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 September 30, 2024

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	**27-4326290**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
101 Cambridgepark Drive Cambridge, MA	**02140**
(Address of principal executive offices)	**(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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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 November 8, 2024, the registrant had 170,738,069 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, requirement for additional funding, business strategy, ability to recognize the benefits of the Transaction (as defined herein), including the Transaction Consideration (as defined herein), prospective products, product approvals, research and development costs, timing and likelihood of success, our ability to continue as a going concern, our ability to transfer the listing of our common stock to The Nasdaq Capital Market, regain compliance with any applicable Nasdaq listing requirements, implement a reverse stock split, or the timing of any of the foregoing, 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:

- The total amount of the Installment Payments (as defined herein) and Milestone Payments (as defined herein) we will receive from the Transaction, 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, and we may face new challenges as a smaller, less diversified company.

- We will need additional funding in order to complete development of our product candidates and commercialize our product candidates, if approved. If we are unable to raise capital when needed, 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.
- We rely on third parties for certain aspects of the manufacture of our product candidates and 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 any potential future commercialization efforts.
- We have received a notice of the failure to satisfy a continued listing rule from The Nasdaq Stock Market LLC.
- 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.
- 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.

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)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 66,824	$ 127,965
Prepaid expenses and other current assets	6,104	8,049
Current assets of discontinued operations	—	39,396
Total current assets	72,928	175,410
Property and equipment, net	12,566	17,614
Operating lease assets	82,910	90,417
Restricted cash	9,873	8,185
Restricted investments	—	1,401
Other non-current assets	465	2,187
Non-current assets of discontinued operations (1)	—	63,386
Total assets	$ 178,742	$ 358,600
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 8,254	$ 3,641
Accrued expenses and other current liabilities	17,716	22,509
Accrued liabilities due to SPN - related party	30,517	—
Operating lease liabilities	8,346	5,587
Current liabilities of discontinued operations (2)	—	66,922
Total current liabilities	64,833	98,659
Long term portion of note payable, net of discount	—	101,544
Operating lease liabilities, net of current portion	85,266	91,652
Accrued liabilities due to SPN, net of current portion - related party	2,941	—
Warrant liabilities	—	546
Other long-term liabilities	1,783	1,628
Non-current liabilities of discontinued operations	—	109,427
Total liabilities	154,823	403,456
Commitments and contingencies (Note 13)		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2024 and December 31, 2023; no shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value; 360,000,000 shares authorized at September 30, 2024 and 240,000,000 shares authorized at December 31, 2023; 170,200,253 and 135,041,467 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	170	135
Additional paid-in capital	986,211	933,244
Accumulated other comprehensive loss	—	—
Accumulated deficit	(962,462)	(978,235)
Total stockholders' equity (deficit)	23,919	(44,856)
Total liabilities and stockholders' equity (deficit)	$ 178,742	$ 358,600

[1] Includes $38,877 as of December 31, 2023 of milestones related to the construction of the Company's dedicated manufacturing suite at BacThera AG, or Bacthera.

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

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

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)

	Common Stock		Additional	Accumulated Other Comprehensive Loss (Income)		Total
	Shares	Par Value	Paid-in Capital		Accumulated Deficit	Stockholders' (Deficit) Equity
Balance at December 31, 2023	135,041,467	$ 135	$ 933,244	$ —	$ (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	609,962	1	(1)	—	—	—
Issuance of common stock under ESPP	423,975	—	353	—	—	353
Issuance of common stock from at the market equity offering, net of issuance costs of $548	15,366,630	15	18,394	—	—	18,409
Stock-based compensation expense	—	—	6,489	—	—	6,489
Net loss	—	—	—	—	(40,133)	(40,133)
Balance at March 31, 2024	151,442,034	$ 151	$ 958,479	$ —	$ (1,018,368)	$ (59,738)
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—
Issuance of common stock upon vesting of RSUs, net of tax withholdings	191,888	1	(1)	—	—	—
Stock-based compensation expense	—	—	5,534	—	—	5,534
Net loss	—	—	—	—	(32,870)	(32,870)
Balance at June 30, 2024	151,633,922	$ 152	$ 964,012	$ —	$ (1,051,238)	$ (87,074)
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—
Issuance of common stock upon vesting of RSUs, net of tax withholdings	830,953	1	(1)	—	—	—
Issuance of common stock under ESPP	164,460	—	134	—	—	134
Issuance of common stock from Securities Purchase Agreement - related party	14,285,715	14	13,502	—	—	13,516
Issuance of common stock from at the market equity offering, net of issuance costs of $196	3,285,203	3	3,381	—	—	3,384
Stock-based compensation expense	—	—	5,183	—	—	5,183
Net income	—	—	—	—	88,776	88,776
Balance at September 30, 2024	170,200,253	$ 170	$ 986,211	$ —	$ (962,462)	$ 23,919

	Common Stock		Additional	Accumulated Other Comprehensive Loss (Income)		Total
	Shares	Par Value	Paid-in Capital		Accumulated Deficit	Stockholders' (Deficit) Equity
Balance at December 31, 2022	125,222,273	$ 125	$ 875,181	$ (12)	$ (864,511)	$ 10,783
Issuance of common stock upon exercise of stock options	56,523	—	188	—	—	188
Issuance of common stock upon vesting of RSUs, net of tax withholdings	259,023	—	—	—	—	—
Issuance of common stock under ESPP	267,615	1	1,228	—	—	1,229
Issuance of common stock from at the market equity offering, net of issuance costs of $225	787,170	1	4,238	—	—	4,239
Stock-based compensation expense	—	—	6,850	—	—	6,850
Other comprehensive income	—	—	—	14	—	14
Net loss	—	—	—	—	(71,174)	(71,174)
Balance at March 31, 2023	126,592,604	$ 127	$ 887,685	$ 2	$ (935,685)	$ (47,871)
Issuance of common stock upon exercise of stock options	49,069	—	168	—	—	168
Issuance of common stock upon vesting of RSUs and PSUs, net of tax withholdings	177,629	—	—	—	—	—
Issuance of common stock from at the market equity offering, net of issuance costs of $304	1,218,377	1	7,490	—	—	7,491
Issuance of warrants (Note 9)	—	—	2,785	—	—	2,785
Stock-based compensation expense	—	—	13,492	—	—	13,492
Other comprehensive loss	—	—	—	(3)	—	(3)
Net income	—	—	—	—	46,552	46,552
Balance at June 30, 2023	128,037,679	$ 128	$ 911,620	$ (1)	$ (889,133)	$ 22,614
Issuance of common stock upon exercise of stock options	155,048	—	521	—	—	521
Issuance of common stock upon vesting of RSUs, net of tax withholdings	102,885	—	—	—	—	—
Issuance of common stock under ESPP	335,077	1	921	—	—	922
Stock-based compensation expense	—	—	8,673	—	—	8,673
Other comprehensive income	—	—	—	1	—	1
Net loss	—	—	—	—	(47,854)	(47,854)
Balance at September 30, 2023	128,630,689	$ 129	$ 921,735	$ -	$ (936,987)	$ (15,123)

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)

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net income (loss)	$ 15,773	$ (72,476)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation expense	17,206	29,015
Depreciation and amortization expense	4,383	4,611
Non-cash operating lease cost	7,223	6,450
Net (accretion) amortization of (discounts) premiums on investments	—	(236)
Gain on sale of VOWST Business, net of transaction costs	(146,707)	—
Amortization of debt issuance costs	1,413	730
Loss associated with extinguishment of debt	23,351	1,625
Loss on disposal of fixed assets	293	—
Impairment of long-lived assets	3,267	—
Change in fair value of warrant liabilities	(546)	(1,144)
Collaboration (profit) loss sharing - related party	—	5,158
Changes in operating assets and liabilities:		
Prepaid expenses and other current and other non-current assets	261	2,504
Collaboration receivable - related party	8,674	(16,857)
Inventories	(33,795)	(18,525)
Deferred income - related party	(4,124)	9,465
Deferred revenue - related party	—	(1,261)
Accounts payable	1,222	(6,539)
Operating lease liabilities	(4,367)	(1,635)
Accrued expenses and other current and long-term liabilities (3)	(3,254)	(10,740)
Net cash used in operating activities	(109,727)	(69,855)
Cash flows from investing activities:		
Purchases of property and equipment	(290)	(7,098)
Purchases of investments	—	(4,426)
Sales and maturities of investments	—	22,983
Sales of restricted investments	1,401	—
Proceeds from sale of VOWST Business	141,272	—
Net cash provided by investing activities	142,383	11,459
Cash flows from financing activities:		
Proceeds from at the market equity offering, net of issuance costs	21,793	11,730
Proceeds from exercise of stock options	—	877
Proceeds from Securities Purchase Agreement - related party	13,516	—
Issuance of common stock under ESPP	487	2,151
Proceeds from issuance of debt, net of issuance costs	—	103,378
Repayment of notes payable	(127,905)	(52,860)
Net cash (used in) provided by financing activities	(92,109)	65,276
Net (decrease) increase in cash, cash equivalents, and restricted cash	(59,453)	6,880
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	—	2
Cash, cash equivalents and restricted cash at beginning of period	136,150	171,215
Cash, cash equivalents and restricted cash at end of period	$ 76,697	$ 178,097
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 10,858	$ 8,966
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment purchases included in accounts payable and accrued expenses	$ 13	$ 370
Prepaid rent reclassified to right-of-use assets	$ —	$ 2,336
Lease liability arising from obtaining right-of-use assets	$ —	$ 1,235
Recognition of warrant liabilities	$ —	$ 2,100
Warrants issued related to Oaktree Term Loan and recorded as debt discount (Note 9)	$ —	$ 2,785

[3] Includes non-cash collaboration profits and losses related to pre-launch activities; subsequent to the approval of VOWST in April 2023, collaboration (profit) loss sharing - related party is included within changes in operating assets and liabilities.

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

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 epithelial barrier integrity, and induce immune tolerance to prevent bacterial bloodstream and antimicrobial resistant ("AMR") infections as well as other pathogen-associated negative clinical outcomes in patients undergoing allogeneic hematopoietic stem cell transplantation ("allo-HSCT"). The placebo-controlled Phase 1b study Cohort 2 results demonstrated that SER-155 was associated with a significant reduction in both bloodstream infections and 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 addition to allo-HSCT, the Company intends to evaluate SER-155 and other cultivated live biotherapeutic candidates in other medically vulnerable patient populations, including autologous-HSCT patients, cancer patients with neutropenia, chimeric antigen receptors therapy ("CAR-T") recipients, individuals with chronic liver disease, solid organ transplant recipients, as well as patients in the intensive care unit and long-term acute care facilities. SER-155 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.

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 $17,900 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 on January 15, 2025 and $25,000 on July 1, 2025 (the "Installment Payments"), 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 SPN;

(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 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 will 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 14,285,715 shares (the "Shares") of common stock at Closing, at a purchase price per share of $1.05, 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. The Securities Purchase Agreement contains customary representations and warranties and closing conditions.

