

#### *Limitations on Effectiveness of Controls and Procedures*

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

#### *Evaluation of Disclosure Controls and Procedures*

Our management, with the participation of our principal executive officer and our principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Quarterly Report. Based on such evaluation, our principal executive officer and principal financial officer concluded that as of March 31, 2025, our disclosure controls and procedures were effective at the reasonable assurance level.

#### *Changes in Internal Control Over Financial Reporting*

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended March 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II - OTHER INFORMATION

### Item 1. Legal Proceedings.

None.

### Item 1A. Risk Factors

*Our business faces significant risks and uncertainties. Accordingly, in evaluating our business, you should carefully consider the risk factors discussed below, as well as the other information included or incorporated by reference in this Quarterly Report, including our condensed consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below or elsewhere in this report could harm our business, financial condition, results of operations or growth prospects.*

#### **Risks Related to Our Financial Position and Need for Additional Capital**

***We will need additional funding in order to advance development of our product candidates (including to complete the planned Phase 2 study of SER-155 in allo-HSCT) and commercialize our product candidates, if approved. If we are unable to raise capital or secure a partnership, we could be forced to delay, reduce or eliminate our product development programs or any potential future commercialization efforts, or pursue other strategic alternatives.***

Our expenses may increase in connection with our ongoing activities, particularly if and as we further SER-155 clinical studies, and research, develop and initiate clinical trials of our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur costs related to product manufacturing and commercialization, including marketing, sales and distribution, and may not generate meaningful product revenues or collaboration profit in the near future. Furthermore, we have incurred and expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital or secure a partnership when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any current or potential future commercialization efforts or pursue other strategic alternatives.

We are actively engaged in discussions seeking a partner to provide financial support and who shares our vision to realize the clinical and commercial value of SER-155. Our strategic partnership discussions are focused on supporting SER-155 clinical advancement to reduce the risk of bloodstream infections, including life-threatening and AMR infections, in medically vulnerable patient populations. We believe that SER-155 and other cultivated live biotherapeutic candidates could be developed in additional patient populations beyond allo-HSCT, 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. We are also exploring collaborations to advance the development of our investigational biotherapeutics in inflammatory and immune diseases, including ulcerative colitis and Crohn's disease.

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. Our future capital requirements will depend on many factors, including:

- the cost of conducting clinical trials for our lead candidate, SER-155 in allo-HSCT and other targeted indications, and other product candidates in our pipeline;
- the total amount of the Second Installment Payment and Milestone Payments we may receive from the Transaction, and the amounts payable or due under the Profit Sharing Payments;
- the cost of manufacturing our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates and research activities;
- the costs, timing and revenue, if any, of potential future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;

- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Additionally, market volatility resulting from current macroeconomic conditions, such as the conflicts involving Ukraine and Russia and Israel and its surrounding regions, a trade war between the U.S. and other nations, including China, or other governmental action related to tariffs or international trade agreements or policies, and related impacts, or other factors could also adversely impact our ability to access capital as and when needed. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders and may decrease our stock price. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell, or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay, or discontinue one or more of our research or development programs or any product candidates, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially adversely affect our business, financial condition and results of operations. As noted above, we are currently actively engaged in discussions seeking partnerships. We may pursue additional strategic partnerships or collaborations or other alternatives with one or more parties. We can provide no assurance that we will be successful in securing any strategic partnership, collaboration, or alternative, or that any such partnership, collaboration or alternative that we secure will achieve its intended benefits or have a positive impact on our financial condition or business.

***We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern.***

Based on our currently available cash resources, including the capital obtained from the Transaction, and the expected receipt of the fixed Second Installment Payment, which is subject to material compliance with the TSA, and considering our future operating plans and our ongoing obligations related to the Transaction, we anticipate that we will require additional funding in the first quarter of 2026. Because the ability to obtain the Second Installment Payment and additional equity or other financing, including through partnerships, with terms favorable or acceptable to us cannot be considered probable according to the applicable accounting standards because they are outside our control, there is substantial doubt about our ability to continue as a going concern for at least 12 months from the date that our condensed consolidated financial statements for the three months ended March 31, 2025 were issued. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing. If potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations. We have prepared our consolidated financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our unaudited consolidated financial statements included in this Quarterly Report on Form 10-Q do not include any adjustments to reflect the possible inability of the Company to continue as a going concern within 12 months after the issuance of such financial statements.

***We are a clinical-stage company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.***

Since inception, we have incurred significant operating losses. Our net loss from continuing operations was \$125.8 million for the year ended December 31, 2024, and we are forecasting a net loss for the year ended December 31, 2025. As of March 31, 2025, we had an accumulated deficit of \$945.4 million. As noted elsewhere in this Quarterly Report on Form 10-Q, we have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. To date, we have financed our operations through the public offerings of our common stock, private placements of our common stock and preferred stock, payments under our prior collaboration agreements and loan facility. We have devoted substantially all of our financial resources and efforts to developing our live biotherapeutics platform, identifying potential product candidates and conducting preclinical studies and clinical trials. We have only developed one FDA-approved product, VOWST, which was sold to SPN in September 2024. We have not completed development of any of our other product candidates, which we call live biotherapeutic candidates, or other drugs or biologics. We expect to continue to incur significant expenses and operating losses for the foreseeable future. While we plan to focus our investment on continuing the development of SER-155 and advancing our other wholly-owned cultivated live biotherapeutic candidates, our expenses may increase substantially in connection with our ongoing and future activities, particularly if and as we:

- continue the clinical development of SER-155 in patients receiving allo-HSCT and for other medically vulnerable populations;
- perform our obligations under the TSA;
- advance research and development activities supported by partnerships;
- make strategic investments in manufacturing capabilities;
- maintain and augment our extensive proprietary live biotherapeutic drug development know-how that may be used to support future research and development efforts, including our intellectual property portfolio and intellectual property that we may opportunistically acquire;
- establish a sales and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we have obtained and in the future may obtain regulatory approval;
- perform our obligations under any agreements with collaborators;
- seek to obtain regulatory approvals for our product candidates; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

To become and remain profitable, we must succeed in developing and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we have already obtained and may in the future obtain regulatory approval. We are in the preliminary stages of many of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product and biological development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress our value and could impair our ability to raise capital, secure a partnership, expand our business, maintain our research and development and any potential future commercialization efforts, diversify our product offerings or even continue our operations.

***Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.***

Since our inception in October 2010, we have devoted substantially all of our resources to developing our clinical and preclinical program, building our intellectual property portfolio, developing our supply chain, planning our business, raising capital and providing general and administrative support for these operations. Other than with respect to VOWST, which was sold to SPN in September 2024, we have not yet demonstrated our ability to obtain regulatory approvals, and we have limited experience in demonstrating our ability to manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, including for example, the impact of the sale of our VOWST Business to SPN, many of which are beyond our control. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history.

***The total amount of the Second Installment Payment and Milestone Payments we may receive from the Transaction, and the amounts payable or due under the Profit Sharing Payments, are subject to various risks and uncertainties.***

In connection with the Closing, SPN assumed certain liabilities with respect to the VOWST Business and agreed to pay to us:

- a cash payment, which was paid at Closing, of \$100 million, less approximately \$17.9 million owed by us to SPN under the prior license agreement between us and the SPN affiliate, less approximately CHF 2.0 million in satisfaction of fees due under the Bacthera Agreement;
- cash installment payments of \$50 million, which was received on January 15, 2025, and \$25 million due on July 1, 2025, or the Second Installment Payment (to be reduced by approximately \$1.5 million related to certain employment obligations assumed by SPN, as described below), conditioned on our material compliance with obligations under the TSA entered into at Closing between us and NESAs;
- prepayment of the \$60 million Prepaid Milestone tied to the achievement of the First Sales Milestone of worldwide annual net sales of the Product of \$150 million, which was paid in cash at Closing, which Prepaid Milestone will accrue interest at a fixed rate of 10% per annum until the First Sales Milestone is achieved and 5% per annum thereafter until the earlier of (x) the date on which the Prepaid Milestone, plus accrued interest thereon, has been repaid in full by set-off and (y) the last day of the Milestone Period; and
- future Milestone Payments of (x) \$125 million tied to the achievement of worldwide annual net sales of the Product of \$400 million and (y) \$150 million tied to the achievement of worldwide annual net sales of the Product of \$750 million, during the Milestone Period from Closing until December 31 of the calendar year in which the tenth anniversary of Closing occurs.

As they are earned, the Milestone Payments will be satisfied as follows: (1) first, by set-off against all accrued interest on the Prepaid Milestone, (2) second, by set-off against the outstanding balance of the Prepaid Milestone until the Prepaid Milestone has been repaid in full and (3) thereafter, in cash. If any amount of the Prepaid Milestone (and any accrued interest thereon) remains outstanding as of following the last day of the Milestone Period, the balance thereof (together with any interest accrued thereon) will be forgiven and the right of set-off of SPN with respect thereto will be deemed forfeited. The Second Installment Payment due on July 1, 2025 will be reduced by approximately \$1.5 million related to certain employment obligations assumed by SPN through the period prior to the Closing Date.

The Second Installment Payment and the Milestone Payments are subject to various risks and uncertainties. We must be in material compliance with our obligations under the TSA in order to receive the Second Installment Payment and, if we are not or if there is a dispute as to compliance, such payment could be withheld or delayed, pending resolution. The Milestone Payments will be based on the achievement of specified worldwide net sales targets for the Product. Interest on the Prepaid Milestone will accrue and will reduce any corresponding Milestone Payments based on the length of time it takes to achieve the milestones. It is not possible to determine with precision as of the date of this Quarterly Report on Form 10-Q the amount or timing of worldwide net sales the Product will generate in the future and, therefore, it is possible that the Milestone Payments will not be earned or will be limited by lower Product net sales than anticipated. The specified worldwide net sales targets for the Product were based on certain assumptions about the future financial performance of the Product, and there can be no assurance that such projections will be achieved or that the Milestone Payments will become payable.

Further, during the Profit Sharing Period, we and SPN share 50/50 in the net profit or net loss achieved during the period. Amounts payable or due under the Profit Sharing Payments are uncertain and could result in financial losses or financial gains that are less than expected.

