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 June 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 August 9, 2024, the registrant had 151,730,995 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, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, manufacturing activities and related timing, expected benefits of our restructuring initiative and cost saving measures, commercialization efforts and related timing, our ability to continue as a going concern, timing and likelihood of completing the pending Transaction (as defined herein), the completion of the production suite and milestone payments under the Bacthera Agreement, our rights and potential resolutions under the Oaktree Credit Agreement and our ability or intention to pursue any remedies thereunder, 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 completion of the Transaction (as defined herein) is subject to conditions, some or all of which may not be satisfied, or completed on a timely basis, if at all. Failure to complete, or unexpected delays in completing, the Transaction or any termination of the Purchase Agreement would have an adverse effect on the Company, its financial condition and results of operations.
- The amount of the Transaction Consideration (as defined herein) we will receive in the Transaction is subject to various risks and uncertainties.

- We may not be able to realize the anticipated benefits of the Transaction.
- Following the Transaction, we will be a smaller, less diversified company.
- We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern.
- We may be unable to realize the expected benefits from our restructuring and other cost reduction efforts.
- We are a commercial-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 will need additional funding in order to complete development of our product candidates and commercialize VOWST and our product candidates, if approved. If we are unable to raise or access capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- The terms of the Credit Agreement and Guarantee with Oaktree Fund Administration, LLC place restrictions on our operating and financial flexibility.
- We rely on third parties for certain aspects of the manufacture of our product and 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 and product candidates or that such quantities may not be available at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- We depend heavily on the commercial success of VOWST, which was only recently approved for marketing by the FDA and launched in the United States. There is no assurance that our commercialization efforts or those of our collaborators will be successful or that we will be able to generate collaboration profit at the levels or within the timing we expect.
- Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.
- Other than VOWST, 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.
- VOWST and our product candidates are based on microbiome therapeutics, 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 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 our 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.
- The collaboration and license agreements with Société des Produits Nestlé S.A., successor in interest to Nestec Ltd., and NHSc Rx License GmbH, successor in interest to NHSc Pharma Partners (collectively, and together with their affiliates and subsidiaries, Nestlé) are important to our business. If we or Nestlé fail to adequately perform under these agreements, or if we or Nestlé terminate the agreements, the development and commercialization of our CDI and IBD product candidates could be delayed or terminated and our business would be adversely affected.
- 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 though VOWST has received FDA approval and even if any of our product candidates receive marketing approval, VOWST and 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 or 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)

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

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

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue:				
Collaboration revenue - related party	$ —	$ 126,473	$ —	$ 125,951
Total revenue	—	126,473	—	125,951
Operating expenses:				
Research and development expenses	17,875	46,792	$ 39,577	90,761
General and administrative expenses	16,059	28,051	$ 31,525	50,521
Collaboration (profit) loss sharing - related party	(2,589)	2,106	$ (171)	5,713
Total operating expenses	31,345	76,949	$ 70,931	146,995
(Loss) income from operations	(31,345)	49,524	$ (70,931)	(21,044)
Other income (expense):				
Interest income	1,230	1,726	$ 2,878	2,758
Interest expense	(3,447)	(3,187)	$ (8,110)	(5,135)
Other income (expense)	692	(1,511)	$ 3,160	(1,201)
Total other expense, net	(1,525)	(2,972)	$ (2,072)	(3,578)
Net (loss) income	$ (32,870)	$ 46,552	$ (73,003)	$ (24,622)
Net (loss) income per share attributable to common stockholders, basic	$ (0.22)	$ 0.36	$ (0.49)	$ (0.19)
Net (loss) income per share attributable to common stockholders, diluted	$ (0.22)	$ 0.36	$ (0.49)	$ (0.19)
Weighted average common shares outstanding, basic	151,514,597	127,713,486	148,808,089	126,793,342
Weighted average common shares outstanding, diluted	151,514,597	129,844,931	148,808,089	126,793,342
Other comprehensive (loss) income:				
Unrealized (loss) income on investments, net of tax of $0	—	(2)	—	10
Currency translation adjustment	—	(1)	—	1
Total other comprehensive (loss) income	—	(3)	—	11
Comprehensive loss (income)	$ (32,870)	$ 46,549	$ (73,003)	$ (24,611)

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

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

	Common Stock		Additional	Accumulated Other Comprehensive		Total
	Shares	Par Value	Paid-in Capital	Loss (Income)	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, 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

	Common Stock		Additional	Accumulated Other Comprehensive		Total
	Shares	Par Value	Paid-in Capital	Loss (Income)	Accumulated Deficit	Stockholders' (Deficit)
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
Other comprehensive income	—	—	—	—	—	—
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
Other comprehensive loss	—	—	—	—	—	—
Net loss	—	—	—	—	(32,870)	(32,870)
Balance at June 30, 2024	151,633,922	$ 152	$ 964,012	$ -	$ (1,051,238)	$ (87,074)

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)