On the Closing Date, the Company entered into a TSA with Nestlé Enterprises S.A., an affiliate of SPN ("NESA"), 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 NESA 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. NESA has agreed to pay the Company for certain fixed costs, including a monthly fixed fee for preserved raw material suspension manufacturing, and will reimburse the Company for certain costs of the transition services performed by the Company under the TSA. The know-how and other intellectual property generated in connection with the performance of the TSA will be owned by NESA 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 preserved raw material suspension manufacturing services to a third party service provider designated by NESA. In the event of a material failure by the Company to deliver preserved raw material suspension 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.

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.

The Company incurred certain significant costs relating to the Transaction, such as legal, accounting, financial advisory, printing and other professional services fees, as well as other customary payments. Through September 30, 2024, these costs amounted to approximately $9,016, which is included within the net income (loss) from discontinued operations, net of tax line item on the Company's condensed consolidated statement of operations.

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 September 30, 2024, the Company had an accumulated deficit of $962,462 and cash and cash equivalents of $66,824.

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 commercializing VOWST and continuing the research and development efforts for other product candidates and preclinical programs, the Company incurred a net loss from continuing operations of $110,134 and had net operating cash outflows of $109,727 for the nine months ended September 30, 2024. 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 September 30, 2024 and for the three and nine months ended September 30, 2024 and 2023 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, 2023 included in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2023, 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, 2023 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 and nine months ended September 30, 2024 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2024.

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 our condensed consolidated balance sheets for the periods presented. 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*.

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.

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, 2023, 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 nine months ended September 30, 2024, with the exception of those detailed below.

Discontinued Operations

The Company accounted for the sale of its VOWST Business in accordance with ASC 205 *Discontinued Operations* and ASU No. 2014-08, *Reporting of Discontinued Operations and Disclosures of Disposals of Components of an Entity*. The Company followed the held-for-sale criteria as defined in ASC 205. ASC 205 requires that a component of an entity that has been disposed of or is classified as held for sale and has operations and cash flows that can be clearly distinguished from the rest of the entity be reported as assets held for sale and discontinued operations. In the period a component of an entity has been disposed of, the results of operations for the periods presented are reclassified into separate line items in the unaudited condensed consolidated statements of operations. In the period a discontinued operation is classified for sale, the assets and liabilities of the discontinued operation are also reclassified into separate line items on the related condensed consolidated balance sheets for the periods presented.

Due to the sale of the VOWST Business during the third quarter of 2024 (see Note 3, *Discontinued Operations*), in accordance with ASC 205, *Discontinued Operations*, the Company has classified the results of the VOWST Business as discontinued operations in its unaudited condensed consolidated statements of operations and cash flows for all periods presented. All assets and liabilities associated with the Company's VOWST Business were therefore classified as assets and liabilities of discontinued operations in its condensed consolidated balance sheets for the periods presented. All amounts included in the notes to the unaudited condensed consolidated financial statements relate to continuing operations unless otherwise noted.

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 $9,873 as of September 30, 2024 and $8,185 as of December 31, 2023, 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):

	September 30, 2024	December 31, 2023
Cash and cash equivalents	$ 66,824	$ 127,965
Restricted cash, non-current	9,873	8,185
Total cash, cash equivalents and restricted cash	$ 76,697	$ 136,150

Recently Issued Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires public entities to disclose significant segment expenses and other segment items on an interim and annual basis, and provide in interim periods all disclosures about a reportable segment's profit or loss and assets that are currently required annually. The ASU does not change how a public entity identifies its operating segments, aggregates them, or applies the quantitative threshold to determine its reportable segments. The new disclosure requirements are also applicable to entities that account and report as a single operating segment entity. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact related to the adoption of ASU 2023-07 on its financial statement disclosures.

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, with early adoption permitted. 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

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 are classified as assets and liabilities of discontinued operations in the condensed consolidated balance sheets and the results of operations from the VOWST Business 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 following table presents the assets and liabilities of the discontinued operations as of December 31, 2023:

	December 31, 2023
Assets	
Current assets:	
Collaboration receivable - related party	$ 8,674
Inventories	29,647
Prepaid expenses and other current assets	1,075
Total current assets of discontinued operations	39,396
Property and equipment, net	4,843
Operating lease assets	19,376
Other non-current assets	39,167
Total non-current assets of discontinued operations	63,386
Total assets of discontinued operations	$ 102,782
Liabilities	
Current liabilities:	
Accrued expenses and other current liabilities	$ 58,102
Operating lease liabilities	1,090
Deferred income - related party	7,730
Total current liabilities of discontinued operations	66,922
Operating lease liabilities, net of current portion	14,063
Deferred revenue, net of current portion - related party	95,364
Total non-current liabilities of discontinued operations	109,427
Total liabilities of discontinued operations	$ 176,349

As of September 30, 2024, there were no assets or liabilities of discontinued operations.

The following table presents the gain on the sale of the VOWST Business as of September 30, 2024, pursuant to the Purchase Agreement:

	September 30, 2024
Consideration received	
Upfront payment (1)	$ 79,788
Prepaid milestone	60,000
Deferred revenue from termination of 2016 License Agreement	95,364
Settlement of net collaboration payable at close	27,465
Premium on equity financing	1,484
Deferred income from termination of 2021 License Agreement	3,606
Accrued liabilities due to SPN - related party	(33,458)
Total fair value transferred for business	$ 234,249
Net assets transferred	
Inventory	$ 63,442
Prepaid expenses and other current assets	2,219
Property and equipment, net	3,966
Operating lease assets	17,929
Other non-current assets	39,328
Accrued expenses and other current liabilities	(31,547)
Operating lease liabilities	(14,413)
Net assets transferred	$ 80,924
Transaction costs	$ 6,618
Gain on sale, pre-tax	$ 146,707
Income tax	—
Gain on sale, net of tax	$ 146,707

[1] The upfront payment 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.

For the three and nine months ended September 30, 2024, the gain from sale of the VOWST Business, net of tax of $146,707 was included in the net income (loss) from discontinued operations, net of tax line item of the Company's condensed consolidated statements of operations and comprehensive loss. While the Company has net income from discontinued operations for the three and nine months ended September 30, 2024, the Company is projecting book and tax losses for the full year ended December 31, 2024, for

which it is more likely than not that the Company will not realize a benefit. The Company has recorded a full valuation allowance against its net deferred tax assets as of September 30, 2024 and December 31, 2023.

The following table presents the financial results of the discontinued operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue:				
Collaboration revenue - related party	$ —	$ 310	$ —	$ 126,261
Total revenue	—	310	—	126,261
Operating expenses:				
Research and development expenses	1,532	3,099	5,809	24,460
General and administrative expenses	550	557	4,066	6,991
Collaboration (profit) loss sharing - related party	(1,325)	(519)	(1,496)	5,194
Total operating expenses	757	3,137	8,379	36,645
(Loss) income from discontinued operations	(757)	(2,827)	(8,379)	89,616
Other income (expense):				
Gain on sale of the VOWST business	146,707	—	146,707	—
Interest expense	(4,083)	(4,012)	(12,192)	(6,679)
Other expense	(2,056)	—	(229)	—
Income (loss) from discontinued operations, pre-tax	$ 139,811	$ (6,839)	$ 125,907	$ 82,937
Income tax	—	—	—	—
Net income (loss) from discontinued operations, net of tax	$ 139,811	$ (6,839)	$ 125,907	$ 82,937

In accordance with ASC 205-20, only expenses specifically identifiable and related to a business to be disposed may be presented in discontinued operations. As such, the research and development and general and administrative expenses in discontinued operations include corporate costs incurred directly to solely support the VOWST Business.

The Company has also entered into a TSA with NESA, through which 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. No expenses have been incurred and no reimbursements have been received in connection with the TSA for the three and nine months ended September 30, 2024.

The Company has estimated costs associated with certain accrued liabilities due to SPN as a loss contingency in accordance with ASC 450, *Contingencies.* These contingent liabilities are presented as Accrued Liabilities due to SPN from continuing operations on the condensed consolidated balance sheet as of September 30, 2024 and consist of the following:

	September 30, 2024
Profit Sharing Payments	$ 16,930
Royalties associated with the MSK Agreement	2,602
VOWST post-marketing safety surveillance study	982
80.1% of lease cost of Waltham facility	1,874
Employment-related costs for conveying employees	1,462
Settlement of collaboration payable (1)	9,608
Total accrued liabilities due to SPN	33,458

[1] Includes $6,594 and $3,014 related to the settlement of the collaboration payable to SPN for the quarters ended June 30, 2024 and September 30, 2024, respectively.

The contingent liabilities accrued on the Company's condensed consolidated balance sheet as of September 30, 2024 will be remeasured at each reporting period based on i) cash payments made by the Company to reduce the accrued liabilities due to SPN and ii) revised estimates of the total remaining liabilities due to SPN.

The Company has excluded from its condensed consolidated balance sheet 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. For the nine months ended September 30, 2024 and 2023, capital expenditures related to the VOWST

Business were $112 and $2,219, respectively. Depreciation expense related to the VOWST Business for the same periods was $989 and $1,468, respectively. Non-cash operating lease costs related to the VOWST Business for the nine months ended September 30, 2024 and 2023 were $1,447 and $1,451, respectively, while the share based compensation expense for the same periods were $1,884 and $1,947 respectively. The collaboration loss sharing (related party) related to the VOWST Business was $0 and $5,158 for the nine months ended September 30, 2024 and 2023, respectively. Excluding the gain of $146,707 recognized on the sale of the VOWST Business presented in the condensed consolidated statements of cash flows for the nine months ended September 30, 2024 there were no other material operating or investing non-cash items related to the VOWST Business for either period presented.

4. Fair Value Measurements

The following tables present the Company's fair value hierarchy for its assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements as of December 31, 2023 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 81	$ —	$ —	$ 81
Total assets	$ 81	$ —	$ —	$ 81
Warrant liabilities	$ —	$ —	$ 546	$ 546
Total liabilities	$ —	$ —	$ 546	$ 546

Money market funds are valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy.

As of September 30, 2024 and December 31, 2023, the Company held a restricted investment of $0 and $1,401, respectively, which represents a certificate of deposit that is classified as Level 2 in the fair value hierarchy.

Level 3 financial liabilities as of December 31, 2023 consisted of the warrant liabilities for which there is no current market such that the determination of fair value requires significant judgment or estimation. Changes in fair value measurements categorized within Level 3 of the fair value hierarchy were analyzed each period based on changes in estimates or assumptions and recorded through other income (expense). The Company used a Monte-Carlo simulation model which includes the Black-Scholes option pricing model to value the Level 3 warrant liabilities at inception and on each subsequent reporting date. This model incorporates transaction details such as the Company's stock price, contractual terms of the underlying warrants, maturity, risk free rates, volatility, as well as the term to achievement of estimated sales targets. The unobservable inputs for all of the Level 3 warrant liabilities are volatility and the term to achievement of estimated sales targets. The Company utilizes its historical and implied volatility, using its closing common stock prices and market data, to reflect future volatility over the expected term of the warrants. The Company estimated the time to achievement of sales targets of VOWST using information and forecasts generated by the Company in consideration of the terms of the 2021 License Agreement. As of September 30, 2024, given the repayment of the Oaktree Term Loan, the fair value of the warrant liabilities was deemed to be $0.