***We may not be able to realize the anticipated benefits of the Transaction, and we may face new challenges as a smaller, less diversified company.***

We may not be able to realize the anticipated benefits from the Transaction, including deploying the proceeds from the Transaction to advance SER-155 and support our pipeline of wholly-owned cultivated live biotherapeutic candidates. Our ability to realize the anticipated benefits of the Transaction and the success of the remaining company is subject to various risks and uncertainties, including the possibility that we may not be able to successfully use our live biotherapeutics platform to build a pipeline of product candidates and develop additional marketable drugs, and the possibility that we will not be able to obtain, or experience delays in obtaining, required regulatory approvals.

The Transaction resulted in the Company being a smaller, less diversified company with a more limited remaining business concentrated on SER-155, which recently completed a Phase 1b study in patients undergoing allogeneic hematopoietic stem cell transplantation, and our other wholly-owned cultivated live biotherapeutic candidates. As a result, we may be more susceptible to changing market conditions, including fluctuations and risks particular to preclinical and clinical-stage companies, than a more diversified company, which could adversely affect our remaining business, financial condition and results of operations. In addition, the diversification of our costs and cash flows diminished following the Transaction, such that our results of operations, cash flows, working capital and financing requirements may be subject to increased volatility and our ability to fund capital expenditures and investments or satisfy other financial commitments may be diminished.

We will need to secure additional funding to maintain operations beyond our current cash runway. Based on our currently available cash resources, including the capital obtained from the Transaction, and the expected receipt of the Second Installment Payment, which is subject to material compliance with the TSA, and considering our future operating plans and our ongoing obligations related to the Transaction, we anticipate that we will require additional funding in the first quarter of 2026. However, due to our smaller business size and the early stage of development of our remaining assets, there can be no assurance that we will be able to raise the required capital on favorable terms, or at all. This potential inability to obtain necessary funding could have a material adverse effect on our prospects, financial condition, and results of operations.

We may also face new challenges with maintaining employee morale and retaining key management and other employees and retaining existing business and operational relationships, including with third parties, employees and other counterparties that otherwise prefer to transact with larger companies (or will only transact with smaller companies on less favorable terms).

*We have broad discretion as to the use of the proceeds from the Transaction, and may not use the proceeds effectively.*

We were obligated to use the proceeds from the completion of the Transaction to fully repay our indebtedness under the Oaktree Credit Agreement. We have broad discretion with respect to the use of the remaining proceeds of the Transaction, including to support the further advancement of SER-155 and our other cultivated live biotherapeutic product candidates. The results and effectiveness of the use of proceeds are uncertain, and we could spend the proceeds in ways that do not improve our remaining business, financial condition or results of operations. Our failure to apply these funds effectively could have an adverse effect on its business, financial condition and results of operations.

#### **Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates**

*We are early in our development efforts of our product candidates and may not be successful in our efforts to use our reverse translational platform to build a pipeline of product candidates and develop additional marketable drugs.*

We are using our reverse translational platform to develop live biotherapeutic candidates. We are at an early stage of development of our product candidates and our platform may never lead to approvable or marketable drugs. We are developing product candidates that are designed to reduce infection and treat diseases where the microbiome is implicated. We may have problems applying our technologies to these areas, and our product candidates may not be effective in reducing infection and disease. Our product candidates may not be suitable for clinical development, including as a result of their harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and, if approved, achieve market acceptance.

The success of our product candidates will depend on several factors, including the following:

- completion of preclinical studies and clinical trials with positive results;
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing our own, commercial manufacturing capabilities;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- entering into new collaborations throughout the development process as appropriate, from preclinical studies through to commercialization;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our product candidates, if approved;
- protecting our rights in our intellectual property portfolio;

- operating without infringing or violating the valid and enforceable patents or other intellectual property of third parties;
- maintaining a continued acceptable safety profile of our product candidates, if approved, following approval; and
- maintaining and growing an organization of scientists and business people who can develop and commercialize our product candidates and technology.

If we or our collaborators do not successfully develop and commercialize our product candidates we will not be able to obtain product revenue or collaboration profit in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

***Our product candidates are based on live biotherapeutics, which is a novel approach to therapeutic intervention.***

Our product candidates are based on live biotherapeutics, a novel class of biological drugs, which are designed to treat disease by modulating the microbiome to restore health by repairing the function of a disrupted microbiome to a non-disease state. To our knowledge, VOWST is the first oral product based on this approach to receive FDA approval. We cannot be certain that our approach will lead to the development of additional approvable or marketable products or that we will be able to manufacture at commercial scale. Finally, the FDA or other regulatory authorities may lack experience in evaluating the safety and efficacy of novel product candidates based on live biotherapeutics, which could result in a longer than expected regulatory review process, increase our expected development costs and delay or prevent any potential future commercialization of our product candidates.

***Clinical drug development involves a risky, lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and potential future commercialization of our product candidates.***

It is difficult to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval, and the risk of failure through the development process is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing, and our clinical trials may not be successful. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim or preliminary results of a clinical trial, that we may from time to time announce, do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks.

In addition, we cannot be certain as to what type and how many clinical trials the FDA, or other regulatory authorities, will require us to conduct before we may successfully gain approval to market any of our product candidates. Prior to approving a new therapeutic product, the FDA (or other regulatory authorities) generally requires that safety and efficacy, or with respect to biological products such as our live biotherapeutic candidates, safety, purity and potency, be demonstrated in two adequate and well-controlled clinical trials. In some situations, evidence from a Phase 2 trial and a Phase 3 trial or from a single Phase 3 trial can be sufficient for FDA approval, such as in cases where the trial or trials provide highly reliable and statistically strong evidence of an important clinical benefit.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- regulatory authorities or institutional review boards or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- failures or delays in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidates may demonstrate undesirable side effects or produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulatory authorities or institutional review boards or ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- regulatory authorities may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- regarding trials managed by any current or future collaborators, our collaborators may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but potentially suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- lose the support of current or any future collaborators, requiring us to bear more of the burden of development of certain compounds;
- not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as we intend or desire;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be subject to increased pricing pressure; or
- have the product removed from the market after obtaining marketing approval.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations and guidelines, and remain subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where such clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. These authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or applicable clinical trial protocols, adverse findings from inspections of clinical trial sites by the FDA or comparable foreign regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators, IRBs or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Additional clinical trials or changes in our development plans could cause us to incur significant development costs, delay or prevent the potential future commercialization of our product candidates or otherwise adversely affect our business.

In addition, many of the factors that cause, or lead to, the termination suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations.

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted with respect to clinical trials. For instance, the regulatory landscape related to clinical trials in the European Union, or EU, recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as contract research organizations, or CROs, may impact our developments plans.

It is currently unclear to what extent the UK will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from the now-repealed EU Clinical Trials Directive (as implemented into UK law, through the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended). The extent to which the regulation of clinical trials in the UK will mirror the (EU) CTR in the long term is not yet certain, however, on December 12, 2024, the UK government introduced a legislative proposal - the Medicines for Human Use (Clinical Trials) Amendment Regulations 2024 - that, if implemented, will replace the current regulatory framework for clinical trials in the UK. The legislative proposal aims to provide a more flexible regime to make it easier to conduct clinical trials in the UK, increase the transparency of clinical trials conducted in the UK and make clinical trials more patient centered. The UK government has provided the legislative proposal to the UK Parliament for its review and approval. Once the legislative proposal is approved (with or without amendment), it will be adopted into UK law which is expected in early 2026. A decision by the UK government not to closely align any new legislation with the new approach that has been adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our business may be impacted.

***Delays or difficulties in the enrollment of patients in clinical trials, could result in our receipt of necessary regulatory approvals being delayed or prevented.***

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. These trials and other trials we conduct may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, patient withdrawal or adverse events. These types of developments could cause us to delay the trial or halt further development.

Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. In addition, there may be limited patient pools from which to draw for clinical studies. In addition to the rarity of some diseases, the eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study.

Patient enrollment is also affected by other factors including:

- the severity of the disease under investigation;
- the patient eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the availability of other treatments for the disease under investigation;

- the existence of competing clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- our payments for conducting clinical trials;
- the patient referral practices of physicians;
- the burden, or perceived burden, of the clinical study;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials or a delayed rate of enrollment would result in significant delays and could require us to abandon one or more clinical trials altogether.

***Interim “top-line” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publicly disclose interim, top-line or preliminary data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

***If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or any collaborators will not be able to commercialize our product candidates or will not be able to do so as soon as anticipated, and our ability to generate revenue will be materially impaired.***

Our product candidates and the activities associated with their development and potential future commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate in any jurisdiction will prevent us and any collaborators from commercializing the product candidate in that jurisdiction and may affect our plans for potential future commercialization in other jurisdictions as well. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate’s safety and efficacy, or with respect to biologics such as our live biotherapeutic candidates, safety, purity and potency. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, risky and may take many years. The scope and amount of clinical data required to obtain marketing approvals can vary substantially from jurisdiction to jurisdiction, and it may be difficult to predict whether a particular regulatory body will require additional or different studies than those conducted by a sponsor, especially for novel product candidates such as our live biotherapeutic candidates. The FDA or foreign regulatory authorities may delay, limit, or deny approval to market our product candidates for many reasons, including: our inability to demonstrate that the clinical benefits of our product candidates outweigh any safety or other perceived risks; the regulatory authority's disagreement with the interpretation of data from nonclinical or clinical studies; the regulatory authority's requirement that we conduct additional preclinical studies and clinical trials; changes in marketing approval policies during the development period; changes in or the enactment of additional statutes or regulations, or changes in regulatory review process for each submitted product application; or the regulatory authority's failure to approve the manufacturing processes or third-party manufacturers with which we contract. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however have a significant impact on the biopharmaceutical industry in the long term.

Additionally, regulatory authorities have substantial discretion in the approval process and may refuse to accept or file a marketing application if deficient. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Of the large number of drugs in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized.