	Six Months Ended June 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (73,003)	$ (24,622)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation expense	12,023	20,342
Depreciation and amortization expense	2,979	2,927
Non-cash operating lease cost	4,780	4,247
Net (accretion) amortization of (discounts) premiums on investments	—	(236)
Amortization of debt issuance costs	950	337
Loss on extinguishment of debt	—	1,625
Loss on disposal of fixed assets	293	—
Impairment of long-lived assets	3,267	—
Change in fair value of warrant liabilities	(546)	(132)
Collaboration (profit) loss sharing - related party (3)	—	5,713
Changes in operating assets and liabilities:		
Prepaid expenses and other current and other non-current assets	2,526	3,579
Collaboration receivable - related party	(9,927)	(7,559)
Inventories	(23,350)	(5,340)
Deferred income - related party	192	2,817
Deferred revenue - related party	—	(951)
Accounts payable	1,184	(3,092)
Operating lease liabilities	(2,261)	(577)
Accrued expenses and other current and long-term liabilities (4)	5,846	(9,678)
Net cash used in operating activities	(75,047)	(10,600)
Cash flows from investing activities:		
Purchases of property and equipment	(161)	(5,301)
Purchases of investments	—	(4,426)
Sales and maturities of investments	—	22,983
Sales of restricted investments	1,401	—
Net cash provided by investing activities	1,240	13,256
Cash flows from financing activities:		
Proceeds from at the market equity offering, net of issuance costs	18,409	11,730
Proceeds from exercise of stock options	—	356
Issuance of common stock under ESPP	353	1,229
Proceeds from issuance of debt, net of issuance costs	—	103,378
Repayment of notes payable	—	(52,860)
Net cash provided by financing activities	18,762	63,833
Net (decrease) increase in cash, cash equivalents, and restricted cash	(55,045)	66,489
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	—	1
Cash, cash equivalents and restricted cash at beginning of period	136,150	171,215
Cash, cash equivalents and restricted cash at end of period	$ 81,105	$ 237,705
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 7,160	$ 2,869
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment purchases included in accounts payable and accrued expenses	$ —	$ 943
Prepaid rent reclassified to right-of-use assets	$ —	$ 2,336
Lease liability arising from obtaining right-of-use assets	$ —	$ 1,210
Recognition of warrant liabilities	$ —	$ 2,100
Warrants issued related to 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

[4] Includes related party amounts of $15,022 and $(3,398) at June 30, 2024 and 2023, respectively (see Note 17, *Related Party Transactions*).

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

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

1. Nature of the Business and Basis of Presentation

Seres Therapeutics, Inc. (the “Company”) was incorporated under the laws of the State of Delaware in October 2010 under the name Newco LS21, Inc. In October 2011, the Company changed its name to Seres Health, Inc., and in May 2015, the Company changed its name to Seres Therapeutics, Inc. The Company is a commercial-stage microbiome therapeutics company focused on the development and commercialization of 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.

The Company’s product, VOWST, formerly called SER-109, was approved by the U.S. Food and Drug Administration (“FDA”) on April 26, 2023 and is the first and only orally administered microbiome therapeutic. VOWST is indicated to prevent the recurrence of *Clostridioides difficile* infection (“CDI”) in patients 18 or older following antibacterial treatment for recurrent CDI. The Company launched VOWST in the United States with its collaborator, Nestlé Health Science (“Nestlé”), in June 2023.

Building upon VOWST, the Company is progressing the Phase 1b clinical trial of SER-155, a live biotherapeutic candidate consisting of a 16-strain consortium of cultivated bacteria designed to prevent gastrointestinal (“GI”)-derived infections and resulting bloodstream infections, as well as induce immune tolerance responses to reduce the incidence of graft-versus-host-disease (“GvHD”) in patients undergoing allogeneic hematopoietic stem cell transplantation (“allo-HSCT”). Study cohort 1, which included 13 participants, was designed to assess safety and drug pharmacology, including the gastrointestinal microbiome data from the first 100 days, which showed the successful engraftment of SER-155 bacterial strains in all nine subjects with evaluable microbiome samples, and a substantial reduction in the cumulative incidence of pathogen domination (a biomarker associated with the risk of serious GI infections and enteric-derived bloodstream infections, as well as GvHD) as compared to a reference cohort of patients. The tolerability profile observed was favorable, with no serious adverse events attributed to SER-155 administration. Enrollment in study cohort 2, which includes 45 participants, was completed in April 2024. Study cohort 2 incorporates a randomized, double-blinded placebo-controlled 1:1 design to further evaluate safety and engraftment as well as clinical outcomes, and data readout is anticipated in September 2024.

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.

On August 5, 2024, the Company entered into an Asset Purchase Agreement (the “Purchase Agreement”) with Société des Produits Nestlé S.A. (“SPN”), a wholly-owned subsidiary of Nestlé S.A., pursuant to which the Company agreed, subject to the satisfaction or waiver of the conditions set forth therein, to sell the Company’s 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, formerly known as SER-109 (the “Product”), as provided for in accordance with the terms of the Purchase Agreement to SPN and its designated affiliates (collectively, “Nestlé Health Science”), and Nestlé Health Science will assume certain liabilities from the Company (the "Transaction"). As consideration for the Transaction, SPN has agreed to pay the Company the following consideration (the “Transaction Consideration”):

(i) a cash payment, payable 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 existing license agreement between the Company and the SPN affiliate, less approximately CHF2,000 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 (as described below) to be 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”), payable 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 an amount related to certain employment obligations assumed by SPN through the period prior to the Closing Date.

The Company and SPN will share 50/50 in the net profit or net loss 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.