As of December 31, 2023, the Level 3 inputs to the warrant liabilities are as follows:

	December 31, 2023
Volatility	101.0 %
Term (in years)	1.3

A reconciliation of the beginning and ending balances for the nine months ended September 30, 2024 for liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows (in thousands):

	Warrant Liabilities
Balance as of December 31, 2023	$ 546
Issuance of warrants	—
Adjustment to fair value	(546)
Balance as of September 30, 2024	$ —

There were no assets or liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the nine months ended September 30, 2023. There were no transfers between Level 1, Level 2, or Level 3 during the three and nine months ended September 30, 2024 and 2023.

5. Investments

As of September 30, 2024 and December 31, 2023, the Company held restricted investments of $0 and $1,401, respectively, the cost of which approximates current fair value. The Company did not hold any other investments as of September 30, 2024 and December 31, 2023.

Investments with original maturities of less than 90 days are included in cash and cash equivalents on the condensed consolidated balance sheets and are not included in the table above. Investments with maturities of less than 12 months are considered current assets and those investments with maturities greater than 12 months are considered non-current assets.

6. Property and Equipment, Net

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

	September 30, 2024	December 31, 2023
Laboratory equipment	$ 24,553	$ 24,665
Computer equipment	3,672	3,672
Furniture and office equipment	4,509	4,752
Leasehold improvements	30,954	32,489
Construction in progress	1,050	1,114
	64,738	66,692
Less: Accumulated depreciation and amortization	(52,172)	(49,078)
	$ 12,566	$ 17,614

Depreciation and amortization expense was $1,404, $4,383, $1,684 and $4,611 for the three and nine months ended September 30, 2024 and 2023, respectively, which includes amounts related to both continuing and discontinued operations. During the nine months ended September 30, 2024 and 2023, the Company disposed of certain assets with a cost basis of $594 and $9, respectively. In addition, during the nine months ended September 30, 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 September 30, 2024. See Note 8, *Leases*, for further details.

7. Accrued Expenses and Other Current Liabilities

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

	September 30, 2024	December 31, 2023
Clinical and development costs	$ 889	$ 1,404
Manufacturing and quality costs	1,863	1,868
Payroll and payroll-related costs	8,276	16,465
Facility and other	6,688	2,772
	$ 17,716	$ 22,509

Included within the Facility and other caption as of September 30, 2024 is $4,578 of accrued transaction costs related to the sale of the VOWST Business. These amounts are expected to be paid in the normal course following the Closing of the Transaction.

8. Leases

The Company leases real estate, primarily laboratory, office and manufacturing space. The Company's leases have remaining terms ranging from approximately one to nine 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.

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 loss.

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

	September 30, 2024	December 31, 2023
Assets:		
Operating lease assets	$ 82,910	$ 90,417
Liabilities:		
Operating lease liabilities	$ 8,346	$ 5,587
Operating lease liabilities, net of current portion	85,266	91,652
Total operating lease liabilities	$ 93,612	$ 97,239

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating lease costs	$ 5,701	$ 5,544	$ 17,177	$ 16,496
Short-term lease costs	381	362	1,127	1,102
Variable lease costs	1,801	1,699	5,729	5,643
Sublease income	(814)	—	(1,884)	—
Total lease costs	$ 7,069	$ 7,605	$ 22,149	$ 23,241

During the three and nine months ended September 30, 2024 and 2023, the Company made cash payments for operating leases of $5,364, $14,321, $4,399, and $11,687, respectively. The lease cost and lease payment amounts above include amounts related to discontinued operations.

As of September 30, 2024, future payments of operating lease liabilities are as follows (in thousands):

	As of September 30, 2024
2024 (remaining 3 months)	$ 4,808
2025	19,442
2026	19,983
2027	20,582
2028	20,863
2029 and thereafter	56,994
Total future minimum lease payments	$ 142,672
Less: interest	(49,060)
Present value of operating lease liabilities	$ 93,612

As of September 30, 2024, the weighted average remaining lease term was 7.21 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 13%. As of September 30, 2023, the weighted average remaining lease term was 8.19 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 13%.

9. Notes Payable

On April 27, 2023 (the "Oaktree Closing Date"), the Company entered into the Credit Agreement and Guaranty (the "Oaktree Credit Agreement") among the Company, the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto (the "Lenders"), and Oaktree Fund Administration, LLC, in its capacity as administrative agent for the Lenders (in such capacity, the "Agent"). The Oaktree Credit Agreement established a term loan facility of $250,000 (the "Oaktree Term Loan") consisting of (i) $80,000 ("Tranche A-1") and (ii) $30,000 ("Tranche A-2" and collectively, "Tranche A Loan"), funded on the Oaktree Closing Date. The Oaktree Term Loan also consisted of (i) $45,000 (the "Tranche B Loan"), (iii) $45,000 (the "Tranche C Loan"), and (iv) $50,000 (the "Tranche D Loan"), which were available upon satisfaction of certain conditions or in Oaktree's sole discretion, but were not drawn before the extinguishment of the Oaktree Term Loan. The Oaktree Term Loan had a maturity date of April 27, 2029 (the "Maturity Date").

Of the $110,000 Tranche A Loan advanced by the Lenders at closing, approximately $53,380 repaid the Company's then existing credit facility with Hercules. After deducting other transaction expenses and fees, the Company received net proceeds of approximately $50,446. The Company accounted for the repayment of the Hercules credit facility as an extinguishment in accordance with the guidance in ASC 470-50, and recognized a loss on extinguishment of $1,625 in other income (expense) in the accompanying condensed consolidated statements of operations and comprehensive loss for the year ended December 31, 2023.

Borrowings under the Oaktree Term Loan bore interest at a rate per annum equal to the three-month term Secured Overnight Financing Rate ("SOFR") (subject to a 2.50% floor and a 5.00% cap), plus an applicable margin of 7.875%, payable quarterly in arrears. The Company was required to make quarterly interest-only payments on the Oaktree Term Loan for the first three years after the Oaktree Closing Date. The Company was obligated to pay the Lenders an exit fee equal to 1.50% of the aggregate amount of the Oaktree Term Loan funded, such exit fee was due and paid upon the prepayment of the outstanding Oaktree Term Loan. Such

prepayment was subject to a customary make-whole for the first two years following the Closing Date plus 4.0% of the principal amount of the Oaktree Term Loan prepaid.

On the Oaktree Closing Date, the Company issued to the Lenders warrants to purchase 647,589 shares (subject to certain adjustments) of the Company's common stock (the "Tranche A Warrant"), at an exercise price per share of $6.69. The Tranche A Warrant is immediately exercisable and the exercise period expires on April 26, 2030. Upon the funding of each of the Tranche B Loan and the Tranche C Loan, the Company was required to issue to the Lenders warrants to purchase 264,922 shares (subject to certain adjustments) of the Company's common stock on each such funding date at an exercise price equal to the trailing volume weighted average price of the Company's common stock for the 30 trading days prior to the funding date for each tranche (the "Tranche B Warrant" and the "Tranche C Warrant," respectively, and together the "Additional Warrants").

The Company determined that the Tranche A Loan, the Tranche A Warrant, the commitment by the Lenders to fund the Tranche B Loan and the Tranche C Loan, and the Tranche B Warrant and Tranche C Warrant, are all freestanding financial instruments. On the Oaktree Closing Date, the Company evaluated the Tranche A Warrant and determined that it meets the requirements for equity classification under ASC 815, *Derivatives and Hedging* ("ASC 815"). The net proceeds from the Tranche A Loan were allocated to the Tranche A Warrant and the Tranche A Loan using the relative fair value method, and the relative fair value of the Tranche A Warrant, $2,785, is recorded as an increase to additional paid-in-capital on the consolidated statements of stockholder's equity (deficit), and as a discount to the Tranche A Loan that will be amortized over the life of the Tranche A Loan using the effective interest method. The Company used the Black-Scholes option pricing model to determine the fair value of the Tranche A Warrant. Assumptions used in the Black-Scholes model included the fair market value per share of common stock on the valuation date of $5.32, the exercise price per warrant equal to $6.69, the expected volatility of 111.6%, the risk-free interest rate of 3.57%, the expected term of 7 years and the absence of a dividend.

The Additional Warrants were considered outstanding instruments at the Oaktree Closing Date of the Oaktree Credit Agreement and in accordance with ASC 815, were initially recognized at their respective fair values as derivative liabilities given the variable settlement amount of their respective aggregate exercise prices. The Company adjusted the carrying values of the Additional Warrants to their respective fair values at each reporting period, until such time that the Additional Warrants were issued and their respective exercise prices became fixed, and the value of the Additional Warrants was reclassified to additional paid-in capital. The Company used a simulation model to determine the fair value of the Additional Warrants, as described in Note 4, *Fair Value Measurements*. As of September 30, 2024, given the Transaction and repayment of the Oaktree Term Loan, the probability of drawing the Tranche B and C Loans that would trigger the issuance of these warrants was deemed to be remote. As a result, the fair value of Tranche B and C Warrants was deemed to be $0. The fair value of the Tranche B Warrant and Tranche C Warrant derivative liabilities was $276 and $270 as of December 31, 2023, respectively.

Changes in the fair values of the Additional Warrants were recorded as other income (expense) in the condensed consolidated statements of operations and comprehensive loss. In addition to the relative fair value of the Tranche A Warrant, the original issue discount and certain debt issuance costs were recorded as a discount to the Tranche A Loan, the total of which will be accreted to the Tranche A Loan as interest expense over the life of the Tranche A Loan using the effective interest method. The fair values of the derivative liabilities associated with the Tranche B Warrant and Tranche C Warrant are recorded as loan commitment prepaid assets on the Oaktree Closing Date, which are included in the condensed consolidated balance sheets in other non-current assets, and will be reclassified as discounts to the associated Oaktree Term Loan balances at such time that they are drawn.

As of December 31, 2023, the carrying value of the Oaktree Term Loan was $101,544, which was classified as a long-term liability on the condensed consolidated balance sheets.

During the three and nine months ended September 30, 2023, the Company recognized $0 and $2,468, respectively, of interest expense related to the Loan and Security Agreement with Hercules, which is reflected in interest expense on the condensed consolidated statements of operations and comprehensive loss.

On September 30, 2024, in connection with the sale of the VOWST Business to SPN, the Company terminated and voluntarily prepaid in full all outstanding amounts due under the Oaktree Credit Agreement. The Company paid $127,905 to Oaktree, representing $110,000 of principal, $3,698 of accrued interest, $12,457 of yield protection premium, $1,650 in exit fee, and $100 in third-party fees and expenses. In connection with the termination and repayment in full of all outstanding amounts under the Oaktree Credit Agreement, Oaktree terminated and released its liens and security interests in the collateral securing the Company's obligations under the Credit Agreement. The Company accounted for the repayment of the Oaktree Credit Facility as an extinguishment in accordance with the guidance in ASC 470-50, and recognized a loss associated with the extinguishment of $23,351 in other income (expense) in the accompanying condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2024.