Furthermore, our product candidates may not receive marketing approval even if they achieve their specified endpoints in clinical trials. Clinical data are often susceptible to varying interpretations and many companies that have believed that their products performed satisfactorily in clinical trials have nonetheless failed to obtain regulatory authority approval for their products. The FDA or foreign regulatory authorities may disagree with our trial design and our interpretation of data from nonclinical and clinical studies, or they may require additional confirmatory or safety evidence beyond our existing clinical studies. Upon the FDA's review of data from any pivotal trial, it may request that the sponsor conduct additional analyses of the data or gather more data and, if it believes the data are not satisfactory, could advise the sponsor to delay submitting a marketing application.

Even if we eventually complete clinical testing and receive approval of a biologics license application, or BLA, or foreign marketing authorization for one of our product candidates, the FDA or the applicable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials, which may be required after approval. The FDA or the applicable foreign regulatory authority may also approve our product candidates for a more limited indication and/or a narrower patient population than we originally request, and the FDA, or applicable foreign regulatory authority, may not approve the labeling that we believe is necessary or desirable for the successful potential future commercialization of our product candidates. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent potential commercialization of our product candidates and would materially adversely impact our business and prospects.

The development of therapeutic products targeting the underlying biology of the human microbiome is an emerging field, and it is possible that the FDA and other regulatory authorities could issue regulations or new policies in the future that could adversely affect our live biotherapeutic candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

***A Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.***

We have and may in the future seek Fast Track designation for some of our product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition, the drug or biologic sponsor may apply for Fast Track designation. We received Fast Track designation for SER-155 to reduce the risk of infection and GvHD in patients undergoing allo-HSCT. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. Once granted, Fast Track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, and a BLA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

The FDA has broad discretion whether or not to grant this designation, and even if we believe another particular product candidate is eligible for this designation, we cannot be certain that the FDA would decide to grant it. Even with Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Fast Track designation does not assure ultimate approval by the FDA. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

***A Breakthrough Therapy, or other similar designations by the FDA for our product candidates may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.***

In December 2024, we received Breakthrough Therapy designation for SER-155 for the reduction of BSIs in patients 18 years and older undergoing allo-HSCT. We may seek these or other designations for future product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed in early clinical development. For drugs or biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development. Drugs designated as breakthrough therapies by the FDA also receive all of the Fast Track program features, including eligibility for rolling review of the associated marketing application.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. The receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, not all products designated as breakthrough therapies ultimately will be shown to have the substantial improvement over available therapies suggested by the preliminary clinical evidence at the time of designation. As a result, if a Breakthrough Therapy designation for any future designation we receive is no longer supported by subsequent data, the FDA may rescind the designation.

***We may seek PRIME designation by EMA or other designations, schemes or tools in the EU for one or more of our product candidates, which we may not receive. Such designations may not lead to a faster development or regulatory review or approval process and do not increase the likelihood that our product candidates will receive marketing authorization.***

We may seek EMA PRIME (PRIority MEDicines) designation or other designations, schemes or tools for one or more of our product candidates. In the EU, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the Breakthrough Therapy designation in the United States. PRIME is a voluntary scheme aimed at enhancing the European Medicines Agency's, or EMA, support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. The benefits of a PRIME designation include the appointment of a rapporteur before submission of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.

Even if we believe one of our product candidates is eligible for PRIME, the EMA may disagree and instead determine not to make such designation. The EMA PRIME scheme or other schemes, designations, or tools, even if obtained or used for any of our product candidates may not lead to a faster development, regulatory review or approval process compared to therapies considered for approval under conventional procedures and do not assure ultimate approval. In addition, even if one or more of our product candidates is eligible to the PRIME scheme, the EMA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for review or approval will not be shortened.

Product developers that benefit from PRIME designation may be eligible for accelerated assessment (in 150 days instead of 210 days), which may be granted for medicinal products of major interest from a public health perspective or that target an unmet medical need, but this is not guaranteed.

The competent regulatory authorities in the EU have broad discretion whether to grant such an accelerated assessment, and, even if such assessment is granted, we may not experience a faster development process, review or authorization compared to conventional procedures. Moreover, the removal or threat of removal of such an accelerated assessment may create uncertainty or delay in the clinical development of our product candidates and threaten the commercialization prospects of our product candidates, if approved. Such an occurrence could materially impact our business, financial condition and results of operations.

***We may seek orphan drug designation for some of our product candidates but may not be able to obtain it.***

We may seek orphan drug designation for some of our future product candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and biologics for relatively small patient populations as orphan drugs. In the United States, the FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, which is defined as a disease or condition that affects fewer than 200,000 individuals in the United States, or a patient population

greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation must be requested before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA.

In addition, if a product with an orphan drug designation subsequently receives the first marketing approval for the disease or condition for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or other regulatory authorities from approving another marketing application for the same drug and same disease or condition during that time period, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. The applicable period is seven years in the United States and ten years in the EU. The European exclusivity period can be reduced to six years if, at the end of the fifth year, it is established that a product no longer meets the criteria for orphan designation, if the product is sufficiently profitable so that market exclusivity is no longer justified, or the prevalence of the condition has increased above the orphan designation threshold. Orphan drug exclusivity may be lost if the FDA or other regulatory authorities determine that the request for designation was materially defective or if the manufacturer is unable to assure a sufficient quantity of the drug or biologic to meet the needs of patients with the rare disease or condition. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective.

Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity for a product may not effectively protect the product from competition because different drugs and biologics can be approved for the same disease or condition. Even after an orphan drug or biologic is approved, the FDA or other regulatory authorities can subsequently approve the same drug or biologic for the same disease or condition if the FDA or other regulatory authorities conclude that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time nor gives the drug any advantage in the regulatory review or approval process.

***Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.***

The ability of the FDA and other regulatory authorities to review and or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's and other regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's and other regulatory authorities' ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other regulatory authorities, such as the EMA, may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary regulatory authorities, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Since the beginning of 2025, the U.S. Secretary of Health and Human Services has terminated probationary staff, offered buy-outs to federal employees, and implemented layoffs at several federal public health agencies, including at the FDA. It remains unclear the degree to which these activities may limit or otherwise adversely affect the FDA's ability to conduct routine operations and activities and the impact it may have on our business.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. If a prolonged government shutdown occurs, or if renewed global health concerns delay or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

#### **Risks Related to our Dependence on Third Parties and Manufacturing**

***We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.***

We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct and manage our clinical trials.

Our reliance on these third parties for research and development activities will reduce our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, safety and welfare of trial participants are protected. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations or similar regulatory requirements outside the United States. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or data privacy and security laws. Other countries' regulatory authorities also have requirements for clinical trials with which we must comply. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, *ClinicalTrials.gov*, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, do not meet expected deadlines, experience work stoppages, terminate their agreements with us or need to be replaced, or do not conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed, or terminated or may need to be repeated. If any of the foregoing occur, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or potential commercialization of our products, if and when approved, producing additional losses and depriving us of potential product revenue.

***We rely on third parties for certain aspects of the manufacture of our product candidates, and we expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or that such quantities may not be available at an acceptable cost, which could delay, prevent or impair our development or potential future commercialization efforts.***

We rely, and expect to continue to rely, on third parties for certain aspects of materials supply for our product candidates in preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates on a timely basis or at all, or that such quantities will be available at an acceptable cost or quality, which could delay, prevent or impair our development or potential future commercialization efforts.

We rely on third-party manufacturers, which entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- failure of third-party manufacturers to perform the manufacturing process adequately;
- breach of supply agreements by the third-party manufacturers;
- failure to supply components, intermediates, services, or product according to our specifications;

- failure to supply components, intermediates, services, or product according to our schedule or at all;
- misappropriation or disclosure of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of agreements by third-party manufacturers at times that are costly or inconvenient for us.

Third-party manufacturers may not be able to comply with current good manufacturing processes, or cGMP, regulations or similar regulatory requirements inside or outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products, if and when approved. If our manufacturers are unable to comply with cGMP regulation or similar regulatory requirements outside the United States or if the FDA or other regulatory authorities do not approve their facility upon a pre-approval inspection, our therapeutic candidates may not be approved or may be delayed in obtaining approval. In addition, there are a limited number of manufacturers that operate under cGMP regulations and similar regulatory requirements outside the United States that might be capable of manufacturing our products, if and when approved. Therefore, our product candidates and any future products that we may develop may compete with other products for access to manufacturing facilities. Any failure to gain access to these limited manufacturing facilities could severely impact the clinical development, marketing approval and potential future commercialization of our product candidates.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. Furthermore, if we breach or are perceived to breach our contractual obligations or otherwise default under our agreements with third parties, or if we otherwise have contractual disputes with such third parties, it may lead to adverse outcomes, including potential delays, unforeseen expenses, or the termination of those contracts. We do not currently have a second source for certain required materials used for the manufacture of finished product. If our current manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products could delay, prevent or impair our development and potential future commercialization efforts.

***We have limited experience manufacturing our product candidates commercially, and we cannot assure you that we can manufacture our product candidates in compliance with regulations at a cost or in quantities necessary to make them commercially viable.***

We have manufacturing facilities at our Cambridge, Massachusetts locations where we conduct process development, scale-up activities, the manufacture of active components for our biotherapeutic candidates, and quality control testing. We additionally utilize third-party contract manufacturers and test labs to perform product packaging and additional quality control testing. We may or may not utilize existing facilities and third-party vendors for future production, including to support commercial scale supply. We have no experience in manufacturing our product candidates to meet potential market demands and we may not be able to develop commercial-scale manufacturing facilities that are adequate to produce materials for commercial use. The FDA and other comparable foreign regulatory authorities must, pursuant to inspections that are conducted after submitting a BLA or relevant foreign marketing submission, confirm that the manufacturing processes for the product meet cGMP or similar regulatory requirements outside the United States. We have not yet had our manufacturing facilities inspected for our product candidates.

The equipment and facilities employed in the manufacture of pharmaceuticals are subject to stringent qualification requirements by regulatory agencies, including validation of facility, equipment, systems, processes and analytics. We may be subject to lengthy delays and expense in conducting validation studies, if we can meet the requirements at all.