The Closing is subject to the approval of the transaction by the Company’s stockholders and other customary conditions. 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”) will be terminated and each of Bacthera and Seres will release one another from any and losses, liabilities or other obligations arising thereunder with respect to the period ending as of the date of the Closing, including without limitation any milestone payments required to be paid to Bacthera thereunder.

As a condition to Closing, the Company and SPN will enter into a securities purchase agreement (the “Securities Purchase Agreement”) pursuant to which SPN will agree to purchase 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 will agree not to sell or transfer the Shares for a period of six months after Closing, subject to certain customary exceptions. The Company will agree 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 the Company’s outstanding shares of common stock, the Company will agree 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 will contain customary representations and warranties and closing conditions.

As a condition to Closing, the parties intend to enter into a Transition Services Agreement (the “TSA”), which will provide for services to be performed by the Company in order to facilitate a transition of the business associated with the VOWST Business to SPN and its affiliates. The scope of the transition services is expected to include 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 and other services, until the later of the period specified in the schedule to the TSA for each service or June 30, 2026. SPN will agree 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 the costs of any 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 SPN 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 SPN request, the Company will transfer the manufacturing services to a third party service provider designated by SPN. In the event of a material failure by the Company to maintain the manufacturing facility under the TSA, SPN 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.

As a condition to Closing, the Company intends to enter into a cross-license agreement with SPN under which the Company will grant 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 CDI and recurrent CDI and associated complications (collectively the “CDI Field”) the license to SPN under such Company patents and know-how would 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 will also grant 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. The license to SPN would be exclusive to SPN for five years after Closing and co-exclusive between SPN and us following that five year period. SPN will grant 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 will terminate and be of no further force or effect, except as contemplated by the Purchase Agreement.

Concurrently with the execution of the Purchase Agreement, the Company’s directors and executive officers and certain stockholders affiliated with Flagship Pioneering, Inc. entered into support agreements with the Company and SPN (the “Support Agreements”), pursuant to which, among other things and subject to the terms and conditions therein, such parties agreed, solely in their capacities as holders of shares of common stock (collectively, the “Subject Shares”), to vote all Subject Shares beneficially owned by such parties at every meeting of the stockholders of the Company (including the special meeting to consider the transactions contemplated by the Purchase Agreement) (i) in favor of adopting and approving the Purchase Agreement and the transactions contemplated by the Purchase Agreement, (ii) against any proposal that would otherwise be reasonably be expected to adversely affect the transactions contemplated by the Purchase Agreement, (iii) against any Acquisition Proposal (as defined therein), and (iv) in favor of approving any proposal to adjourn or postpone the special meeting of stockholders to a later date, if there are not sufficient votes for the adoption of the Purchase Agreement on the date on which such meeting is held. In addition, each stockholder party to a Support Agreement provided an irrevocable proxy to SPN to vote such party’s Subject Shares in favor of adopting and approving the Purchase Agreement and the transactions contemplated by the Purchase Agreement.

As a condition to Closing, the parties intend to enter into assignment and assumption of lease agreements (the “Assignment and Assumption Agreements”). Under the Assignment and Assumption Agreements, the Company will assign to SPN or its designated affiliates the Company’s rights in, to and under certain real property leases, and SPN or its designated affiliates will assume the liabilities related thereto.

As a condition to Closing, the parties intend to enter 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 accept employment with SPN or one of its designated affiliates will provide 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 will reimburse 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.

The Company is obligated to use the proceeds from the completion of the Transaction to fully retire 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 expects to incur 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 June 30, 2024, these costs amounted to approximately $2,398. In the event that the Purchase Agreement is terminated, the Company may be required under the Purchase Agreement under certain circumstances to reimburse SPN's expenses in the amount of $4,700.

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. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to potential commercialization. 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 June 30, 2024, the Company had an accumulated deficit of $1,051,238 and cash and cash equivalents of $71,232.

The Company's primary focus has been supporting commercialization, including the manufacture of VOWST, and the completion of the SER-155 Phase 1b study Cohort 2, which requires capital and resources. Other than VOWST, 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 of $73,003 and had net operating cash outflows of $75,047 for the six months ended June 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 receipt of the upfront payments due upon closing of the Transaction and subsequent payments that are contingent upon compliance with the TSA, as well as other potential financing transactions, including selling shares under the Company's at the market equity offering. The Transaction is subject to stockholder approval, which has not been received as of the date of this Quarterly Report on Form 10-Q. Additionally, 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 obtaining stockholder approval for and satisfying other closing conditions to the Transaction and 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.

Unaudited Interim Financial Information

The accompanying unaudited condensed consolidated financial statements as of June 30, 2024 and for the three and six months ended June 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 six months ended June 30, 2024 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2024.

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 six months ended June 30, 2024.

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 amounts of revenue and expenses during the reporting periods. In the unaudited condensed consolidated financial statements, the Company uses estimates and assumptions related to revenue recognition and 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 June 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):

	June 30, 2024	December 31, 2023
Cash and cash equivalents	$ 71,232	$ 127,965
Restricted cash, non-current	9,873	8,185
Total cash, cash equivalents and restricted cash	$ 81,105	$ 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.

3. 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 June 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 consist 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 are analyzed each period based on changes in estimates or assumptions and recorded through other income (expense). The Company uses 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 estimates 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 June 30, 2024, given the anticipated Transaction and expected 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 the warrant liabilities at June 30, 2024 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 six months ended June 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 June 30, 2024	$ —

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

4. Investments

As of June 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 June 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.