10. Common Stock and Stock-Based Awards

On September 30, 2024, the Company entered into the Securities Purchase Agreement with SPN, pursuant to which SPN purchased 14,285,715 Shares at the Closing at a purchase price per share of $1.05, 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 February 22, 2024, the Company's board of directors adopted a resolution to amend the Restated Certificate of Incorporation, subject to stockholder approval, by increasing the number of authorized shares of the Company's Common Stock from 240,000,000 shares to 360,000,000 shares, (the “Share Increase Amendment”). At the Company’s annual meeting of stockholders held on April 4, 2024, the Company’s stockholders approved the Share Increase Amendment. On April 5, 2024, the Company amended its Restated Certificate of Incorporation to reflect the Share Increase Amendment.

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 under which Cowen acts as sales agent. During the three and nine months ended September 30, 2024, the Company sold 3,285,203 and 18,651,833 shares, respectively, of common stock under the Sales Agreement, at an average price of $1.09 and approximately $1.21 per share, respectively, raising aggregate net proceeds of approximately $3,384 and $21,793, after deducting an aggregate commission of approximately 3% and other issuance costs. During the three and nine months ended September 30, 2023, the Company sold 0 and 2,005,547 shares, respectively, of common stock under the Sales Agreement, at an average price of approximately $0 and $6.11 per share, respectively, raising aggregate net proceeds of approximately $0 and $11,730, respectively, 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, 2023:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	14,844,112	$ 9.64	5.71	$ —
Granted	7,817,641	$ 1.05		
Exercised	—	$ —		
Forfeited	(3,537,588)	$ 7.55		
Outstanding as of September 30, 2024	19,124,165	$ 6.52	6.62	$ 245
Vested or expected to vest as of September 30, 2024	19,124,165	$ 6.52	6.62	$ 245
Options exercisable as of September 30, 2024	10,066,354	$ 10.10	4.90	$ —

The weighted average grant date fair value of stock options granted during the three and nine months ended September 30, 2024 and 2023 was $0.88, $0.93, $3.14 and $4.52 per share, respectively.

During the year ended December 31, 2021, the Company granted performance-based stock options to employees for the purchase of an aggregate of approximately 562,000 shares of common stock with a grant date fair value of $5.53 per share. These stock options are exercisable only upon achievement of specified performance targets. In April 2023, the performance target associated with 50% of the performance-based stock options was achieved. Accordingly, the Company recorded $0, $8, $109 and $2,481 of compensation expense during the three and nine months ended September 30, 2024 and 2023, respectively, with respect to these performance-based stock options, which represents a cumulative catch-up from the grant date through the achievement of the performance targets, and vesting of the remaining 50% of the options beginning in April 2023. The remaining compensation expense associated with these performance-based stock options was recognized as of April 2024, for all such options for which ongoing performance targets were achieved and service requirements were met.

During the three months ended March 31, 2024, the Company granted stock options to certain executives for the purchase of an aggregate of 2,550,010 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 $1.10 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 and nine months ended September 30, 2024, the Company recognized $207 and $633 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, 2023:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted stock units as of December 31, 2023	3,377,804	$ 4.26
Granted	1,288,127	$ 1.09
Vested	(1,407,615)	$ 3.64
Forfeited	(503,327)	$ 3.16
Unvested restricted stock units as of September 30, 2024	2,754,989	$ 3.29

During the three and nine months ended September 30, 2024 and 2023, the Company granted 0, 1,288,127, 85,308 and 1,806,103 RSUs, respectively. During the three and nine months ended September 30, 2024 and 2023, the Company granted 0, 0, 0 and 1,322,715 PSUs, respectively. 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.

In November 2023, as part of the corporate restructuring described in Note 12, *Restructuring*, the Company issued retention awards to employees of the Company in the form of RSUs which vested as to the first tranche on August 15, 2024, and which will vest as to the second tranche on May 15, 2025, subject to remaining actively employed with the Company through such date. The compensation expense associated with these awards will be recognized ratably over the vesting period. For the three and nine months ended September 30, 2024, the Company recognized $178 and $536, respectively, in compensation expense with respect to the retention awards.

During the three months ended March 31, 2023, the Company granted PSUs to employees for the purchase of an aggregate of 1,322,715 shares of common stock with a grant date fair value of $5.50. These PSUs begin to vest ratably only upon achievement of specified performance targets, which were achieved in April 2023. Accordingly, the Company recorded $194, $721, $1,610 and $4,378 in compensation expense during the three and nine months ended September 30, 2024 and 2023, respectively, with respect to these PSUs. The remaining $71 in compensation expense associated with these PSUs will be recognized ratably through October 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 loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development expenses	$ 2,955	$ 4,744	$ 9,400	$ 16,326
General and administrative expenses	2,228	3,929	7,806	12,689
	$ 5,183	$ 8,673	$ 17,206	$ 29,015

Stock-based compensation expense related to discontinued operations is included in the table above and is disclosed within the financial results of discontinued operations in Note 3.

11. Net Loss per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss from continuing operations attributable to common stockholders	$ (51,035)	$ (41,015)	$ (110,134)	$ (155,413)
Net income (loss) from discontinuing operations attributable to common stockholders	$ 139,811	$ (6,839)	$ 125,907	$ 82,937
Net income (loss) attributable to common stockholders	$ 88,776	$ (47,854)	$ 15,773	$ (72,476)
Denominator:				
Weighted-average shares outstanding - basic and diluted	152,648,238	128,289,871	150,097,482	127,297,667
Net loss from continuing operations per share attributable to common stockholders, basic and diluted	$ (0.33)	$ (0.32)	$ (0.73)	$ (1.22)
Net income (loss) from discontinued operations per share attributable to common stockholders, basic and diluted	$ 0.92	$ (0.05)	$ 0.84	$ 0.65
Net income (loss) per share attributable to common stockholders, basic and diluted	$ 0.58	$ (0.37)	$ 0.11	$ (0.57)
Anti-dilutive potential common stock equivalents excluded from the calculation of net (loss) income per share:				
Stock options to purchase common stock	19,124,165	16,370,123	19,124,165	16,370,123
Unvested restricted stock units	2,754,989	3,826,695	2,754,989	3,826,695
Shares issuable under employee stock purchase plan	100,059	139,649	33,596	47,061
Warrants to purchase common stock	647,589	1,177,433	647,589	1,177,433

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 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 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.

The Company's potential dilutive securities, which include stock options, unvested restricted common stock and shares issuable under the 2015 Employee Stock Purchase Plan, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share and therefore be anti-dilutive. Additionally, for the three and nine months ended September 30, 2024 and 2023, the warrants to purchase common stock were excluded because the exercise price of the Tranche A Warrants was greater than the average fair value of the Company's common shares, and the necessary conditions for exercise of the Tranche B and Tranche C Warrants had not been met.

12. Restructuring

On November 2, 2023, the Company announced a restructuring plan to prioritize the commercialization of VOWST and the completion of the SER-155 Phase 1b study, while significantly reducing costs and supporting longer-term business sustainability. The restructuring plan included (i) a reduction of the Company's workforce by approximately 41% across the organization, resulting in the elimination of approximately 160 positions; (ii) significantly scaling back all non-partnered research and development activities other than the completion of the SER-155 Phase 1b study; and (iii) reducing general and administrative expenses, including consolidating office space.

During the year ended December 31, 2023, the Company recognized a restructuring charge of $5,606, which was incurred entirely in the fourth quarter of 2023, and which represents all restructuring charges expected to be incurred. Restructuring charges included approximately $5,345 of employee related termination costs in the form of salary continuation and cash severance payments, and $261 related to the acceleration of vesting of certain previously granted RSUs and PSUs.

The unpaid restructuring charges are included in accrued expenses and other current liabilities in the Company's consolidated balance sheets. The following table presents changes in the restructuring liability for the nine months ended September 30, 2024 (in thousands):

	As of September 30, 2024
Restructuring expenses	$ 5,606
Less: stock-based compensation	(261)
Cash payments made through September 30, 2024	(5,191)
Remaining liability included in accrued expenses and other current liabilities	$ 154

The Company expects the remaining accrued restructuring charges to be paid in cash by March 31, 2025.

Retention Awards

In November 2023, upon recommendation of the Company's Compensation Committee, the board of directors approved retention awards for employees of the Company in the form of RSUs, which vested as to the first tranche on August 15, 2024, and which will vest as to the second tranche on May 15, 2025, subject to remaining actively employed with the Company through such date. The $1,255 in compensation expense associated with these awards will be recognized ratably over the vesting period.

13. Commitments and Contingencies

Leases

Refer to Note 8, 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 September 30, 2024 or December 31, 2023.

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 September 30, 2024 or December 31, 2023.

14. Income taxes

The Company did not provide for any income taxes in its condensed consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2024 and 2023. While the Company has net income for the three and nine months ended September 30, 2024, the Company is projecting book and tax losses for the full year ended December 31, 2024, 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 September 30, 2024 and December 31, 2023, and has not recorded any income taxes for the three and nine months ended September 30, 2024 and 2023. Management reevaluates the positive and negative evidence at each reporting period.

15. Related Party Transactions

As described in Note 1, *Nature of the Business and Basis of Presentation* and Note 3, *Discontinued Operations*, 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 14,285,715 shares of common stock at a purchase price of $1.05 per share.

As of September 30, 2024, there was $33,458 included in Accrued Liabilities due to SPN 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*. Other than the net settlement of outstanding amounts owed to an affiliate of SPN under the prior license agreement between the Company and the SPN affiliate, no amounts were paid to SPN during the three and nine months ended September 30, 2024 and 2023 related to the Purchase Agreement.

As described in Note 3, *Discontinued Operations*, the Company entered into a Transition Services Agreement with NESA, an affiliate of SPN, in connection with the Transaction, through which the Company will provide manufacturing services until December 31, 2025, and other services, for the duration specified in the schedule to the TSA for each service. No expenses have been incurred and no reimbursements have been received in connection with the TSA for the three and nine months ended September 30, 2024. As of September 30, 2024 and December 31, 2023, there are no amounts due from SPN pursuant to the Purchase Agreement or the TSA.

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 epithelial barrier integrity, and induce immune tolerance to prevent bacterial bloodstream and antimicrobial resistant, or AMR, infections as well as other pathogen-associated negative clinical outcomes in patients undergoing allogeneic hematopoietic stem cell transplantation, or allo-HSCT. The placebo-controlled Phase 1b study Cohort 2 results demonstrated that SER-155 was associated with a significant reduction in both bloodstream infections and 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. 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.

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 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.

In addition to allo-HSCT, we intend to evaluate 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, or 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. Additional efforts in the early-stage portfolio are focused on the SER-301 program in inflammatory bowel disease, or IBD, and programmatic objectives that are 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 combination 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 net loss from continuing operations was $110.1 million for the nine months ended September 30, 2024. As of September 30, 2024, we had an accumulated deficit of $962.5 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 public or private equity or debt financings or other sources, which may include collaborations with third parties. 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 or interest rates. 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 as and when needed 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 September 30, 2024, we had cash and cash equivalents totaling $66.8 million. Based on our currently available cash resources, the capital obtained from the Transaction, and the expected receipt of the fixed Installment Payments (defined below), which are subject to material compliance with the TSA (as defined below), and considering our future operating plans and our ongoing obligations related to the Transaction, we will require additional funding by the fourth quarter of 2025. 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 from approximately 200 to 100, 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, 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 on January 15, 2025 and $25 million on July 1, 2025, or the Installment Payments, 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 Installment Payments and Milestone Payments we will 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 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 will 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 on our condensed consolidated balance sheet as of the Closing. The contingent liabilities include $16.9 million associated with the Profit Sharing Payments, $2.6 million associated with the MSK Agreement, $6.6 million and $3.0 million related to the settlement of the collaboration payable to SPN for the quarters ended June 30, 2024 and September 30, 2024, respectively, $1.9 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 $1.0 million associated with our ongoing post-marketing safety study of VOWST. The contingent liabilities will be remeasured at each reporting period based on (i) cash payments made by the Company to reduce the accrued liabilities due to SPN and (ii) revised estimates of the total remaining liabilities due to SPN.