#### **Risks Related to Our Product Candidates and Other Legal Matters**

***Our product candidates may fail to achieve the degree of market acceptance by physicians, patients, hospitals, third-party payors and others in the medical community necessary for commercial success.***

Even if any of our product candidates receive marketing approval, our product candidates may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates (if and when they are approved) do not achieve an adequate level of acceptance, we may not become profitable. The degree of market acceptance of any of our product candidates, if approved, will depend on a number of factors, including:

- their efficacy, safety and other potential advantages compared to alternative treatments;
- the clinical indications for which such products are approved;
- our ability to offer them for sale at competitive prices;
- their convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for our product candidates;
- the prevalence and severity of their side effects and their overall safety profiles;
- any restrictions on the use of our products, if and when approved, together with other medications;
- interactions of our products, if and when approved, with other medicines patients are taking; and
- the ability of patients to take our products, if and when approved.

***If we are unable to establish effective sales, marketing and distribution capabilities or enter into agreements with third parties with such capabilities, we may not be successful in commercializing any of our product candidates if and when they are approved.***

We have employees with experience in sales and marketing, but we have limited sales or marketing infrastructure and, as a company, have little experience in the sale, marketing, and distribution of pharmaceutical products. To achieve commercial success for any other product for which we obtain marketing approval, we will need to establish a sales and marketing organization and we may not be successful in doing so.

In the future, we expect to build a focused sales and marketing infrastructure, or certain components of such infrastructure, if we were to market our product candidates, if and when they are approved in the United States and potentially elsewhere. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay the launch of any approved product. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we or any collaborators cannot retain or reposition sales and marketing personnel.

Factors that may inhibit efforts to commercialize our product candidates, if and when approved, include:

- inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or educate physicians on the benefits of our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies.

Outside the United States, we intend to rely and may increasingly rely on third parties to sell, market and distribute our product candidates, if and when approved. We may not be successful in entering into arrangements with such third parties or may be unable to do so on terms that are favorable to us. In addition, our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates, if and when they are approved, effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

***We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.***

The development and commercialization of new drug and biologic products is highly competitive and is characterized by rapid and substantial technological development and product innovations. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. We are aware of a number of large pharmaceutical and biotechnology companies, as well as smaller, early-stage companies, that are pursuing the development or commercialization of products, including live biotherapeutics, for disease indications we are targeting. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others may be based on entirely different approaches. Potential competitors also include academic institutions, government agencies, not-for-profits, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors.

These third parties compete with us in recruiting and retaining qualified scientific, sales and marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we have or may in the future develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market, especially for any competitor developing a live biotherapeutic which will likely share our same regulatory approval requirements. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic or biosimilar products.

***Even if we are able to commercialize any of our product candidates, if approved, the products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, any of which would harm our business.***

Our ability to commercialize any of our product candidates successfully will depend, in part, on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and impact reimbursement levels.

Obtaining and maintaining adequate reimbursement for our product candidates may be difficult. We cannot be certain if and when we will obtain an adequate level of reimbursement for our product candidates by third-party payors. Even if we do obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review, and increasingly question the coverage of, and challenge the prices charged for, drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. We may also be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval, and potential royalties resulting from the sales of those products may also be adversely impacted.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost treatment approaches and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be reimbursed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control, including possible price reductions, even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. There can be no assurance that our product candidates, if they are approved for sale in the United States or in other

countries, will be considered medically necessary for a specific indication or cost-effective, or that coverage or an adequate level of reimbursement will be available.

***Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and an even greater risk with the commercial sale of any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- decreased demand for product candidates or products, if any;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize products that we develop, if any.

We currently hold \$10.0 million in product liability insurance coverage in the aggregate, with a per occurrence limit of \$10.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials, or if we commence commercialization of our product candidates, if and when approved. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

***We may face competition from biosimilars, which may have a material adverse impact on the future commercial prospects of our product candidates.***

If we obtain approval or any of our product candidates, we may face competition from biosimilars. In the United States, the Biologics Price Competition and Innovation Act, or BPCIA, enacted in 2010 as part of the Patient Protection and Affordable Care Act, created an abbreviated approval pathway for biological products that are demonstrated to be “highly similar,” or biosimilar, to or “interchangeable” with an FDA-approved biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until four years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. This pathway could allow competitors to reference data from innovative biological products 12 years after the time of approval of the innovative biological product, though the FDA may not approve an application relying on such data for a further eight years. This data exclusivity does not prevent another company from developing a product that is highly similar to the innovative product, generating its own data and seeking approval. Data exclusivity only assures that another company cannot rely upon the data within the innovator’s application to support the biosimilar product’s approval.

We believe that any of our product candidates approved as a biological product under a BLA should also qualify for the 12-year period of reference product exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated.

In the EU, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data supporting approval of an innovative biological product but will not be able to get on the market until 10 years after the time of approval of the innovative product. This 10-year marketing exclusivity period can be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilars in other countries that could compete with our product candidates. If competitors are able to obtain marketing approval for biosimilars referencing our

product candidates, our product candidates may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

***Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.***

In order to market and sell our product candidates in the EU and many other jurisdictions, we or our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval in foreign countries may differ substantially from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals for our product candidates from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our product candidates in any market.

***Any product candidate for which we obtain marketing approval will remain subject to significant post-marketing regulatory requirements and oversight.***

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to the continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP and similar foreign requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. We and our contract manufacturers will also be subject to continual review and periodic inspections to assess compliance with cGMP and similar foreign requirements. Accordingly, we, and any collaborator and others with whom we work, must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to specific conditions of approval, including a requirement to implement a risk evaluation and mitigation strategy, which could include requirements for a medication guide, communication plan, or restricted distribution system. If any of our product candidates receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the product.

The FDA or other regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of our approved products. The FDA or other regulatory authorities closely regulates the post-approval marketing and promotion of drugs and biologics to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Violations of the FDA's and other regulatory authorities' restrictions relating to the promotion of prescription drugs by us or any collaborators may also lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, if a regulatory authority, we or any collaborators later discover previously unknown problems with our product candidates, such as adverse events of unanticipated severity or frequency, problems with manufacturers or manufacturing processes, or failure to comply with regulatory requirements, the regulatory authority may impose restrictions on the products or us and any collaborators, including requiring withdrawal of the product from the market. Any failure by us or any collaborators to comply with applicable regulatory requirements may yield various results, including:

- litigation involving patients taking our products, if and when they are approved;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of products from the market;
- suspension or termination of ongoing clinical trials;

- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products, if and when they are approved;
- product seizure or detention;
- injunctions; or
- imposition of civil or criminal penalties.

Noncompliance with similar EU requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with U.S. and foreign regulatory requirements regarding the development of products for pediatric populations and the protection of personal health information can also lead to significant penalties and sanctions.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity.

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

***The FDA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses.***

If we or any collaborators are found to have improperly promoted off-label uses of approved products, including any of our product candidates that may be approved in the future, we may become subject to significant liability. The FDA and other regulatory authorities strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory authorities as reflected in the product's approved labeling. Physicians may nevertheless prescribe a product candidate that is approved in future, if any, to their patients in a manner that is inconsistent with the approved label. If we or any collaborators are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

***Our relationships and any collaborators' relationships with customers, physicians and third-party payors are and will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us or any collaborators to criminal sanctions, civil penalties, exclusion from governmental healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our and any collaborators' current and future arrangements with third-party payors, physicians and customers expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may restrict the business or financial arrangements and relationships through which we market, sell and distribute any other products for which we may in the future obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be

made under a federal healthcare program, such as Medicare and Medicaid; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the False Claims Act, imposes, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier. To the extent our patient assistance programs are found to be inconsistent with applicable laws, we may be required to restructure or discontinue such programs, or be subject to other significant penalties;
- HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them to have committed a violation;
- the federal Physician Payment Sunshine Act requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiology assistants, and certified nurse midwives), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; manufacturers are required to submit reports to the government by the 90th day of each calendar year; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to our business practices, including but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government (or foreign governments) and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, pricing information or marketing expenditures.

The risk of us or any collaborators being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us or any collaborators for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain a robust system to comply with multiple jurisdictions with different compliance and reporting requirements increases the possibility that we may violate one or more of the requirements.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement, and the curtailment or restructuring of our operations.

***Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our other potential product candidates are the following:

- establishment of a new pathway for approval of lower-cost biosimilars to compete with biologic products, such as those we are developing or commercializing;
- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, enacted in August 2011, required sequestration that included aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2032, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will increase in future years of the sequester. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and an increase in the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, in March 2021, the American Rescue Plan Act of 2021 was signed into law, which, among other things, eliminated the statutory cap on drug manufacturers' Medicaid Drug Rebate Program rebate liability, effective January 1, 2024. Drug manufacturers' Medicaid Drug Rebate Program rebate liability was previously capped at 100% of the average manufacturer price for a covered outpatient drug. We expect that other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to price our product candidates, if and when they are approved, at what we consider to be a fair or competitive price, generate revenue, attain profitability, or commercialize our product candidates, if approved.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Individual states in the United States have become increasingly active in implementing regulations designed to contain pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Most significantly, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. The Centers for Medicare & Medicaid Services, or CMS, has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and has published the list of the subsequent 15 drugs that will be subject to negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our ability to price our product candidates, if and when they are approved, appropriately, which could negatively impact our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

***Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.***

In some countries, particularly the EU member states, the pricing of certain pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various EU member states and parallel distribution or arbitrage between low-priced and high-priced member states, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. Even if a pharmaceutical product obtains a marketing authorization in the EU, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all. If coverage and reimbursement of our product candidates, if and when they are approved, are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels that impacts our ability to compete with other products or our ability to recoup our costs of developing our product candidates, our business could be harmed, possibly materially.

### **Risks Related to Our Intellectual Property**

***If we are unable to adequately protect our proprietary technology or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.***

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions. Prosecution of our patent portfolio is at various stages. We have successfully obtained multiple patents (both U.S. and foreign) in some patent families. In others, prosecution is at an early stage (e.g., provisional or PCT stage). For many patent applications in our portfolio, we have filed national stage applications based on our Patent Cooperation Treaty, or PCT, applications, thereby limiting the jurisdictions in which we can pursue patent protection for the various inventions claimed in those applications. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as, with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results.

We have obtained licenses from third parties and may obtain additional licenses and options in the future. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. We may also require the cooperation of our licensors to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license could have a material adverse impact on our business.