5. Inventories

Capitalized inventories consist of the following (in thousands):

	June 30, 2024	December 31, 2023
Raw materials	$ 4,934	$ 4,426
Work in process	48,063	25,221
Finished goods	—	—
Total	$ 52,997	$ 29,647

Prior to the FDA's approval for VOWST on April 26, 2023, all costs for the manufacture of product supplies to support clinical development and commercial launch, including pre-launch inventory, were expensed as incurred or otherwise accounted for pursuant to the 2021 License Agreement. Pre-launch inventory manufactured prior to the FDA approval of VOWST, which was not capitalized into inventory but instead was expensed as research and development in previous periods, will be used in commercial production until it is depleted. Pre-launch inventory expensed as research and development totaled $0, $0, $11,181 and $26,794 for the three and six months ended June 30, 2024 and 2023, respectively.

Inventory amounts written down as a result of excess, obsolescence, or unmarketability and determined not to be recoverable pursuant to the 2021 License Agreement are expensed in the period in which they are identified. There were no such write-downs during the three and six months ended June 30, 2024.

6. Property and Equipment, Net

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

	June 30, 2024	December 31, 2023
Laboratory equipment	$ 29,003	$ 29,081
Computer equipment	4,142	4,142
Furniture and office equipment	5,187	5,430
Leasehold improvements	32,039	33,549
Construction in progress	1,239	1,393
	71,610	73,595
Less: Accumulated depreciation and amortization	(53,816)	(51,138)
	$ 17,794	$ 22,457

Depreciation and amortization expense was $1,420, $2,979, $1,527 and $2,927 for the three and six months ended June 30, 2024 and 2023, respectively. During the six months ended June 30, 2024 and 2023, the Company disposed of certain assets with a cost basis of $594 and $9, respectively. In addition, during the six months ended June 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 June 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):

	June 30, 2024	December 31, 2023
Clinical and development costs	$ 1,132	$ 1,404
Manufacturing and quality costs	30,448	31,917
Payroll and payroll-related costs	7,437	16,465
Collaboration payable - related party (Note 17)	43,075	28,053
Facility and other	4,264	2,772
	$ 86,356	$ 80,611

As of June 30, 2024 and December 31, 2023, the Company accrued a total of $28,138 and $30,049, respectively, payable to Bacthera upon the substantial completion of a dedicated production suite for long-term supply of VOWST. This amount is included in the Manufacturing and quality costs category above. This liability is expected to be settled by SPN concurrent with the Closing of the Transaction, as the manufacturing agreement between the Company and Bacthera is being assigned and terminated as part of the Transaction. Pursuant to the termination of the Bacthera manufacturing agreement, SPN will pay a termination payment to Bacthera in full and final settlement of all outstanding liabilities owed to Bacthera.

Additionally, included within payroll and payroll-related costs as of June 30, 2024 and December 31, 2023 is $359 and $5,080, respectively, of accrued severance related to the Company's restructuring plan. See Note 12, *Restructuring*, for further details.

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 April 2022, the Company entered into a lease for additional laboratory and office space in Spring House, Pennsylvania, with a lease term of ten years and a renewal option, subject to certain conditions, for an additional five-year term. The undiscounted minimum lease payments were $3,029, net of a tenant improvement allowance of $1,184, over the original ten-year term. The lease commenced in April 2023, at which point, the Company recorded a right-of-use asset of $3,546, which consists of the lease liability of $1,210, and $2,336 of leasehold improvements that revert back to the lessor at the termination of the lease.

In June 2023, the Company entered into a lease for a donor collection facility in Irvine, California, with a lease term of approximately six years and a renewal option, subject to certain conditions, for an additional five-year term. The undiscounted minimum lease payments are $1,079 over the original term. The lease commenced in December 2023, at which point, the Company recorded a right-of-use asset of $1,830, which consists of the lease liability of $768, and $1,062 of leasehold improvements that revert back to the lessor at the termination of the lease.

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):

	June 30, 2024	December 31, 2023
Assets:		
Operating lease assets	$ 103,282	$ 109,793
Liabilities:		
Operating lease liabilities	$ 9,195	$ 6,677
Operating lease liabilities, net of current portion	100,936	105,715
Total operating lease liabilities	$ 110,131	$ 112,392

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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating lease costs	$ 5,705	$ 5,543	$ 11,476	$ 10,953
Short-term lease costs	371	372	745	740
Variable lease costs	1,961	2,180	3,928	3,943
Sublease income	(695)	—	(1,071)	—
Total lease costs	$ 7,342	$ 8,095	$ 15,078	$ 15,636

During the three and six months ended June 30, 2024 and 2023, the Company made cash payments for operating leases of $5,361, $8,957, $3,875, and $7,289, respectively.