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 14,285,715 shares of our common stock, or the Shares, at Closing, at a purchase price per share of $1.05, 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. 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. 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 NESA, which provides for services to be performed by us in order to facilitate a transition of the business associated with the VOWST Business to NESA 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. NESA has agreed to pay us for certain fixed costs, including a monthly fixed fee for preserved raw material suspension manufacturing, 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 NESA 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 NESA's request, we will transfer the specifications for materials and documentation necessary to enable preserved raw material suspension manufacturing services to a third party service provider designated by NESA. In the event of a material failure by us to deliver preserved raw material suspension 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 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.

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 pathogens and improve 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 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 antimicrobial resistant infections, or 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 epithelial barrier integrity, and induce immune tolerance to prevent bacterial bloodstream infections, or BSIs, and AMR infections 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 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 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.

SER-155 Phase 1b Study

SER-155 has been evaluated in a Phase 1b placebo-controlled 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 α=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 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.

Other pipeline programs, including SER-147

We continue to develop another proprietary live biotherapeutic composition, SER-147, designed to prevent bacterial bloodstream, AMR 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 advancing IND-enabling activities in 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.

The letter had no immediate effect on the listing of our common stock, which continues to trade on The Nasdaq Global Select Market under the symbol "MCRB," subject to our compliance with the other continued listing requirements of The Nasdaq Global Select Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial compliance period of 180 calendar days from receipt of the letter, or until May 6, 2025, to regain compliance with the Bid Price Requirement. To regain compliance, the closing bid price for our common stock must be at least $1.00 per share for a minimum of 10 consecutive business days during the 180-day period prior to May 6, 2025.

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

If we do not regain compliance within the applicable compliance period(s), we expect that Nasdaq will provide written notification to us that the common stock will be subject to delisting. At that time, we may appeal the delisting determination to a Nasdaq Listing Qualifications Panel.

We intend to monitor the closing bid price of our common stock and may, if appropriate, consider taking actions to regain compliance with the Bid Price Requirement, including, subject to approval of our board of directors and our stockholders, implementing a reverse stock split.

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 application families, which includes 20 nationalized applications and one at the PCT stage. To date, we have obtained issuance of 31 U.S. patents (which includes three as licensee).

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.

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, 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; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

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 2024 as compared to the prior year, as the restructuring plan implemented in 2023 significantly reduced research and development activities other than the completion of the SER-155 Phase 1b study. Research and development expenses may increase in the future if and as we resume development of any clinical or preclinical programs using proceeds from the Transaction with Nestlé.

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.

We expect that our general and administrative expenses will decrease in 2024 as compared to the prior year as the restructuring plan resulted in lower personnel expenses due the workforce reduction and lower external expenses as a result of the elimination of non-essential expenses and consolidation of office space. We expect for these decreases to be partially offset by an increase in transaction costs, including legal, accounting, and tax-related services in relation to the Transaction with Nestlé. 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.

Other Expense, 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 our loan and security agreement with Hercules Capital, Inc. and Oaktree, including the accretion of the discount on our Oaktree Term Loan.

Other Income (Expense)

Other income (expense) primarily consists of amortization of premiums or accretion of discounts on investments, gains and losses on foreign currency transactions, and changes in the fair values of our warrant liabilities associated with our Oaktree Term Loan. For the three and nine months ended September 30, 2024, other expense also includes the loss associated with the extinguishment of the Oaktree Term Loan.

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 and nine months ended September 30, 2024 or 2023.

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, 2023, filed with the SEC on March 5, 2024, 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 and nine months ended September 30, 2024, with the exception of those detailed in Note 2, *Summary of Significant Accounting Policies*, to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

Results of Operations

Comparison of Three Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		
	2024	2023	Change
Operating expenses:			
Research and development	16,460	25,154	(8,694)
General and administrative	12,710	19,432	(6,722)
Total operating expenses	29,170	44,586	(15,416)
Loss from continuing operations	(29,170)	(44,586)	15,416
Other (expense) income:			
Interest income	652	2,572	(1,920)
Interest expense	—	—	-
Other (expense) income	(22,517)	999	(23,516)
Total other (expense) income, net	(21,865)	3,571	(25,436)
Net loss from continuing operations	$ (51,035)	$ (41,015)	$ (10,020)

Research and Development Expenses

	Three Months Ended September 30,		
	2024	2023	Change
Microbiome therapeutics platform and research and development operations	$ 7,458	$ 9,024	$ (1,566)
SER-155	1,652	1,935	(283)
Early stage programs	(7)	382	(389)
Total direct research and development expenses	9,103	11,341	(2,238)
Personnel-related (including stock-based compensation)	7,357	13,813	(6,456)
Total research and development expenses	$ 16,460	$ 25,154	$ (8,694)

Research and development expenses were $16.5 million for the three months ended September 30, 2024 and $25.2 million for the three months ended September 30, 2023. The decrease of $8.7 million was primarily due to the following:

- a decrease in personnel-related costs of $6.5 million primarily due to a decrease in salaries, bonus, employee benefits expenses, and payroll taxes as a result of the restructuring plan implemented in 2023;
- a decrease of $1.6 million in expenses related to our microbiome therapeutics platform and research and development operations, primarily due to a decrease of $0.9 million primarily due to a reduction in the use of contractors following the implementation of the restructuring plan, and a decrease in consulting expenses of $0.6 million;
- a decrease of $0.4 million in expenses related to our early stage programs due to the restructuring plan; and
- a decrease of $0.3 million in expenses related to our SER-155 program due to lower lab supplies and consumables as the clinical trial material for the Phase 1b study had been manufactured in prior periods.

General and Administrative Expenses

	Three Months Ended September 30,		
	2024	2023	Change
Personnel related (including stock-based compensation)	$ 5,596	$ 8,930	$ (3,334)
Professional fees	2,283	4,525	(2,242)
Facility-related and other	4,831	5,977	(1,146)
Total general and administrative expenses	$ 12,710	$ 19,432	$ (6,722)

General and administrative expenses were $12.7 million for three months ended September 30, 2024 compared to $19.4 million for the three months ended September 30, 2023. The decrease of $6.7 million was primarily due to the following:

- a decrease in personnel related costs of $3.3 million primarily due to a decrease in salaries, bonus, employee benefits expenses, and stock-based compensation expenses due to the restructuring plan that was implemented in 2023;
- a decrease in professional fees of $2.2 million primarily due to a decrease in professional services, consulting, and recruiting fees; 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 restructuring plan that was implemented in 2023.

Other (Expense) Income, Net

Other (expense) income, net was $21.9 million of expense and $3.6 million of income, respectively, for the three months ended September 30, 2024 and 2023. The change in other (expense) income, net was primarily due to the $23.4 million loss associated with the extinguishment of the Oaktree Term Loan recorded in the three months ended September 30, 2024 in connection with the sale of the VOWST Business to SPN. For more information, see Note 9, *Notes Payable*, to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report. Additionally, interest income decreased by $1.9 million due to our lower cash balance.

Comparison of Nine Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
Operating expenses:			
Research and development	51,759	94,554	(42,795)
General and administrative	40,721	63,519	(22,798)
Total operating expenses	92,480	158,073	(65,593)
Loss from continuing operations	(92,480)	(158,073)	65,593
Other (expense) income:			
Interest income	3,530	5,330	(1,800)
Interest expense	—	(2,468)	2,468
Other expense	(21,184)	(202)	(20,982)
Total other (expense) income, net	(17,654)	2,660	(20,314)
Net loss from continuing operations	$ (110,134)	$ (155,413)	$ 45,279

Research and Development Expenses

	Nine Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
Microbiome therapeutics platform and research and development operations	$ 23,309	$ 35,732	$ (12,423)
SER-155	6,258	5,578	680
Early stage programs	84	1,208	(1,124)
Total direct research and development expenses	29,651	42,518	(12,867)
Personnel-related (including stock-based compensation)	22,108	52,036	(29,928)
Total research and development expenses	$ 51,759	$ 94,554	$ (42,795)

Research and development expenses were $51.8 million for the nine months ended September 30, 2024 and $94.6 million for the nine months ended September 30, 2023. The decrease of $42.8 million was primarily due to the following:

- a decrease in personnel-related costs of $29.9 million primarily due to a decrease of $24.0 million in salaries, bonus, and employee benefits expenses as a result of the restructuring plan implemented in 2023, and a decrease of $6.9 million in stock-based compensation expense, which was primarily as a result of options and awards with performance conditions that were achieved during the three months ended June 30, 2023, partially offset by an increase of $1.0 million in payroll taxes primarily related to tax credits we received during the three months ended March 31, 2023;
- a decrease of $12.4 million in expenses related to our microbiome therapeutics platform and research and development operations which includes a decrease of $3.5 million due to a reduction in the use of contractors and a decrease in employee travel and expense costs following the implementation of the restructuring plan, a decrease in consulting expenses of $2.4 million, a decrease of $2.0 million in clinical trial, analytical and other manufacturing costs, a decrease of $2.4 million in lab supplies and consumables, and a decrease of $1.6 million in facilities and depreciation; and
- a decrease of $1.1 million in expenses related to our early stage programs due to the restructuring plan;

partially offset by:

- an increase of $0.7 million in expenses related to our SER-155 program primarily due to an increase in clinical trial costs as the Phase 1b trial advanced.

General and Administrative Expenses

	Nine Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
Personnel related (including stock-based compensation)	$ 17,936	$ 28,403	$ (10,467)
Professional fees	7,002	17,739	(10,737)
Facility-related and other	15,783	17,377	(1,594)
Total general and administrative expenses	$ 40,721	$ 63,519	$ (22,798)

General and administrative expenses were $40.7 million for the nine months ended September 30, 2024 compared to $63.5 million for the nine months ended September 30, 2023. The decrease of $22.8 million was primarily due to the following:

- a decrease in personnel related costs of $10.5 million primarily due to a decrease in salaries, bonus, employee benefits expenses, and stock-based compensation expenses due to the restructuring plan that was implemented in 2023;
- a decrease in professional fees of $10.7 million primarily due to a decrease in professional services, consulting, and recruiting fees; and
- a decrease in facility-related and other costs of $1.6 million primarily related to information technology costs, laboratory and office rent expenses, license costs and office supplies.