We have had in the past, and may have in the future, certain funding arrangements. Such funding arrangements impose various obligations on us, including reporting obligations, and may subject certain of our intellectual property, such as intellectual property made using the applicable funding, to the rights of the U.S. government under the Bayh-Dole Act. Any failure to comply with our obligations under a funding arrangement may have an adverse effect on our rights under the applicable agreement or our rights in the applicable intellectual property. Compliance with our obligations or the exercise by the government or other funder of its rights, may limit certain opportunities or otherwise have an adverse effect on our business.

Our patent portfolio currently includes 21 active patent families (which includes exclusive licenses to certain IP from Memorial Sloan Kettering Cancer Center). Of these, 19 applications have been nationalized, one is at the PCT stage, and one is at the provisional stage. To date, we have obtained issuance of 32 U.S. patents (which includes three as licensee). Of the issued U.S. patents, 13 U.S. patents (including one as licensee) have been assigned to Nestlé Health Science as part of its purchase of VOWST. We cannot provide any assurances that any of our pending patent applications will mature into issued patents and, if they do, that such patents or our current patents will include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. For example, we are pursuing claims to therapeutic, binary compositions of certain bacterial populations. Any claims that may issue may provide coverage for such binary compositions and/or their use. However, there can be no assurance that an alternative composition that may fall outside the scope of such claims will not be equally effective. Further, while our product candidates are made up of specific cultivated bacteria, third-party compositions may have greater complexity and variability (e.g., lot to lot variations), and it is possible that a patent claim may provide coverage for some but not all third-party compositions. These and other factors may provide opportunities for our competitors to design around our patents, should they issue.

Moreover, other parties have developed technologies that may be related or competitive to our approach and may have filed or may file patent applications and may have received or may receive patents that may overlap or conflict with our patent applications, either by claiming similar methods or by claiming subject matter that could dominate our patent position or cover one or more of our product candidates. In addition, given the on-going prosecution of our portfolio, we continue development of our understanding of how patent offices react to our patent claims and whether they identify prior art of relevance that we have not already considered.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in any owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions, nor can we know whether those from whom we may license patents were the first to make the inventions claimed or were the first to file. For these and other reasons, the issuance, scope, validity, enforceability and commercial value of our patent rights are subject to a level of uncertainty. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

We may be subject to third-party preissuance submissions of prior art to the United States Patent and Trademark Office, or USPTO, or in a foreign jurisdiction in which our applications are filed, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. For example, on April 25, 2017, we filed a notice of opposition in the European Patent Office challenging the validity of a patent issued to The University of Tokyo. See “—*Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.*” The oral proceedings were held at the European Patent Office on February 18, 2019 and the Opposition Division required The University of Tokyo to narrow the scope of the claims of the patent. The University of Tokyo appealed certain aspects of the Opposition Division’s decision, as did we and other opponents. On November 18, 2022, The University of Tokyo requested termination of the appeal proceeding and revocation of its patent. On December 19, 2022, the Opposition Division officially terminated the appeal proceeding, and European Patent No. 2 575 835 B1 has been revoked in its entirety.

An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates. The issuance, scope, validity, enforceability and commercial value of our patents are subject to a level of uncertainty.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering biotechnological and pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if issued, a patent’s validity, inventorship, ownership or enforceability is not conclusive. Accordingly, rights under any existing patent or any patents we might obtain or license may not cover our product candidates, or may not provide us with sufficient protection for our product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our pending patent applications, if issued, will include claims having a scope sufficient to protect any products or product candidates;
- any of our pending patent applications will issue as patents at all;
- we will be able to successfully commercialize any of our product candidates, if approved, before our relevant patents expire;
- we were the first to make the inventions covered by any existing patent and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe or design around our patents;
- others will not use pre-existing technology to effectively compete against us;
- any of our patents, if issued, will be found to ultimately be valid and enforceable;
- third parties will not compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we will be able to obtain and/or maintain necessary or useful licenses on reasonable terms or at all;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- our commercial activities or products will not infringe upon the patents or proprietary rights of others.

Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. Even if we are successful, domestic or foreign litigation, or USPTO or foreign patent office proceedings, may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential collaborators, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

***If we are unable to protect the confidentiality of our trade secrets and know-how, our business and competitive position may be harmed.***

In addition to seeking patents for some of our technology and product candidates, we also utilize our trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also seek to enter into confidentiality and invention or patent assignment agreements with our employees, advisors and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, patent reform legislation could further increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular the first to file provisions, became effective on March 16, 2013. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Thus, for our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. Moreover, some of the patent applications in our portfolio will be subject to examination under the pre-Leahy-Smith Act law and regulations, while other patent applications in our portfolio will be subject to examination under the law and regulations, as amended by the Leahy-Smith Act. This introduces additional complexities into the prosecution and management of our portfolio.

In addition, the Leahy-Smith Act limits where a patentee may file a patent infringement suit and provides opportunities for third parties to challenge any issued patent in the USPTO. These provisions apply to all of our U.S. patents, even those filed before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a federal court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims because it may be easier for them to do so relative to challenging the patent in a federal court action. It is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. From time to time, the Supreme Court, other federal courts, Congress, or the USPTO, may change the standards of patentability and any such changes could have a negative impact on our business.

A number of cases decided by the Supreme Court have involved questions of when claims reciting abstract ideas, laws of nature, natural phenomena and/or natural products are eligible for a patent, regardless of whether the claimed subject matter is otherwise novel and inventive. These cases include *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 12-398 (2013); *Alice Corp. v. CLS Bank International*, 573 U.S. 13-298 (2014); and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 10-1150 (2012). In response to these cases, the USPTO has issued guidance to the examining corps.

The USPTO first issued a memorandum reflecting the USPTO's interpretation of the cases related to patent eligibility of natural products on March 4, 2014, which it subsequently revised and expanded upon in several additional updates now incorporated into its Manual of Patent Examination Procedure. The USPTO's interpretation of the case law and new guidelines for examination may influence, possibly adversely, prosecution and defense of certain types of claims in our portfolio.

In addition to increasing uncertainty with regard to our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on these and other decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change or be interpreted in unpredictable ways that would weaken our ability to obtain new patents or to enforce any patents that may issue to us in the future. In addition, these events may adversely affect our ability to defend any patents that may issue in procedures in the USPTO or in courts.

***Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.***

Our commercial success depends upon our ability, and the ability of any collaborators, to develop, manufacture, market and sell our product candidates, if approved, and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. For example, on August 20, 2024, Vedanta Biosciences, Inc. and The University of Tokyo filed a complaint against us and Nestlé S.A., Nestlé Health Science S.A., Nestlé Health Science US Holdings, Inc. and SPN in the United States District Court for the District of Delaware alleging that the making, sale and use of VOWST infringes on U.S. Patent Nos. 9,433,652, 9,662,381, 9,808,519, 10,555,978, and 11,090,343. The complaint seeks unspecified damages, fees, expenses and injunctive relief. We believe the complaint is without merit and intend to defend ourselves vigorously against the claims. While we have not been held by any court to have infringed a third party's intellectual property rights, we cannot guarantee that our technology or our product candidates, or use of our product candidates do not infringe third-party patents.

We are aware of numerous patents and pending applications owned by third parties in the fields in which we are developing product candidates, both in the United States and elsewhere. However, we may have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology or our product candidates. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of our product candidates, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies or our product candidates or the use of our product candidates. We are aware of several pending patent applications containing one or more claims that could be construed to cover some of our product candidates or technology, should those claims issue in their original form or in the form presently being pursued. In addition, we are aware of third-party patent families that include issued and allowed patents, including in the United States, including claims that, if valid and enforceable, could be construed to cover some of our product candidates or their methods of use. On April 25, 2017, we filed a notice of opposition in the European Patent Office challenging the validity of a patent issued to The University of Tokyo and requesting that it be revoked in its entirety for the reasons set forth in our opposition. The oral proceedings were held at the European Patent Office on February 18, 2019 and the Opposition Division required The University of Tokyo to narrow the scope of the claims of the patent. The University of Tokyo appealed certain aspects of the Oppositions Division's decision, as did we and other opponents. On November 18, 2022, The University of Tokyo requested termination of the appeal proceeding and revocation of its patent. On December 19, 2022, the Opposition Division officially terminated the appeal proceeding, and European Patent No. 2 575 835 B1 has been revoked in its entirety.

The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that our product candidates, or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including interference or derivation proceedings before the USPTO and similar bodies in other countries. Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future. If we were to challenge the validity of an issued U.S. patent in court, such as an issued U.S. patent of potential relevance to some of our product candidates or methods of use, we would need to overcome a statutory presumption of validity that attaches to every U.S. patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. There is no assurance that a court would find in our favor on questions of infringement or validity.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. If we are found or believe there is a risk we may be found, to infringe a third party's intellectual property rights, we could be required or may choose to obtain a license from such third party to continue developing and marketing our product candidates and technology. However, we may not be able to obtain any such license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our product candidates. Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease developing, selling or otherwise commercializing our product candidates;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and
- in the case of trademark claims, redesign, or rename, some or all of our product candidates or other brands to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

***Issued patents covering our product candidates could be found invalid or unenforceable or could be interpreted narrowly if challenged in court.***

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. If we initiated legal proceedings against a third party to enforce a patent, if and when issued, covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement, or failure to claim patent eligible subject matter. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Moreover, even if not found invalid or unenforceable, the claims of our patents could be construed narrowly or in a manner that does not cover the allegedly infringing technology in question. Such a loss of patent protection would have a material adverse impact on our business.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.***

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and, in some jurisdictions, during the pendency of a patent application. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

***We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.***

It is our policy to enter into confidentiality and intellectual property assignment agreements with our employees, consultants, contractors and advisors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. For example, even if we have a consulting agreement in place with an academic advisor pursuant to which such academic advisor is required to assign any inventions developed in connection with providing services to us, such academic advisor may not have the right to assign such inventions to us, as it may conflict with his or her obligations to assign all such intellectual property to his or her employing institution.

Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.***

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may also engage advisors and consultants who are concurrently employed at universities or other organizations or who perform services for other entities. Although we try to ensure that our employees, advisors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, advisors or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such party's former or current employer or in violation of an agreement with another party. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims.