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

	As of June 30, 2024
2024 (remaining 6 months)	$ 10,912
2025	22,062
2026	22,674
2027	23,347
2028	23,580
2029 and thereafter	65,819
Total future minimum lease payments	$ 168,394
Less: interest	(58,263)
Present value of operating lease liabilities	$ 110,131

As of June 30, 2024, the weighted average remaining lease term was 7.46 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 13%. As of June 30, 2023, the weighted average remaining lease term was 8.47 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 "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 establishes a term loan facility of $250,000 (the "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 Closing Date. The Term Loan also consists of (i) $45,000 (the "Tranche B Loan") and (iii) $45,000 (the "Tranche C Loan"), each of which the Company may borrow subject to certain conditions, and (iv) $50,000 (the "Tranche D Loan") available in Oaktree's sole discretion. The Tranche B Loan may be drawn by the Company until September 30, 2024, if VOWST net sales for the trailing six consecutive months are at least $35,000 and at least 4.5% greater in the calendar quarter prior to the Applicable Funding Date (as defined in the Oaktree Credit Agreement) over the calendar quarter immediately preceding it. The Tranche C Loan may be drawn until September 30, 2025, if VOWST net sales for the trailing 12 consecutive months are at least $120,000 and at least 4.5% greater in each of the two calendar quarters prior to the Applicable Funding Date relative, in each case, to the calendar quarter immediately preceding it. The Term Loan has 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 Term Loan bear 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. If certain VOWST net sales targets are met, the applicable margin will be reduced from 7.875% to 7.50% through the Maturity Date. The Company is required to make quarterly interest-only payments on the Term Loan for the first three years after the Closing Date. Beginning on June 30, 2026, the Company will be required to make quarterly payments of interest, plus repay 7.50% of the outstanding principal of the Term Loan in quarterly installments until the Maturity Date, unless the interest only period is extended based upon the achievement of certain VOWST net sales targets.

The Company is obligated to pay the Lenders an exit fee equal to 1.50% of the aggregate amount of the Term Loan funded, such exit fee to be due and payable upon the earliest to occur of (1) the Maturity Date, (2) the acceleration of the outstanding Term Loan, and (3) the prepayment of the outstanding Term Loan. The Company may voluntarily prepay the outstanding Term Loan, subject to a customary make-whole for the first two years following the Closing Date plus 4.0% of the principal amount of the Term Loan prepaid, and thereafter a prepayment premium equal to (i) 4.0% of the principal amount of the Term Loan prepaid, if prepaid after the second anniversary of the Closing Date through and including the third anniversary of the Closing Date, (ii) 2.0% of the principal amount of the Term Loan if prepaid after the third anniversary of the Closing Date through and including the fourth anniversary of the Closing Date, (iii) 1.0% of the principal amount of the Term Loan if prepaid after the fourth anniversary of the Closing Date through and including the fifth anniversary of the Closing Date, with no prepayment premium due after the fifth anniversary of the Closing Date through the Maturity Date.

The Company's obligations under the Oaktree Credit Agreement and the other Loan Documents (as defined in the Oaktree Credit Agreement) will be guaranteed by any domestic subsidiaries of the Company that become Guarantors (as defined in the Oaktree Credit Agreement), subject to certain exceptions. The Company's and the Guarantors' (collectively, the "Loan Parties") respective obligations under the Oaktree Credit Agreement and the other Loan Documents are secured by first priority security interests in substantially all assets of the Loan Parties, including intellectual property, subject to certain customary thresholds and exceptions. As of June 30, 2024, there were no Guarantors.

The Oaktree Credit Agreement contains customary representations, warranties and affirmative and negative covenants, including a financial covenant requiring the Company to maintain certain levels of cash and cash equivalents in accounts subject to a control agreement in favor of the Agent of at least $30,000 at all times commencing from 30 days after the Closing Date and decreasing to $25,000 of cash and cash equivalents in such controlled accounts after the Company borrows any Tranche B Loan. As of June 30, 2024, the Company was in compliance with all financial covenants pursuant to the Oaktree Credit Agreement.

In addition, the Oaktree Credit Agreement contains certain events of default that entitle the Agent to cause the Company's indebtedness under the Oaktree Credit Agreement to become immediately due and payable, and to exercise remedies against the Loan Parties and the collateral securing the Term Loan, including cash. In an event of default and for its duration, as defined in the Oaktree Credit Agreement, an additional default interest rate equal to 2.0% per annum may apply to all obligations owed under the Oaktree Credit Agreement.

On the 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 is 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 Additional Warrants will be immediately exercisable upon issuance, and the exercise period will expire seven years from the date of issuance.

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 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 are considered outstanding instruments at the Closing Date of the Oaktree Credit Agreement and in accordance with ASC 815, are initially recognized at their respective fair values as derivative liabilities given the variable settlement amount of their respective aggregate exercise prices. The Company adjusts the carrying values of the Additional Warrants to their respective fair values at each reporting period, until such time that the Additional Warrants are issued and their respective exercise prices become fixed, and the value of the Additional Warrants is reclassified to additional paid-in capital. The Company uses a simulation model to determine the fair value of the Additional Warrants, as described in Note 3, *Fair Value Measurements*. As of June 30, 2024, given the anticipated Transaction and expected 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 at June 30, 2024 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 are 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 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 Term Loan balances at such time that they are drawn.