Other (Expense) Income, Net

Other (expense) income, net was $17.7 million of expense and $2.7 million of income, respectively for the nine months ended September 30, 2024 and 2023. The change in other (expense) income, net was primarily due to $23.4 million of loss associated with the extinguishment of the Oaktree Term Loan, compared to the $1.6 million of Hercules credit facility during the nine months ended September 30, 2023, as well as a decrease in interest income of $1.8 million. Additionally, during the nine months ended September 30, 2024, we recognized a decrease of $2.5 million of interest expense incurred in the prior period relating to the Hercules credit facility, and an increase of $1.9 million of sublease income, partially offset by a decrease of $0.6 million on gain on warrant revaluation.

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 on January 15, 2025 and $25 million on July 1, 2025, 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 Installment Payment due on July 1, 2025 will be reduced by an amount related to certain employment obligations assumed by SPN through the period prior to the Closing date.

We and SPN will 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 14,285,715 shares of Common Stock at Closing, at a purchase price per share of $1.05, 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 September 30, 2024, we have sold 27,018,032 shares of common stock under the Sales Agreement, at an average price of approximately $1.71 per share, raising aggregate net proceeds of approximately $44.4 million after deducting an aggregate commission of approximately 3% and other issuance costs.

As of September 30, 2024, we had cash and cash equivalents totaling $66.8 million and an accumulated deficit of $962.5 million. For the nine months ended September 30, 2024, we incurred a net loss from continuing operations of $110.1 million, and used cash in operations of $109.7 million. We expect that our operating losses and negative cash flows will continue for the foreseeable future. Our future viability beyond 12 months from issuance of these condensed consolidated financial statements is dependent on our ability to raise additional capital to finance our operations. We may seek to raise additional capital through financing or other strategic transactions, including potential business development transactions, and selling shares under the Company's at the market equity offering.

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 fixed Installment Payments and sufficient additional equity 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, the capital obtained from the Transaction, and the expected receipt of the fixed Installment Payments, which are subject to material compliance with the TSA, and considering our future operating plans and our ongoing obligations related to the Transaction, we will require additional funding by the fourth quarter of 2025. 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:

	Nine Months Ended September 30,	
	2024	2023
	(in thousands)	
Cash used in operating activities	$ (109,727)	$ (69,855)
Cash provided by investing activities	142,383	11,459
Cash (used in) provided by financing activities	(92,109)	65,276
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (59,453)	$ 6,880

Operating Activities

During the nine months ended September 30, 2024, operating activities used $109.7 million of cash, primarily due to non-cash charges of $90.1 million and changes in our operating assets and liabilities of $35.4 million, partially offset by net income of $15.8 million. Non-cash charges consisted of stock-based compensation expense of $17.2 million, $7.2 million related to the amortization of right-of-use assets, $4.4 million of depreciation and amortization, $1.4 million of amortization of debt issuance costs, $23.4 million of loss associated with the extinguishment of the Oaktree Term Loan, $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 the $146.7 million gain on sale of VOWST Business and $0.5 million decrease in the fair value of the Additional Warrants. Changes in our operating assets and liabilities during the nine months ended September 30, 2024 consisted of a decrease in operating lease liabilities of $4.4 million, a decrease in deferred income - related party of $4.1 million, a decrease in accrued expenses and other current and long-term liabilities of $3.3 million, and a decrease in inventories of $33.8 million in connection with the sale of the VOWST Business to SPN, partially offset by a decrease in

collaboration receivable - related party of $8.7 million, a decrease in prepaid expenses and other current and other non-current assets of $0.3 million, and an increase in accounts payable of $1.2 million.

During the nine months ended September 30, 2023, operating activities used $69.9 million of cash, primarily due to a net loss of $72.5 million and changes in our operating assets and liabilities of $43.6 million, partially offset by non-cash charges of $46.2 million. Non-cash charges consisted of stock-based compensation expense of $29.0 million, loss sharing under the 2021 License Agreement with Nestlé of $5.2 million, $6.5 million related to the amortization of right-of-use assets, $4.6 million of depreciation and amortization, and $1.6 million of loss from the extinguishment of the Hercules Credit Facility. These were partially offset by a $1.1 million increase in the fair value of the Additional Warrants. Changes in our operating assets and liabilities during the nine months ended September 30, 2023 consisted of a decrease in accrued expenses and other current and long-term liabilities of $10.7 million, primarily due to total payments of $25.9 million to Nestlé for its share of collaboration expenses under the 2021 License Agreement, a decrease in accounts payable of $6.5 million, a decrease in deferred revenue of $1.3 million, a decrease in operating lease liabilities of $1.6 million, an increase in inventories of $18.5 million and an increase in collaboration receivable - related party of $16.9 million, as a result of the commencement of our commercial operations since the FDA approval of VOWST in April 2023, partially offset by a decrease in prepaid expenses and other current and other non-current assets of $2.5 million and an increase in deferred income - related party of $9.5 million.

Investing Activities

During the nine months ended September 30, 2024, net cash provided by investing activities was $142.4 million, consisting of $141.3 million of proceeds from the sale of the VOWST Business and a $1.4 million sale of a restricted investment relating to a security deposit on one of our leases that was reclassified as restricted cash, partially offset by $0.3 million of purchases of property and equipment.

During the nine months ended September 30, 2023, net cash provided by investing activities was $11.5 million, consisting of sales and maturities of investments of $23.0 million, partially offset by purchases of investments of $4.4 million and purchases of property and equipment of $7.1 million.

Financing Activities

During the nine months ended September 30, 2024, net cash used in financing activities was $92.1 million, consisting of $127.9 million repayment of the Oaktree Term Loan, partially offset by $21.8 million from the issuance of common stock under our at the market equity program, net of issuance costs, $13.5 million from the issuance of common stock in connection with the sale of the VOWST Business to SPN, and $0.5 million from the issuance of common stock under our 2015 Employee Stock Purchase Plan, or ESPP.

During the nine months ended September 30, 2023, net cash provided by financing activities was $65.3 million, consisting of $103.4 million in proceeds from the issuance of the Oaktree Term Loan, offset by $52.9 million for the repayment of the Hercules Credit Facility. Cash provided by financing activities also consisted of $11.7 million from the issuance of common stock under our at the market equity program, net of issuance costs. We also received $0.9 million from the issuance of common stock associated with the exercise of stock options, and $2.2 million in connection with the issuance of common stock under our 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 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 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 Installment Payments and Milestone Payments we will 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.

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. Our Hercules Loan Agreement and Oaktree Term Loan included, and any additional 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 or debt financings 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 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, the capital obtained from the Transaction, and the expected receipt of the fixed Installment Payments, which are subject to material compliance with the TSA, and considering our future operating plans and our ongoing obligations related to the Transaction, we will require additional funding by the fourth quarter of 2025.

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, except as described herein.

Asset Purchase Agreement

On August 5, 2024, we entered into the Purchase Agreement with SPN, pursuant to which we agreed to sell the VOWST Business to SPN and SPN assumed certain liabilities from us, for the Transaction Consideration. See *Overview – Sale of our VOWST Business to SPN* for further details.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this Item.

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 September 30, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

On September 30, 2024, we completed the sale of the VOWST Business to SPN under the Purchase Agreement entered into as of August 5, 2024. As a result, during the three months ended September 30, 2024, we made the following modifications to our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act), including changes to accounting policies and procedures, operational processes, and documentation practices that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting:

- added internal controls over the identification of accounts and transactions related to the sale of the VOWST Business;
- added controls and documentation processes related to the accounting for the discontinued operation; and
- added controls to address related disclosures for the discontinued operation.

Other than the items described above, there were no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2024 that have materially affected, or are 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

The total amount of the Installment Payments and Milestone Payments we will 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 on January 15, 2025 and $25 million on July 1, 2025, conditioned on our material compliance with obligations under the TSA entered into at Closing between us and NESA;
- 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 Installment Payment due on July 1, 2025 will be reduced by an amount related to certain employment obligations assumed by SPN through the period prior to the Closing Date.

The Installment Payments 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 Installment Payments and, if we are not or if there is a dispute as to compliance, such payments 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 will 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, which, with the cash paid upon Closing and the Installment Payments expected to be obtained from the Transaction, we will require additional funding by the fourth quarter of 2025, subject to performance under the TSA. 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 growth 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 Facility. 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.

We will need additional funding in order to complete development of our product candidates and commercialize our product candidates, if approved. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or any potential future commercialization efforts.

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 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.

As noted above, 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 total amount of the Installment Payments and Milestone Payments we will 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, 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.

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, the capital obtained from the Transaction, and the expected receipt of the fixed Installment Payments, which are subject to material compliance with the TSA, and considering our future operating plans and our ongoing obligations related to the Transaction, we will require additional funding by the fourth quarter of 2025. Because the ability to obtain the fixed Installment Payments and additional equity or other financing 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 consolidated financial statements for the three and nine months ended September 30, 2024 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 was $113.7 million for the year ended December 31, 2023, and $110.1 million for the nine months ended September 30, 2024. As of September 30, 2024, we had an accumulated deficit of $962.5 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, 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.

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 foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become 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 United Kingdom, or UK, will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency, or MHRA, launched an eight-week consultation on reframing the UK legislation for clinical trials with the aim to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation. These resulting legislative amendments will be closely watched and will determine how closely the UK regulations are aligned with the CTR. Under the terms of the Protocol on Ireland/Northern Ireland, provisions of the CTR which relate to the manufacture and import of investigational medicinal products and auxiliary medicinal products apply in Northern Ireland. On February 27, 2023, the UK Government and the European Commission reached a political agreement on the "Windsor Agreement" which will revise the Protocol on Ireland/Northern Ireland in order to address some of the perceived shortcomings in its operation. Once implemented, this may have further impact on the application of the CTR in Northern Ireland. 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 (not expected before early 2026) and may 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, and for SER-287 for the induction and maintenance of clinical remission in adults with mild-to-moderate UC. 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.

We have applied for Breakthrough Therapy and Qualified Infectious Disease Product designations for SER-155 in allo-HSCT and may seek such 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 previously obtained orphan drug designation from the FDA for SER-109 for recurrent CDI and SER-287 for pediatric UC and may seek orphan drug designation and exclusivity 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, following its relocation to Amsterdam and resulting staff changes, 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, over the last several 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.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities, any resurgence of the virus or emergence of new variants may lead to further inspectional or administrative delays. If a prolonged government shutdown occurs, or if 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 location where we conduct process development, scale-up activities and a portion of the manufacture of our biotherapeutic candidates as well as conduct quality control. 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. In the future, we may establish a manufacturing facility for any of our product candidates for production at a commercial scale. We have no experience in manufacturing, without reliance on third-party manufacturers, sufficient volume of 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 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. It is possible that Congress or the FDA may take these or other measures to reduce or eliminate periods of exclusivity. The BPCIA is complex and continues to be interpreted and implemented by the FDA, and such FDA implementation could have a material adverse effect on the future commercial prospects for our product candidates.

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;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices;
- 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 (beginning 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. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, 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 application families (which includes exclusive licenses to certain IP from Memorial Sloan Kettering Cancer Center). Of these, 20 applications have been nationalized and one is at the PCT stage. While we have obtained issuance of 31 U.S. patents, 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 ourself 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 may 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, 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 climate change), 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, customers 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 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, CCPA, requires certain 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. 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, or joint ventures 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, or dispose of assets. 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 or disposition may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions or dispositions, or the effect that any such transactions might have on our operating results.