In addition, while it is our policy to require our employees, consultants, advisors and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Similarly, we may be subject to claims that an employee, advisor or consultant performed work for us that conflicts with that person's obligations to a third party, such as an employer, and thus, that the third party has an ownership interest in the intellectual property arising out of work performed for us. Litigation may be necessary to defend against these claims. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

***We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.***

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than in the United States, assuming that rights are obtained in the United States and assuming that rights are pursued outside the United States. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications. For each of the patent families that we believe provide coverage for our product candidates, we decide whether and where to pursue protection outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, even if we do elect to pursue patent rights outside the United States, we may not be able to obtain relevant claims and/or we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Additionally, Europe's Unified Patent Court, or UPC, may present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. Although this new court has been implemented to provide more certainty and efficiency to patent enforcement throughout Europe, it will also provide our competitors with a new forum to use to centrally challenge our patents if opted into the UPC, rather than having to seek invalidity or non-infringement decisions on a country-by-country basis. It will be several years before the scope of patent rights that will be recognized and the strength of patent remedies that will be provided is known.

Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biotechnology. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

If our ability to obtain and, if obtained, enforce our patents to stop infringing activities is inadequate, third parties may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Accordingly, our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property we develop or license.

### **Risks Related to Our Operations**

***Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.***

We are highly dependent on Eric Shaff, our President and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and potential future commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy and execution. Our consultants and advisors

may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

***A variety of risks associated with operating internationally could materially adversely affect our business.***

We currently have limited international operations, but our business strategy incorporates potentially expanding internationally if any of our product candidates receive regulatory approval. We have conducted clinical studies in Australia and New Zealand in the past, and will likely in the future conduct clinical studies in other countries as well. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, including tariffs, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our product candidates in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- global macroeconomic conditions, including a continued increase in inflation rates or interest rates, labor shortages, supply chain shortages, disruptions and instability in the banking industry and other parts of the financial services sector, or other economic, political or legal uncertainties or adverse developments;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our product candidates and exposure to foreign currency exchange rate fluctuations;
- terrorism and/or political instability, unrest and wars, such as the conflicts involving Ukraine and Russia or Israel and its surrounding regions, which could delay or disrupt our business, and if such political unrest escalates or spills over to or otherwise impacts additional regions it could heighten many of the other risk factors included in this Item 1A;
- natural disasters (including as a result of severe weather events, climate change, or otherwise), which could cause significant damage to the infrastructure upon which our business operations rely, and the timing, nature or severity of which we may be unable to prepare for;
- economic instability, outbreak of disease or epidemics, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our results of operations.

***Our business and operations may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity.***

In the ordinary course of our business, we collect and store sensitive data, including personally identifiable information, intellectual property and proprietary business information owned or controlled by ourselves or our employees and other third parties. We manage and maintain our applications and data utilizing a combination of on-site systems and cloud-based data centers. We utilize external security and infrastructure vendors to manage parts of our data centers, and as a result a number of third-party vendors may or could have access to our confidential information. These applications and data encompass a wide variety of business-critical information, including research and development information, customer information, commercial information and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate or unauthorized access, use, modification or disclosure, and the risk of our being unable to adequately monitor and audit and modify our controls over our confidential information. This risk extends to the third-party vendors and subcontractors we use to manage this sensitive data or otherwise process it on our behalf. The secure processing, storage, maintenance and transmission of this

critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take reasonable measures to protect sensitive data from unauthorized access, use or disclosure, our information technology systems and those of our third-party service providers, strategic partners and other contractors or consultants are vulnerable to attack, damage and interruption from computer viruses and malware (e.g., ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization.

We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who continue to work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

We and certain of our service providers are from time to time subject to cyberattacks and security attempts or incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure of our trade secrets, personal information or other proprietary or sensitive information or other similar disruptions. If we or our third-party vendors were to experience a significant cybersecurity breach of our or their information technology systems or data, the costs associated with the investigation and remediation could be material. Any such real or perceived unauthorized access or use, breach, or other loss of confidential information could also result in regulatory scrutiny, reputational harm, legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, and regulatory enforcement, including penalties or fines. Notice of breaches may be required to affected individuals or state, federal or foreign regulators, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such notifications could be costly, harm our reputation and our ability to compete. Although we have implemented security measures to prevent unauthorized access, such data is currently accessible through multiple channels, and there is no guarantee that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and data from breach.

***Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.***

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials in the U.S. and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our results of operations, financial performance and business.

In the U.S., HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, or collectively HIPAA, imposes privacy, security and breach notification obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. Most healthcare providers, including research institutions from which we obtain clinical trial information, are subject to privacy and security regulations promulgated under HIPAA. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not regulated under HIPAA. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various

courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act or collectively, the CCPA, requires covered businesses that process personal information of California residents to, among other things: provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt-out of certain disclosures of their personal information; and enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Additional compliance investment and potential business process changes may also be required. Similar laws have passed in other states, and continue to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Furthermore, the Federal Trade Commission, or FTC, and many State Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. For example, in Europe, the European Union General Data Protection Regulation, or the GDPR, went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the European Economic Area, or EEA, or in the context of our activities within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant undertaking, whichever is greater. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/ or civil claims (including class actions). Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the EU states that reliance on the standard contractual clauses, or SCCs - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-U.S. Data Privacy Framework, or DPF, rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF.

We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Since the beginning of 2021, after the end of the transition period following the UK's departure from the European Union, we are also subject to the UK General Data Protection Regulation and Data Protection Act 2018, or collectively, the UK GDPR, which imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to £17.5 million or 4% of a noncompliant undertaking's global annual revenue for the preceding financial year, whichever is greater. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a data transfer mechanism from the UK to U.S. entities self-certified under the DPF. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

***Acquisitions, dispositions, joint ventures, or other strategic alternatives could disrupt our business, cause dilution to our stockholders and otherwise harm our business.***

We may from time to time acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses, investments in complementary businesses, dispose of assets, or pursue other strategic alternatives. We have not made any acquisitions to date, and our ability to do so successfully is unproven. On September 30, 2024, we completed the sale of our VOWST Business to SPN, which included all inventory and equipment, certain patents and patent applications, know-how, trade secrets, trademarks, domain names, marketing authorizations and related rights, documents, materials, business records and data and contracts that are used or held for use primarily in the development, commercialization and manufacturing of VOWST. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with future customers or with current or future distributors or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies or disposed assets or businesses;
- additional exposure to cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure;
- difficulties retaining or integrating acquired personnel, technologies and operations;
- diversion of management time and focus from operating our business to transaction, acquisition integration, or disposition-related challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- possible write-offs or impairment charges relating to acquired or disposed businesses; and
- inability to develop a sales force for any additional product candidates.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the anticipated benefit of any acquisition, disposition, or any other transaction or strategic alternative may not materialize. Future acquisitions, dispositions, or alternatives could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities, amortization expenses, or write-offs of goodwill, and may not achieve their intended benefits, any of which could harm our financial condition and our business. We cannot predict the number, timing or size of any transactions, or the effect that any such transactions might have on our operating results, our business, or our financial condition.

***We have in the past been subject to securities class action litigation and may be subject to similar or other litigation in the future, which may harm our business.***

Securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. On September 28, 2016, a purported stockholder filed a putative class action lawsuit in the U.S. District Court for the District of Massachusetts against us entitled *Mariusz Mazurek v. Seres Therapeutics, Inc., et.al.* alleging false and misleading statements and omissions about our clinical trials for our then product candidate SER-109 in our public disclosures between June 25, 2015 and July 29, 2016. Although this lawsuit has been dismissed by the court, should we face similar or other litigation again, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business. In addition, the uncertainty of a pending lawsuit or potential filing of additional lawsuits could lead to more volatility and a reduction in our stock price.

***We are subject to complex and changing laws and regulations, which exposes us to potential liabilities, increased costs and other adverse effects on our business.***

We are subject to complex and changing laws, regulations, and executive orders, and compliance with these laws and regulations and executive orders is onerous and expensive. New and changing laws, regulations, and executive orders can adversely affect our business by increasing our costs, limiting the Company's ability to pursue or offer a product candidate or product, and requiring changes to our business. New and changing laws, regulations, and executive orders can also create uncertainty about how such laws and regulations will be interpreted and applied. Regulatory changes and other actions that materially adversely affect our business may be announced with little or no advance notice we may not be able to effectively mitigate all adverse impacts from such measures. Differing interpretations of such legal obligations can expose us to significant fines, government investigations, litigation and reputational harm. If we are found to have violated laws, regulations, or executive orders, it could materially adversely affect our business, reputation, results of operations and financial condition.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials such as human stool. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***Our ability to use our net operating loss carryforwards and research and development credits to offset future taxable income or income tax liabilities may be subject to certain limitations.***

As of December 31, 2024, we had net operating loss carryforwards, or NOLs, of \$580.1 million for federal income tax purposes and \$543.6 million for state income tax purposes, which may be available to offset our future taxable income, if any. Our federal NOLs subject to expiration begin to expire in various amounts in 2035. Our federal NOLs generated in taxable years beginning after December 31, 2017 are not subject to expiration, but may generally only be used to offset 80% of taxable income in years beginning after December 31, 2020. Our state NOLs also begin to expire in various amounts in 2035. As of December 31, 2024, we also had federal and state research and development and other tax credit carryforwards of approximately \$46.5 million and \$8.1 million, respectively, net of uncertain tax position reserves, available to reduce future income tax liabilities, if any. Our federal and state tax credit carryforwards begin to expire in various amounts in 2031 and 2028, respectively. The federal research and development tax credit carryforwards include an orphan drug credit carryforward of \$25.9 million. These NOLs and tax credit carryforwards could expire unused, to the extent subject to expiration, and be unavailable to offset future taxable income or income tax liabilities.

In addition, in general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change" is subject to limitations on its ability to use its pre-change NOLs and tax credit carryforwards to offset future taxable income and income taxes. For these purposes, an ownership change generally occurs where the aggregate change in stock ownership of one or more stockholders or groups of stockholders owning at least 5% of a corporation's stock exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We have experienced ownership changes in the past, per a Section 382 study performed through December 31, 2024. We believe that none of our existing tax assets will expire unused as a result of the calculated limitations resulting from such ownership changes. However, we may have experienced additional ownership changes since December 31, 2024, and we may experience ownership changes in the future as a result of future transactions in our stock, some of which may be outside our control. If we have undergone additional ownership changes, or if we undergo ownership changes in the future, our ability to use our NOLs and tax credit carryforwards could be further limited. For these reasons, we may not be able to use a material portion of our NOLs or tax credit carryforwards, even if we attain profitability. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future tax benefits of such assets.