The effective interest rate in effect as of June 30, 2024 was 15.9%. As of June 30, 2024 and December 31, 2023, the carrying value of the Term Loan was $102,494 and $101,544, which is classified as a long-term liability on the condensed consolidated balance sheets. The future principal payments due under the Oaktree Credit Agreement, excluding interest and the end of term charge, are as follows:

Year Ending December 31,		Principal
2024 (remaining 6 months)	$	—
2025		—
2026		24,750
2027		33,000
2028		33,000
Thereafter		19,250
Total	$	110,000

During the three and six months ended June 30, 2024 and 2023, the Company recognized $4,064, $8,110, $2,518, and $2,518, respectively, of interest expense related to the Term Loan, which is reflected in interest expense on the condensed consolidated statements of operations and comprehensive loss. During the three and six months ended June 30, 2023, the Company recognized $520 and $2,468, respectively, of interest expense related to the Loan and Security Agreement with Hercules.

On May 1, 2024, the Company received a Notice of Default and Reservation of Rights (the “Notice”) from the Agent under the Oaktree Credit Agreement. The Notice specified that in the Agent’s view, one or more events of default have occurred under the Oaktree Credit Agreement due to (a) the Company’s non-payment of a milestone payment to Bacthera under the Bacthera Agreement which the Agent characterized as “Indebtedness” that would not be permitted under the Oaktree Credit Agreement and (b) the Company’s failure to deliver written notice to the Agent regarding such non-payment.

The Company has responded by letter to the Notice, advising the Agent that no default or event of default under the Oaktree Credit Agreement has occurred or is continuing, because the payment under the Bacthera Agreement is not due, and, as a result, no notice of non-payment was required. Moreover, even if the payment were due, the Company does not believe such payment would constitute Indebtedness (as defined in the Oaktree Credit Agreement).

Based on the above, the Company believes that it is not in default under the Oaktree Credit Agreement, and that the Agent does not have the right to accelerate the indebtedness or otherwise pursue remedies thereunder. As a result, the Company continues to classify the carrying value of the Term Loan as non-current on its condensed consolidated balance sheet as of June 30, 2024. If the Agent were to pursue any such actions, the Company intends to vigorously defend itself against them and to pursue any counterclaims available to it. The Company is attempting to resolve this matter with the Agent consensually. The Bacthera Agreement is being assigned and terminated as part of the Transaction. Pursuant to the termination of the Bacthera Agreement, SPN will pay a termination payment to Bacthera in full and final settlement of all outstanding liabilities owed to Bacthera.

The outstanding indebtedness under the Oaktree Credit Agreement, including accrued and unpaid interest, prepayment fees, and exit fees, will be repaid concurrent with the closing of the Transaction with Nestlé, as the Company is obligated to use the proceeds from the completion of the Transaction to fully retire its senior secured debt facility with Oaktree.

10. Common Stock and Stock-Based Awards

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 six months ended June 30, 2024, the Company sold 0 and 15,366,630 shares, respectively, of common stock under the Sales Agreement, at an average price of $0 and approximately $1.23 per share, respectively, raising aggregate net proceeds of approximately $0 and $18,409, after deducting an aggregate commission of approximately 3% and other issuance costs. During the three and six months ended June 30, 2023, the Company sold 1,218,377 and 2,005,547 shares, respectively, of common stock under the Sales Agreement, at an average price of approximately $6.40 and $6.11 per share, respectively, raising aggregate net proceeds of approximately $7,491 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	7,173,731	$ 1.05		
Exercised	—	$ —		
Forfeited	(2,710,547)	$ 8.56		
Outstanding as of June 30, 2024	19,307,296	$ 6.60	7.39	$ —
Vested or expected to vest as of June 30, 2024	19,307,296	$ 6.60	7.39	$ —
Options exercisable as of June 30, 2024	9,715,178	$ 10.07	5.62	$ —

The weighted average grant date fair value of stock options granted during the three and six months ended June 30, 2024 and 2023 was $0.65, $0.93, $4.54 and $4.56 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 $(37), $8, $2,373 and $2,373 of compensation expense during the three and six months ended June 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 six months ended June 30, 2024, the Company recognized $284 and $426 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	(521,869)	$ 5.73
Forfeited	(336,619)	$ 3.24
Unvested restricted stock units as of June 30, 2024	3,807,443	$ 3.07

During the three and six months ended June 30, 2024 and 2023, the Company granted 5,186, 1,288,127, 28,700 and 1,720,795 RSUs, respectively. During the three and six months ended June 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 vest in two tranches on August 15, 2024, and 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 six months ended June 30, 2024, the Company recognized $173 and $358, 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 $267, $527, $2,768 and $2,768 in compensation expense during the three and six months ended June 30, 2024 and 2023, respectively, with respect to these PSUs. The remaining $398 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development expenses	$ 2,835	$ 7,851	$ 6,445	$ 11,582
General and administrative expenses	2,699	5,641	5,578	8,760
	$ 5,534	$ 13,492	$ 12,023	$ 20,342