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.

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, including from the novel coronavirus SARS-CoV-2, which causes the COVID-19 disease, 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, 2023, we had net operating loss carryforwards, or NOLs, of $527.1 million for federal income tax purposes and $504.2 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, 2023, we also had federal and state research and development and other tax credit carryforwards of approximately $45.1 million and $7.7 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, 2020. 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, 2020, 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 received 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. The notice had no immediate effect on the listing of our common stock, which continues to trade on The Nasdaq Global Select Market under the symbol "MCRB". 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. If we do not regain compliance with this requirement by May 6, 2025, we may be eligible for an additional 180-calendar day compliance period by transferring the listing of our common stock to The Nasdaq Capital Market and satisfying certain requirements. To qualify for the additional grace period, we would be required to submit a transfer application for transfer between Nasdaq market tiers and pay an application fee. In addition, we would be required to meet the continued listing requirement for the market value of our publicly held shares and all other applicable initial listing standards for The Nasdaq Capital Market, with the exception of the Bid Price Requirement, and would need to provide written notice of our intention to cure the deficiency during the second grace period. If we fail to regain compliance during the compliance period (including a second compliance period provided by a transfer to The Nasdaq Capital Market, if applicable), then we expect that Nasdaq will notify us of its determination to delist our common stock, at which point we may appeal Nasdaq's delisting determination to a Nasdaq hearing panel or pursue other available options to regain compliance

We intend to actively monitor the closing bid price of our common stock and will consider all available options to regain compliance with the Bid Price Requirement, which may include transferring the listing to The Nasdaq Capital Market and/or seeking stockholder approval to effect a reverse stock split. However, there can be no assurance that any such reverse stock split, if approved by the stockholders and implemented, would increase the market price of our common stock in proportion to the reverse split ratio or result in a sustained increase in the market price of our common stock. In addition, it is possible that the reduced number of issued shares of common stock resulting from such a reverse stock split could adversely affect the liquidity of our common stock. There can also be no assurance that we will 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 and, as a result, we expect our securities would be quoted on an over-the-counter 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 43% of our outstanding voting stock as of December 31, 2023. 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 by the fourth quarter of 2025;
- 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. However, while we remain a non-accelerated filer, we will not 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 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 and diversity, equity and inclusion matters. 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 in connection with any of these matters. In turn, we may take certain actions, including the establishment of ESG-related goals or targets, to improve our ESG profile and/or respond to stakeholder demand; 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.

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

Except as previously disclosed in our Current Reports on Form 8-K filed on August 6, 2024 and October 1, 2024, we did not make any unregistered sales of equity securities during the period covered by this Quarterly Report on Form 10-Q.

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 September 30, 2024, 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	Incorporated by Reference			Filing Date	Filed/ Furnished Herewith
		Form	File No.	Exhibit		
2.11††	Asset Purchase Agreement, dated August 5, 2024, by and between Seres Therapeutics, Inc. and Société des Produits Nestlé S.A.	8-K	001-37465	2.1	8/6/24	
3.1	Restated Certificate of Incorporation, filed on July 1, 2015	8-K	001-37465	3.1	7/1/15	
3.2	Certificate of Amendment to Restated Certificate of Incorporation of Seres Therapeutics, Inc., dated June 27, 2023	8-K	001-37465	3.1	6/28/23	
3.3	Certificate of Amendment to Restated Certificate of Incorporation of Seres Therapeutics, Inc., dated April 5, 2024	8-K	001-37465	3.1	4/8/24	
3.4	Amended and Restated Bylaws	8-K	001-37465	3.1	1/2/24	
10.1	Securities Purchase Agreement, dated September 30, 2024, by and between Seres Therapeutics, Inc. and Société des Produits Nestlé S.A.	8-K	001-37465	10.1	10/1/24	
10.2†	Transition Services Agreement, dated September 30, 2024, by and between Seres Therapeutics, Inc. and Nestlé Enterprises S.A.	8-K	001-37465	10.2	10/1/24	
10.3	Cross-License Agreement, dated September 30, 2024, by and between Seres Therapeutics, Inc. and Société des Produits Nestlé S.A.	8-K	001-37465	10.3	10/1/24	
10.4	Employee Support Agreement, dated September 30, 2024, by and between Seres Therapeutics, Inc. and Société des Produits Nestlé S.A.	8-K	001-37465	10.4	10/1/24	
10.5†	Assignment and Termination of Manufacturing Agreement, dated August 5, 2024, by and between Seres Therapeutics, Inc. and Bacthera AG	10-Q	001-37465	10.5	8/13/24	
10.6	Mutual Termination of License Agreement dated September 30, 2024, by and between Seres Therapeutics, Inc. and NHSc Rx License GmbH					*
10.7	Mutual Termination of Collaboration and License Agreement dated September 30, 2024, by and between Seres Therapeutics, Inc. and Société des Produits Nestlé S.A.					*
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer					*
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer					*
32.1	Section 1350 Certification of Chief Executive Officer					**
32.2	Section 1350 Certification of Chief Financial Officer					**
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.
† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Regulation S-K, Item 601(b)(10)(iv). Such omitted information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.
†† Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC.

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: November 13, 2024

By: /s/ Marella Thorell

Marella Thorell

Executive Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 10.6

MUTUAL TERMINATION OF LICENSE AGREEMENT

This **MUTUAL TERMINATION OF LICENSE AGREEMENT** (the "**US License Agreement Termination Agreement**") is effective on September 30, 2024 ("**US License Agreement Termination Effective Date**"), and is made by and between Seres Therapeutics, Inc., a corporation organized and existing under the laws of Delaware, having an office located at 101 Cambridge Park Drive, Cambridge, MA 02140, USA ("**Seres**") and Société des Produits Nestlé S.A., a *société anonyme* organized under the laws of Switzerland, having an office located at Avenue Nestlé 55, 1800 Vevey, Switzerland ("**NHSc**"). Seres and NHSc are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

WHEREAS, Seres and NHSc Pharma Partners (as predecessor to NHSc) entered into that certain License Agreement dated July 1, 2021 (the "**US License Agreement**"), pursuant to which Seres has granted to NHSc certain co-exclusive rights and licenses with respect to the commercialization of SER-109 (as defined in the US License Agreement) in the United States and Canada;

WHEREAS, the Parties have entered into that certain Asset Purchase Agreement dated August 5, 2024 (the "**APA**") and certain Ancillary Agreements (as defined in the APA), pursuant to which NHSc acquired from Seres certain assets relating to the exploitation of the Product (as defined in the APA) worldwide; and

WHEREAS, in connection with the APA, the Parties desire to terminate the US License Agreement by mutual agreement in connection with the transactions contemplated by the APA and provide mutual releases as set forth below.

NOW, **THEREFORE**, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the amount and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. Termination and Effect of Termination.

   a) Notwithstanding any provision in the US License Agreement, the Parties hereby agree to terminate the US License Agreement by mutual agreement, effective as of the US License Agreement Termination Effective Date.

   b) Notwithstanding any provision in the US License Agreement, the following sections (and no other parts) of the US License Agreement shall continue in full force and effect after the US License Agreement Termination Effective Date in accordance with the terms thereof: Sections 8.1 through 8.3 (in each case solely to the extent payments accrued pursuant to the US License Agreement but remain unpaid as of the US License Agreement Termination Effective Date), 8.4, 10.1 through 10.10 (in each case solely to the extent any information was disclosed pursuant to the US License Agreement prior to the US License Agreement Termination Effective Date), 11.1 (except to the extent expressly modified in the APA and the Ancillary Agreements (as defined in the APA), 11.4(d), 15.5, 16.1 through

16.5 (in each case solely to the extent the applicable Third Party Claim (as defined in the US License Agreement) arose out of or occurred as a result of events that occurred prior to the US License Agreement Termination Effective Date), 16.6, 16.7, 18.2 through 18.7 and 18.10 through 18.14.

c) All amounts due or payable to a Party that were accrued, or that arise out of acts or events occurring, under the US License Agreement prior to the US License Agreement Termination Effective Date shall remain due and payable; no additional amounts shall be payable under the US License Agreement based on events occurring on or after the US License Agreement Termination Effective Date. For the avoidance of doubt, the Royalty Payment Amount (as defined in the US License Agreement), the True Up Delta (as defined in the US License Agreement) and the corresponding True Up Amount(as defined in the US License Agreement) shall be calculated on a prorated basis in accordance with the US License Agreement as of the US License Agreement Termination Effective Date and paid by the party responsible for such payment on the terms set forth therein.

2. Release. Except for the obligations of the Parties expressly set forth in this US License Agreement Termination Agreement, each Party to this US License Agreement Termination Agreement will and hereby does, on behalf of itself and its affiliates (collectively, the "**Releasing Parties**"), forever release and discharge the other Party and all of its affiliates, officers, directors, managers, employees, agents, representatives, shareholders, members, predecessors, successors, and assigns (collectively, the "**Released Parties**"), from any and all causes of action, judgments, liens, indebtedness, damages, losses, claims, liabilities, and demands of every kind and character in any manner attributable to or arising out of, whether past, present, or future, at law or in equity, whether known or unknown, contingent or otherwise (collectively, "**Causes of Action**"), which such Releasing Parties, or any of them had, has, or may have had at any time up to and including the US License Agreement Termination Effective Date against the Released Parties, or any of them, which relate solely to or arise solely out of the US License Agreement, including any performance thereunder or termination thereof; provided that the foregoing release shall not release a Released Party for any Cause of Action arising from or in connection with any fraud committed by such Party prior to the U.S. License Agreement Termination Effective Date. For the avoidance of doubt, nothing set forth in this Section 2 shall relieve any Released Party for Causes of Action arising from or in connection with the APA or any Ancillary Agreements (as defined in the APA), or any other agreement entered into in connection therewith.