## Risks Related to Our Common Stock

***We have in the past and may again in the future receive a notice of the failure to satisfy a continued listing rule from Nasdaq.***

Nasdaq maintains several requirements for continued listing of our common stock, one of which is the maintenance of a minimum closing bid price of \$1.00. On November 7, 2024, we received written notice from Nasdaq notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the \$1.00 Bid Price Requirement for continued inclusion on The Nasdaq Global Select Market. Pursuant to the Nasdaq listing rules, we were provided a period of 180 calendar days, or until May 6, 2025 to regain compliance with the Bid Price Requirement.

On April 10, 2025, at our 2025 annual meeting of stockholders, our stockholders approved an amendment to our certificate of incorporation to effect a reverse stock split of all outstanding shares of our common stock. On April 21, 2025, we effected a 1-for-20 reverse stock split of our common stock. The reverse stock split had no impact on the number of authorized shares or the par value of preferred and common stock. Trading of our common stock on The Nasdaq Global Select Market commenced on a split-adjusted basis on April 22, 2025.

On May 6, 2025, we were notified by the Nasdaq Listing Qualifications staff that the closing bid price of our common stock had been at \$1.00 per share or greater for 10 consecutive business days, from April 22, 2025 to May 5, 2025. Accordingly, we have regained compliance with the Bid Price Requirement and this matter is now closed. If our common stock again closes below the \$1.00 per share minimum bid price required by Nasdaq for 30 consecutive business days, we would again receive another notice of non-compliance with Nasdaq's listing standards and face the risk of delisting.

If, in the future, our common stock fails to meet the Bid Price Requirement and we have effected a reverse stock split within the prior one-year period, we will not be eligible for any compliance period to address the bid price deficiency and would be issued a delisting determination rather than be granted a compliance period. Under these circumstances, we could appeal the delisting determination to a Nasdaq hearing panel, during which time any suspension or delisting action will ordinarily be stayed. If we were eligible for a compliance period, there can also be no assurance that we would regain compliance with the Bid Price Requirement during the 180-day compliance period, secure a second 180-day period to regain compliance, maintain compliance with the other Nasdaq listing requirements, or be successful in appealing any delisting determination.

If our common stock is delisted in the future, it is unlikely that we will be able to list our common stock on another national securities exchange on a timely basis or at all, and, as a result, we expect our securities would be quoted on an OTC market. If this were to occur, we and our stockholders could face significant material adverse consequences, including limited availability of market quotations and analyst coverage for our common stock, and reduced liquidity for the trading of our securities. Delisting also could result in, among other things, a loss of investor confidence or interest in strategic transactions or opportunities, us being subject to regulation in each state in which we offer our securities, and difficulty in recruiting and retaining personnel through equity incentive awards.

***Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to significantly influence all matters submitted to stockholders for approval.***

Our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock and their respective affiliates, in the aggregate, hold shares representing approximately 38% of our outstanding voting stock as of December 31, 2024. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management and the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

***A significant portion of our total outstanding shares are eligible to be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We have also registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

***We are a “smaller reporting company,” and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.***

We are a “smaller reporting company” as defined under the rules promulgated under the Exchange Act. We will remain a smaller reporting company until the fiscal year following the determination that both (i) the value of our voting and non-voting common shares held by non-affiliates is more than \$250.0 million measured on the last business day of our second fiscal quarter and (ii) our annual revenues are more than \$100.0 million during the most recently completed fiscal year and the value of our voting and non-voting common shares held by non-affiliates is \$700.0 million or more as measured on the last business day of our second fiscal quarter. Smaller reporting companies are able to provide simplified executive compensation disclosure and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, or supplemental financial information.

We have elected to take advantage of certain of the reduced reporting obligations, and may in the future take advantage of these or others. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile.

***Provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders’ meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer’s own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

***Our certificate of incorporation designates the Court of Chancery of the State of Delaware, subject to certain exceptions, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders and our bylaws designate the federal district courts of the United States as the exclusive forum for actions arising under the Securities Act of 1933, as amended, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders. In addition, our bylaws provide that the federal district courts of the United States are the exclusive forum for any complaint raising a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our restated certificate of incorporation and bylaws described above.

We believe these choice of forum provisions benefit us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes and in the application of the Securities Act by federal judges, as applicable, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provisions may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our restated certificate of incorporation or bylaws to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provisions contained in our restated certificate of incorporation or bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

***Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our stockholders.***

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

#### **General Risk Factors**

***The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.***

Our stock price is likely to be volatile. Furthermore, the stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price they paid for their common stock. The market price for our common stock may be influenced by many factors, including:

- our ability to realize the benefits of the Transaction with SPN;
- our ability to execute and realize the benefits of strategic plans;
- our requirement for additional funding in the first quarter of 2026;
- our continued compliance with stock exchange listing standards;
- the success of competitive products or technologies;
- actual or anticipated changes in our growth rate relative to our competitors;
- results of clinical trials of our product candidates or those of our competitors;
- the success of any potential future commercialization efforts;
- developments related to any future collaborations;
- regulatory or legal developments in the United States and other countries;
- development of new product candidates that may address our markets and may make our product candidates less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;

- announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

***If securities or industry analysts issue an adverse or misleading opinion regarding our business, our common stock price and trading volume could decline.***

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical studies and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

***We will continue to incur costs as a result of being a public company, and our management will continue to devote substantial time to compliance initiatives and corporate governance practices.***

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote and will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, we expect that these rules and regulations will continue to make it more difficult and more expensive for us to maintain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in future uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.***

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations.

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. Additionally, at such time that we are no longer a non-accelerated filer, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are unable to maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a public company or comply with the requirements of the Securities and Exchange Commission or Section 404. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

***Failure to keep up with evolving and conflicting laws, regulations, trends and stakeholder expectations relating to environmental, social and governance, or ESG, practices or reporting could adversely impact our reputation, share price and access to and cost of capital or otherwise adversely impact our business.***

Certain institutional investors, investor advocacy groups, investment funds, creditors and other influential financial market participants, as well as governments, regulators, customers, patients, employees and other stakeholders or third parties, have become increasingly focused on companies' ESG practices, including the impact of business on the environment. Certain organizations also provide ESG ratings, scores and benchmarking studies that assess companies' ESG practices. Although there are no universal standards for such ratings, scores or benchmarking studies, they are used by some investors to inform their investment and voting decisions. It is possible that our future stockholders or organizations that report on, rate or score ESG practices will not be satisfied with our ESG strategy or performance. Unfavorable press about or ratings or assessments of our ESG strategies or practices, regardless of whether or not we comply with applicable legal requirements, may lead to negative investor sentiment toward us, which may hinder the Company's access to capital.

Our reputation could be damaged if we do not, or are perceived not to, meet evolving stakeholder demand with respect to ESG matters, which could adversely affect our business, financial condition, profitability and cash flows. We may be criticized for our lack of ESG initiatives or goals or perceived as not taking sufficient action or for taking too much action in connection with any of these matters. In turn, we may take certain or terminate other actions to respond to evolving demand by regulators, governmental officials, investors, employees and other stakeholder; however, such actions may be costly or be subject to numerous conditions that are outside our control, and we cannot guarantee that we will meet these goals or targets or that such actions will have the desired effect even if met.

There has been an increase in litigation related to corporate diversity, equity and inclusion programs. Relatedly, both advocates and opponents to certain environmental and social matters are increasingly resorting to a range of activism forms, including media campaigns, shareholder proposals, and litigation, to advance their perspectives. To the extent we are subject to such litigation, activism or pressure, we may be required to incur costs or it may otherwise adversely impact our business or reputation.

Additionally, we and/or other parties in our value chain are subject to, or are expected to be subject to additional climate and other ESG-related obligations arising from legislation and regulation in the United States, the European Union and other jurisdictions, including new reporting requirements, even as the availability and quality of the information that may be required to comply with such laws and regulations remains limited. We expect for our compliance costs with these laws, regulations, and reporting requirements to increase in the future, and any failure, or perceived failure, by us to adhere to such laws, regulations, and reporting requirements, or meet evolving and varied stakeholder expectations and standards, could harm our business, reputation, financial condition, and operating results.

## **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None.

## **Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

None.

**Item 5. Other Information.**

a) *Disclosure in lieu of reporting on a Current Report on Form 8-K.*

None.

b) *Material changes to the procedures by which security holders may recommend nominees to the board of directors.*

None.

c) *Insider trading arrangements and policies.*

During the three months ended March 31, 2025, no director or officer of the Company adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

**Item 6. Exhibits.**

Exhibit Number	Exhibit Description	Form	Incorporated by Reference		Filing Date	Filed/ Furnished Herewith
			File No.	Exhibit		
3.1	<a href="#">Restated Certificate of Incorporation, filed on July 1, 2015</a>	8-K	001-37465	3.1	7/1/15	
3.2	<a href="#">Certificate of Amendment to Restated Certificate of Incorporation of Seres Therapeutics, Inc., dated June 27, 2023</a>	8-K	001-37465	3.1	6/28/23	
3.3	<a href="#">Certificate of Amendment to Restated Certificate of Incorporation of Seres Therapeutics, Inc., dated April 5, 2024</a>	8-K	001-37465	3.1	4/8/24	
3.4	<a href="#">Certificate of Amendment to Restated Certificate of Incorporation of Seres Therapeutics, Inc., dated April 21, 2025</a>	8-K	001-37465	3.1	4/22/25	
3.6	<a href="#">Amended and Restated Bylaws</a>	8-K	001-37465	3.1	1/2/24	
10.1	<a href="#">Seres Therapeutics, Inc. 2025 Incentive Award Plan</a>	8-K	001-37465	10.1	4/14/25	
10.2	<a href="#">Non-Employee Director Compensation Policy</a>					*
31.1	<a href="#">Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer</a>					*
31.2	<a href="#">Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer</a>					*
32.1	<a href="#">Section 1350 Certification of Chief Executive Officer</a>					**
32.2	<a href="#">Section 1350 Certification of Chief Financial Officer</a>					**
101.INS	Inline XBRL Instance Document - the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

\* Filed herewith.  
\*\* Furnished herewith.