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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Basic Earnings Per Share:				
Numerator:				
Net (loss) income	$ (32,870)	$ 46,552	$ (73,003)	$ (24,622)
(Loss) income attributable to common stockholders - basic	$ (32,870)	$ 46,552	$ (73,003)	$ (24,622)
Denominator:				
Weighted-average shares outstanding	151,514,597	127,713,486	148,808,089	126,793,342
Net (loss) income per share applicable to common stockholders - basic	$ (0.22)	$ 0.36	$ (0.49)	$ (0.19)
Diluted Earnings Per Share:				
Numerator:				
Net (loss) income	$ (32,870)	$ 46,552	$ (73,003)	$ (24,622)
(Loss) income attributable to common stockholders - diluted	$ (32,870)	$ 46,552	$ (73,003)	$ (24,622)
Denominator:				
Weighted-average shares outstanding	151,514,597	127,713,486	148,808,089	126,793,342
Dilutive impact from:				
Stock options to purchase common stock	—	1,597,058	—	—
Unvested restricted stock units	—	519,338	—	—
Shares issuable under employee stock purchase plan	—	15,049	—	—
Weighted-average shares outstanding - diluted	151,514,597	129,844,931	148,808,089	126,793,342
Net (loss) income per share applicable to common stockholders - diluted	$ (0.22)	$ 0.36	$ (0.49)	$ (0.19)
Anti-dilutive potential common stock equivalents excluded from the calculation of net (loss) income per share:				
Stock options to purchase common stock	19,307,296	11,946,170	19,307,296	16,755,599
Unvested restricted stock units	3,807,443	879,557	3,807,443	3,938,868
Shares issuable under employee stock purchase plan	306,240	—	193,503	193,454
Warrants to purchase common stock	1,177,433	1,177,433	1,177,433	1,177,433

The effect of dilutive securities was calculated using the treasury stock method. The anti-dilutive potential common stock equivalents for the three months ended June 30, 2023 were excluded from the computation of diluted net income per share attributable to common stockholders because those stock options to purchase common stock and restricted stock units had an anti-dilutive impact due to the assumed proceeds per share using the treasury stock method being greater than the average fair value of the Company's common shares for those periods.

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 for the three months ended June 30, 2024, and the six months ended June 30, 2024 and 2023 as the effect would be to reduce the net loss per share and therefore be anti-dilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same for those periods. Additionally, for the three and six months ended June 30, 2024 and 2023, the warrants to purchase common stock were excluded because the exercise price of the Tranche A Warrants is greater than the average fair value of the Company's common shares, 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 six months ended June 30, 2024 (in thousands):

	As of June 30, 2024
Restructuring expenses	$ 5,606
Less: stock-based compensation	(261)
Cash payments made through June 30, 2024	(4,986)
Remaining liability included in accrued expenses and other current liabilities	$ 359

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 vest in two tranches on August 15, 2024, and 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. Revenue from Contracts with Customers

License Agreement with NHSc Rx License GmbH (Nestlé)

Summary of Agreement

In July 2021, the Company entered into the 2021 License Agreement with NHSc Pharma Partners, succeeded by NHSc Rx License GmbH (together with SPN, their affiliates, and their subsidiaries, "Nestlé") (the "2021 License Agreement"). Under the terms of the 2021 License Agreement, the Company granted Nestlé a co-exclusive, sublicensable (under certain circumstances) license to develop, commercialize and conduct medical affairs activities for (i) therapeutic products based on the Company's microbiome technology (including VOWST, previously the Company's SER-109 product candidate) that are developed by the Company or on the Company's behalf for the treatment of CDI and recurrent CDI, as well as any other indications pursued for the products upon mutual agreement of the parties (the "2021 Field") in the United States and Canada (the "2021 Licensed Territory"), and (ii) VOWST and any improvements and modifications thereto developed pursuant to the terms of the 2021 License Agreement (the "2021 Collaboration Products") for any indications in the 2021 Licensed Territory. The Company was responsible for completing development of the first 2021 Collaboration Product, which is VOWST, in the 2021 Field in the United States until first regulatory approval, which was obtained on April 26, 2023.

Nestlé has the sole right to commercialize the 2021 Collaboration Products in the 2021 Licensed Territory in accordance with a commercialization plan. Both parties will perform medical affairs activities in the 2021 Licensed Territory in accordance with a medical affairs plan. The Company is responsible for the manufacturing and supply for commercialization under a supply agreement that has been executed between the parties. Both parties performed pre-launch activities of VOWST prior to the first commercial sale in the United States, which occurred in June 2023. The Company was responsible for funding the pre-launch activities until first commercial sale of VOWST in the 2021 Licensed Territory and in accordance with a pre-launch plan, up to a specified cap. The Company is entitled to share equally in the commercial profits and losses of VOWST.

In connection with the 2021 License Agreement, the Company received an upfront payment of $175,000, and the Company received an additional $125,000 milestone payment in May 2023 after FDA approval of VOWST. The Company is eligible to receive additional payments of up to $235,000 if certain regulatory and sales milestones are achieved. The potential future milestone payments include up to $10,000 for the achievement of specified regulatory milestones and up to $225,000 for the achievement of specified net sales milestones.

The 2021 License Agreement continues in effect until all development and commercialization activities for all 2021 Collaboration Products in the 2021 Licensed Territory have permanently ceased. The 2021 License Agreement may be terminated by either party upon sixty days' written notice for the other party's material breach that remains uncured during such sixty-day period, or immediately upon written notice for the other party's insolvency. Nestlé may also terminate the 2021 License Agreement at-will with twelve months' prior written notice, effective only on or after the third anniversary of first commercial sale of VOWST in the 2021 Licensed Territory. The Company may also terminate the 2021 License Agreement immediately upon written notice if Nestlé challenges any licensed patent in the 2021 Licensed Territory. Upon termination of the 2021 License Agreement, all licenses granted to Nestlé by the Company will terminate. If the Company commits a material breach of the 2021 License Agreement, Nestlé may elect not to terminate the 2021 License Agreement but instead apply specified adjustments to the payment terms and other terms and conditions of the 2021 License Agreement.