3. Miscellaneous.

a) Governing Law. This US License Agreement Termination Agreement, and any dispute arising out of, relating to or in connection with this US License Agreement Termination Agreement, shall be governed by, and enforced in accordance with, the internal laws of the State of Delaware, without giving effect to any laws, rules or provisions of the State of Delaware that would cause the application of the laws, rules or provisions of any jurisdiction other than the State of Delaware. Each of the Parties hereto further agrees to waive and hereby irrevocably waives, to the fullest extent permitted by law, any objection

which it may now have or hereafter have to the laying of venue of, and the defense of an inconvenient forum to the maintenance of, any such action in any such court.

b) Jurisdiction, Service, and Venue. Each Party agrees: (i) to submit to the exclusive jurisdiction of the Court of Chancery of the State of Delaware (or, only if the Court of Chancery of the State of Delaware declines to accept or does not have jurisdiction over a particular matter, any federal or other state court sitting in New Castle County within the State of Delaware) (the "**Specified Courts**") for any action, claim, suit, litigation, proceeding, arbitration, mediation, audit, hearing, investigation or dispute ("**Action**") arising out of or relating to this US License Agreement Termination Agreement; (ii) to commence any Action arising out of or relating to this US License Agreement Termination Agreement only in the Specified Courts; (iii) that service of any process, summons, notice, or document by U.S. registered mail to the address of such Party set forth in Section 10.2 of the APA will be effective service of process for any Action brought against such Party in any of the Specified Courts (provided that, in the case of NHSc, service of process must be delivered to the registered agent in Delaware of Nestlé USA, Inc.); (iv) to waive any objection to the laying of venue of any Action arising out of or relating to this US License Agreement Termination Agreement in the Specified Courts; and (v) to waive and not to plead or claim that any such Action brought in any of the Specified Courts has been brought in an inconvenient forum; provided, however, that such submission to the jurisdiction of the Specified Courts is solely for the purpose referred to in this Section 3 and shall not be deemed to be a general submission to the jurisdiction of such courts or any other courts other than for such purpose.

c) WAIVER OF TRIAL BY JURY. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS US LICENSE AGREEMENT TERMINATION AGREEMENT. EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT (A) NO REPRESENTATIVE OF THE OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, (B) SUCH PARTY UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER, (C) SUCH PARTY MAKES THIS WAIVER VOLUNTARILY, AND (D) SUCH PARTY HAS BEEN INDUCED TO ENTER INTO THIS US LICENSE AGREEMENT TERMINATION AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 3(C).

d) Interpretation. The Parties have participated jointly in the negotiation and drafting of this US License Agreement Termination Agreement. This US License Agreement Termination Agreement shall be construed without regard to any presumption or rule requiring construction or interpretation against the Party drafting or causing any instrument to be drafted.

e) Counterparts. This US License Agreement Termination Agreement and any amendment or supplement hereto may be executed in any number of counterparts, each of which shall

be deemed an original, and all of which taken together shall constitute one and the same instrument. This US License Agreement Termination Agreement shall become binding when any number of counterparts, individually or taken together, shall bear the signatures of all Parties. This US License Agreement Termination Agreement may be executed and delivered by facsimile or any other electronic means, including ".pdf" or ".tiff" files, and any facsimile or electronic signature shall constitute an original for all purposes.

[signature page follows]

IN WITNESS WHEREOF, the Parties have executed this US License Agreement Termination Agreement as of the US License Agreement Termination Effective Date.

SERES THERAPEUTICS, INC.

By: /s/ Eric D. Shaff

Name: Eric D. Shaff

Title: President and Chief Executive Officer

NHSC RX LICENSE GMBH

By: /s/ Claudio Kuoni

Name: Claudio Kuoni

Title: Vice President

[Signature Page to Mutual Termination of License Agreement]

Exhibit 10.7

MUTUAL TERMINATION OF COLLABORATION AND LICENSE AGREEMENT

This **MUTUAL TERMINATION OF COLLABORATION AND LICENSE AGREEMENT** (the "**ROW License Agreement Termination Agreement**") is effective on September 30, 2024 ("**ROW License Agreement Termination Effective Date**"), and is made by and between Seres Therapeutics, Inc., a corporation organized and existing under the laws of Delaware, having an office located at 101 Cambridge Park Drive, Cambridge, MA 02140, USA ("**Seres**") and Société des Produits Nestlé S.A., a *société anonyme* organized under the laws of Switzerland, having an office located at Avenue Nestlé 55, 1800 Vevey, Switzerland ("**NHSc**"). Seres and NHSc are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

WHEREAS, Seres and Nestec Ltd. (as predecessor to NHSc) entered into that certain Collaboration and License Agreement dated January 9, 2016 (the "**ROW License Agreement**"), pursuant to which Seres granted to NHSc certain exclusive rights and licenses for the exploitation of certain products outside of the United States and Canada;

WHEREAS, the Parties have entered into that certain Asset Purchase Agreement dated August 5, 2024 (the "**APA**") and certain Ancillary Agreements (as defined in the APA), pursuant to which NHSc acquired from Seres certain assets relating to the exploitation of the Product (as defined in the APA) worldwide; and

WHEREAS, in connection with the APA, the Parties desire to terminate the ROW License Agreement by mutual agreement in connection with the transactions contemplated by the APA and provide mutual releases as set forth below.

NOW, **THEREFORE**, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the amount and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. Termination and Effect of Termination.

   a) Pursuant to Section 13.1 of the ROW License Agreement, the Parties hereby agree to terminate the ROW License Agreement by mutual agreement, effective as of the ROW License Agreement Termination Effective Date.

   b) Notwithstanding any provision in the ROW License Agreement, the following sections (and no other parts) of the ROW License Agreement shall continue in full force and effect after the ROW License Agreement Termination Effective Date in accordance with the terms thereof: (i) Sections 4.7, 8.8 through 8.11 (in each case solely to the extent payments accrued pursuant to the ROW License Agreement but remain unpaid as of the ROW License Agreement Termination Effective Date), 8.12, 10.1 (except to the extent expressly modified in the APA and Ancillary Agreements (as defined in the APA)), 11.1 through 11.6 (in each case solely to the extent any information was disclosed under the ROW License Agreement prior to the ROW License Agreement Termination Effective Date), 12.1 through 12.3 (in each case solely to the extent the applicable Third Party Claim (as

defined in the ROW License Agreement) arose out of or occurred as a result of events that occurred prior to the ROW License Agreement Termination Effective Date), 15.1, 15.2, 15.4, 15.6 through 15.10, 15.14 and 15.15, and (ii) as applicable to all Collaboration Products (as defined in the ROW License Agreement) other than SER-109 (as described in Exhibit A of the ROW License Agreement), Sections 13.3.2(a), (b), (c), (d), (e), (f), (g), (h) and (i).

c) All amounts due or payable to a Party that were accrued, or that arise out of acts or events occurring, under the ROW License Agreement prior to the ROW License Agreement Termination Effective Date shall remain due and payable; no additional amounts shall be payable under the ROW License Agreement based on events occurring on or after the ROW License Agreement Termination Effective Date.

2. Release. Except for the obligations of the Parties expressly set forth in this ROW License Agreement Termination Agreement, each Party to this ROW License Agreement Termination Agreement will and hereby does, on behalf of itself and its affiliates (collectively, the "**Releasing Parties"),** forever release and discharge the other Party and all of its affiliates, officers, directors, managers, employees, agents, representatives, shareholders, members, predecessors, successors, and assigns (collectively, the "**Released Parties**"), from any and all causes of action, judgments, liens, indebtedness, damages, losses, claims, liabilities, and demands of every kind and character in any manner attributable to or arising out of, whether past, present, or future, at law or in equity, whether known or unknown, contingent or otherwise (collectively, "**Causes of Action**"), which such Releasing Parties, or any of them had, has, or may have had at any time up to and including the ROW License Agreement Termination Effective Date against the Released Parties, or any of them, which relate solely to or arise solely out of the ROW License Agreement, including any performance thereunder or termination thereof; provided that the foregoing release shall not release a Released Party from any Cause of Action arising from or in connection with any fraud committed by such Party prior to the ROW License Agreement Termination Effective Date. For the avoidance of doubt, nothing set forth in this Section 2 shall relieve any Released Party for Causes of Action arising from or in connection with the APA or any Ancillary Agreements (as defined in the APA), or any other agreement entered into in connection therewith.

3. Miscellaneous.

a) Governing Law. This ROW License Agreement Termination Agreement, and any dispute arising out of, relating to or in connection with this ROW License Agreement Termination Agreement, shall be governed by, and enforced in accordance with, the internal laws of the State of Delaware, without giving effect to any laws, rules or provisions of the State of Delaware that would cause the application of the laws, rules or provisions of any jurisdiction other than the State of Delaware. Each of the Parties hereto further agrees to waive and hereby irrevocably waives, to the fullest extent permitted by law, any objection which it may now have or hereafter have to the laying of venue of, and the defense of an inconvenient forum to the maintenance of, any such action in any such court.

b) Jurisdiction, Service, and Venue. Each Party agrees: (i) to submit to the exclusive jurisdiction of the Court of Chancery of the State of Delaware (or, only if the Court of

Chancery of the State of Delaware declines to accept or does not have jurisdiction over a particular matter, any federal or other state court sitting in New Castle County within the State of Delaware) (the "**Specified Courts**") for any action, claim, suit, litigation, proceeding, arbitration, mediation, audit, hearing, investigation or dispute ("**Action**") arising out of or relating to this ROW License Agreement Termination Agreement; (ii) to commence any Action arising out of or relating to this ROW License Agreement Termination Agreement only in the Specified Courts; (iii) that service of any process, summons, notice, or document by U.S. registered mail to the address of such Party set forth in Section 10.2 of the APA will be effective service of process for any Action brought against such Party in any of the Specified Courts (provided that, in the case of NHSc, service of process must be delivered to the registered agent in Delaware of Nestlé USA, Inc.); (iv) to waive any objection to the laying of venue of any Action arising out of or relating to this ROW License Agreement Termination Agreement in the Specified Courts; and (v) to waive and not to plead or claim that any such Action brought in any of the Specified Courts has been brought in an inconvenient forum; provided, however, that such submission to the jurisdiction of the Specified Courts is solely for the purpose referred to in this Section 3 and shall not be deemed to be a general submission to the jurisdiction of such courts or any other courts other than for such purpose.

c) WAIVER OF TRIAL BY JURY. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS US LICENSE AGREEMENT TERMINATION AGREEMENT. EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT (A) NO REPRESENTATIVE OF THE OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, (B) SUCH PARTY UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER, (C) SUCH PARTY MAKES THIS WAIVER VOLUNTARILY, AND (D) SUCH PARTY HAS BEEN INDUCED TO ENTER INTO THIS US LICENSE AGREEMENT TERMINATION AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 3(C).

d) Interpretation. The Parties have participated jointly in the negotiation and drafting of this ROW License Agreement Termination Agreement. This ROW License Agreement Termination Agreement shall be construed without regard to any presumption or rule requiring construction or interpretation against the Party drafting or causing any instrument to be drafted.

e) Counterparts. This ROW License Agreement Termination Agreement and any amendment or supplement hereto may be executed in any number of counterparts, each of which shall be deemed an original, and all of which taken together shall constitute one and the same instrument. This ROW License Agreement Termination Agreement shall become binding when any number of counterparts, individually or taken together, shall bear the signatures of all Parties. This ROW License Agreement Termination Agreement may be executed and delivered by facsimile or any other electronic means, including ".pdf" or ".tiff" files, and any facsimile or electronic signature shall constitute an original for all purposes.

[signature page follows]

IN WITNESS WHEREOF, the Parties have executed this ROW License Agreement Termination Agreement as of the ROW License Agreement Termination Effective Date.

SERES THERAPEUTICS, INC.

By: /s/ Eric D. Shaff

Name: Eric D. Shaff

Title: President and Chief Executive Officer

[Signature Page to the Mutual Termination of Collaboration and License Agreement]

SOCIÉTÉ DES PRODUITS NESTLÉ S.A.

By: /s/ Claudio Kuoni

Name: Claudio Kuoni

Title: Vice President

[Signature Page to the Mutual Termination of Collaboration and License Agreement]

Exhibit 31.1

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: November 13, 2024

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

Exhibit 31.2

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: November 13, 2024

By: /s/ Marella Thorell

Marella Thorell

Executive Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 32.1

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 September 30, 2024 (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.

November 13, 2024

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

Exhibit 32.2

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 September 30, 2024 (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.

November 13, 2024

/s/ Marella Thorell

Marella Thorell
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)