**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 thereunto duly authorized.

**SERES THERAPEUTICS, INC.**

Date: May 7, 2025

By: /s/ Marella Thorell

Marella Thorell

Executive Vice President and Chief Financial Officer

*(Principal Financial and Accounting Officer)*

## SERES THERAPEUTICS, INC.

## NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

(as amended effective March 27, 2025) (the “*Effective Date*”)

Non-employee members of the board of directors (the “*Board*”) of Seres Therapeutics, Inc. (the “*Company*”) shall receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program (this “*Program*”). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board (other than the determination by the Compensation and Talent Committee of the number of Shares subject to an Initial Award as set forth in Section II(A)), to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a “*Non-Employee Director*”) who is entitled to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors. No Non-Employee Director shall have any rights hereunder, except with respect to stock options granted pursuant to the Program.

**I. CASH COMPENSATION**

A. Annual Retainers. Each Non-Employee Director shall receive an annual retainer of \$45,000 for service on the Board.

B. Additional Annual Retainers. In addition, each Non-Employee Director shall receive the following annual retainers:

1. *Chairman of the Board or Lead Independent Director*. A Non-Employee Director serving as Chairman of the Board or Lead Independent Director shall receive an additional annual retainer of \$35,000 for such service.

2. *Audit Committee*. A Non-Employee Director serving as Chairperson of the Audit Committee shall receive an additional annual retainer of \$20,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Audit Committee shall receive an additional annual retainer of \$10,000 for such service.

3. *Compensation and Talent Committee*. A Non-Employee Director serving as Chairperson of the Compensation and Talent Committee shall receive an additional annual retainer of \$15,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Compensation and Talent Committee shall receive an additional annual retainer of \$7,500 for such service.

4. *Nominating and Corporate Governance Committee*. A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance

Committee shall receive an additional annual retainer of \$10,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of \$5,000 for such service.

5. *Research and Clinical Development Committee.* A Non-Employee Director serving as Chairperson of the Research and Clinical Development Committee shall receive an additional annual retainer of \$15,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Research and Clinical Development Committee shall receive an additional annual retainer of \$7,500 for such service.

C. Payment of Retainers. The annual retainers described in Sections I(A) and I(B) shall be earned on a quarterly basis based on a calendar quarter and shall be paid in cash by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section I(B), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

D. Annual Retainer Election.

1. *Election.* Prior to 5:00 p.m. Eastern time on (a) April 30, 2024 for the first Service Year (as defined below) commencing after the Effective Date (the “**Initial Service Year**”) and (b) for each Service Year after the Initial Service Year, December 31 of the immediately preceding Service Year (in each case, the “**Election Deadline**”), by delivery to the Company of a written election in a form provided by the Company (an “**Election**”), a Non-Employee Director may elect to receive payment of the entire annual retainer payable to the Non-Employee Director pursuant to Sections I(A) and, if applicable, I(B)(1) for services performed during the period beginning on July 1 occurring after the Election Deadline and ending on June 30 of the following calendar year (each such period, a “**Service Year**”) in the form of one or more options (each, an “**Elective Option**”) to purchase shares of the Company’s common stock (“**Shares**”) as set forth in this Section I(D) and Section II(D) rather than in cash in accordance with Section I(A) and I(B)(1). A Non-Employee Director who makes an Election will be granted a separate Elective Option for the annual retainer in Section I(A) and for the annual retainer in Section I(B)(I) that such Non-Employee Director would, as of the applicable Issue Date (defined below), otherwise have been entitled to receive under this Program in cash for service on the Board during the applicable Service Year.

2. *Terms of Elective Option.* Each Elective Option will be granted automatically, without further action of the Board, on July 1 occurring after the Election Deadline (such date, the “**Issue Date**”), under and subject to the terms of the Company’s 2015 Incentive Award Plan or any other applicable Company equity incentive plan then maintained by the Company (the “**Equity Plan**”) and an award agreement, including attached exhibits, in substantially the form previously approved by the Board. The number of Shares subject to an Elective Option granted to a Non-Employee Director on the Issue Date will be determined by dividing (i) the cash amount of the annual retainer in Section I(A) or I(B)(1), as applicable that, absent the Non-Employee Director’s Election, would have otherwise been payable under this

Program (as in effect on the Issue Date) to the Non-Employee Director for the applicable Service Year by (ii) the Elective Option's Black-Scholes Value (as defined below) on the Issue Date, rounded to the nearest whole Share.

3. *Withdrawal and Service.* A Non-Employee Director may withdraw his or her Election at any time prior to the Election Deadline for a given Service Year, and thereafter, any Elections delivered to the Company and not previously withdrawn will become irrevocable with respect to the Service Year. Notwithstanding anything in this Section I(D) or any Election to the contrary, if a Non-Employee Director is not serving as a Non-Employee Director on the Issue Date or if the grant of an Elective Option described in this Section I(D) is otherwise prohibited under applicable laws, exchange listing rules or the terms of the Equity Plan, the Non-Employee Director's annual retainer, to the extent earned, shall be paid in cash under and subject to the terms of Section I(A) or I(B)(II), as applicable. A Non-Employee Director whose service as a Non-Employee Director on the Board commences during a given Service Year shall not be eligible to make an Election under this Program until the first Election Deadline that occurs following the date such Non-Employee Director commences service as a Non-Employee Director on the Board.

4. *Black-Scholes Value.* For purposes of this Section I(D), "**Black-Scholes Value**" means, with respect to an Elective Option, the per share fair value of the Elective Option determined as of the applicable Issue Date using the Black-Scholes or other option pricing model that the Company most recently applied when valuing grants of options with service-based vesting conditions for purposes of preparing its (audited or unaudited) consolidated financial statements that have been filed with the Securities Exchange Commission and using as inputs to such model (i) the simple average of the closing trading prices of a Share on each trading day occurring during the month of June that immediately precedes the Issue Date and (ii) such other assumptions as shall be determined by the Company's Chief Accounting Officer on or before the Issue Date.

## II. EQUITY COMPENSATION

Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Equity Plan and shall be granted subject to award agreements, including attached exhibits, in substantially the form previously approved by the Board. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein, and all grants of stock options hereby are subject in all respects to the terms of the Equity Plan and the applicable award agreement. For the avoidance of doubt, the share numbers in Sections II(A) and II(B) shall be subject to adjustment as provided in the Equity Plan, including without limitation with respect to any stock dividend, stock split, reverse stock split or other similar event affecting the Company's common stock that is effected prior to the Effective Date.

A. Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall receive an option to purchase 200,000 shares of the Company's common stock on the date of such initial election or appointment. The awards described in this Section II(A) shall be referred to as "**Initial Awards**." No Non-Employee Director shall be granted more than one Initial Award.

B. Subsequent Awards. A Non-Employee Director who (i) has been serving as a Non-Employee Director on the Board for at least six months as of the date of any annual meeting of the Company's stockholders after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall be automatically granted an option to purchase 100,000 Shares on the date of such annual meeting. The awards described in this Section II(B) shall be referred to as "**Subsequent Awards**." For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an annual meeting of the Company's stockholders shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Award on the date of such meeting as well.

C. Termination of Service of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section II(A) above, but to the extent that they are otherwise entitled, will receive, after termination from service with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section II(B) above.

D. Terms of Awards Granted to Non-Employee Directors

1. *Exercise Price*. The per share exercise price of each option granted to a Non-Employee Director shall equal the Fair Market Value (as defined in the Equity Plan) of a Share on the date the option is granted.

2. *Vesting*. Each Initial Award shall vest and become exercisable in four substantially equal annual installments following the date of grant, such that the Initial Award shall be fully vested on the fourth anniversary of the date of grant, subject to the Non-Employee Director continuing in service as a Non-Employee Director through each such vesting date. Each Subsequent Award shall vest and become exercisable on the earlier of the first anniversary of the date of grant or the day immediately prior to the date of the next annual meeting of the Company's stockholders occurring after the date of grant, in either case subject to the Non-Employee Director continuing in service on the Board as a Non-Employee Director through the applicable vesting date. Each Elective Option shall vest and become exercisable in four equal quarterly installments occurring on each October 1, January 1, April 1 and July 1 following the Issue Date, provided that if the next annual meeting of the Company's stockholders after the Issue Date occurs before the first anniversary of the Issue Date, the final quarterly vesting installment will vest on the day immediately prior to the date of such annual meeting, in each case, subject to the Non-Employee Director continuing in service on the Board as a Non-Employee Director through the applicable vesting date. Unless the Board otherwise determines, any portion of an Elective Option, Initial Award or Subsequent Award which is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board as a Non-Employee Director shall be immediately forfeited upon such termination of service and shall not thereafter become vested and exercisable. All of a Non-Employee Director's Elective Options, Initial Awards and Subsequent Awards shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.

**3. *Term.* The maximum term of each stock option granted to a Non-Employee Director hereunder shall be ten (10) years from the date the option is granted.**

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## CERTIFICATIONS

I, Eric D. Shaff, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Seres Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2025

By: /s/ Eric D. Shaff  
Eric D. Shaff  
President and Chief Executive Officer  
(Principal Executive Officer)

## CERTIFICATIONS

I, Marella Thorell, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Seres Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2025

By: /s/ Marella Thorell  
Marella Thorell  
Executive Vice President and Chief Financial Officer  
(Principal Financial and Accounting Officer)

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Eric D. Shaff, President and Chief Executive Officer of Seres Therapeutics, Inc. (the “Company”), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2025 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 7, 2025

/s/ Eric D. Shaff

Eric D. Shaff

President and Chief Executive Officer

*(Principal Executive Officer)*

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Marella Thorell, Executive Vice President and Chief Financial Officer of Seres Therapeutics, Inc. (the “Company”), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2025 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 7, 2025

/s/ Marella Thorell

Marella Thorell

Executive Vice President and Chief Financial Officer  
*(Principal Financial and Accounting Officer)*

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