Accounting Analysis

The 2021 License Agreement represents a separate contract between Nestlé and the Company. The 2021 License Agreement is within the scope of Accounting Standard Update 2018-18, *Collaborative Arrangements (Topic 808)* (see Note 14*, Collaboration Profit and Loss),* and has elements that are within the scope of ASC 606 - *Revenue From Contracts with Customers (Topic 606)* and Topic 808.

The Company identified the following promises in the 2021 License Agreement that were evaluated under the scope of Topic 606: (i) delivery of a co-exclusive license for VOWST to develop, commercialize and conduct medical affairs in the United States and Canada; (ii) services to be performed in accordance with the development and regulatory activity plan to obtain regulatory approval of VOWST in the United States. The Company also evaluated whether certain options outlined within the 2021 License Agreement represented material rights that would give rise to a performance obligation and concluded that none of the options convey a material right to Nestlé and therefore are not considered separate performance obligations within the 2021 License Agreement.

The Company assessed the above promises and determined that the co-exclusive license for VOWST and the services to obtain regulatory approval of VOWST in the United States are reflective of a vendor-customer relationship and therefore represent performance obligations within the scope of Topic 606. The co-exclusive license for VOWST in the United States and Canada is considered functional intellectual property and distinct from other promises under the contract as Nestlé can benefit from the license on its own or together with other readily available resources. The services performed by the Company to obtain regulatory approval of VOWST were not complex or specialized, could be performed by another qualified third party, were not expected to significantly modify or customize the license given that VOWST was late-stage intellectual property that completed clinical development and the services were performed over a short period of time. Therefore, the license and the services each represents a separate performance obligation within a contract with a customer under the scope of Topic 606 at contract inception.

The up-front payment of $175,000 compensated the Company for: (i) the co-exclusive license for VOWST to develop, commercialize and conduct medical affairs in the United States and Canada, (ii) services performed in accordance with the development and regulatory activity plan to obtain regulatory approval of VOWST in the United States and (iii) pre-launch activities performed by Nestlé and the Company until the first commercial sale of VOWST in the United States. The commercialization activities, which include the commercial manufacturing, participation on joint steering committees and medical affairs work, that occur after regulatory approval of VOWST in the United States, are part of the 50/50 sharing of commercial profits. Therefore, the up-front payment of $175,000 does not compensate the Company for these activities.

The Company allocated the $175,000 between the Topic 606 unit of account and the Topic 808 unit of account by determining the standalone selling price (SSP) of each good or service. The selling price of each good or service was determined based on the Company's SSP with the objective of determining the price at which it would sell such an item if it were to be sold regularly on a standalone basis. The Company determined the transaction price under Topic 606 to be $139,500 and the Topic 808 amount to be $35,500 at the inception of the 2021 License Agreement (see Note 14*, Collaboration Profit and Loss)*.

The Topic 606 transaction price of $139,500 was allocated to the co-exclusive license for VOWST and the services performed in accordance with the development and regulatory activity plan to obtain regulatory approval of VOWST in the United States based on the Company's SSP. The Company recognized revenue for the license performance obligation at a point in time, that is upon transfer of the license to Nestlé. As control of the license was transferred in July 2021, the Company recognized $131,343 of collaboration revenue - related party during the year ended December 31, 2021 pertaining to the license performance obligation. The remaining amount of the Topic 606 transaction price of $8,157 was allocated to the services performance obligation and was recognized over time as the Company performed the services, which it completed in April 2023. During the three and six months ended June 30, 2024 and 2023, the Company recognized $0, $0, $853, and $1,975 of collaboration revenue - related party, respectively, related to the services performance obligation under the 2021 License Agreement.

The Company recognized the $125,000 regulatory milestone payment received in May 2023, which was fully allocated to the license performance obligation, as revenue in the consolidated statements of operations and comprehensive loss during the year ended December 31, 2023.

The Company determined that any variable consideration related to the remaining regulatory milestones is deemed to be fully constrained and therefore excluded from the transaction price due to the high degree of uncertainty and risk associated with these potential payments, as the Company determined that it could not assert that it was probable that a significant reversal in the amount of cumulative revenue recognized will not occur. The Company also determined that sales milestones relate solely to the license of intellectual property and are therefore excluded from the transaction price under the sales- or usage-based royalty exception of Topic 606. Revenue related to these sales milestones will only be recognized when the associated sales occur, and relevant thresholds are met.

Collaboration and License Agreement with Société des Produits Nestlé S.A. (Nestlé)

Summary of Agreement

In January 2016, the Company entered into a collaboration and license agreement with Nestec Ltd., succeeded by SPN (together with NHSc Rx License GmbH, their affiliates and their subsidiaries, "Nestlé") (the "2016 License Agreement") for the development and commercialization of certain product candidates for the treatment and management of CDI and inflammatory bowel disease ("IBD"), including UC and Crohn's disease. The 2016 License Agreement supports the development of the Company's portfolio of products for CDI and IBD in markets outside of the United States and Canada (the "2016 Licensed Territory").

Under the 2016 License Agreement, the Company granted to Nestlé an exclusive, royalty-bearing license to develop and commercialize, in the 2016 Licensed Territory, certain products based on its microbiome technology that are being developed or commercialized, as applicable, for the treatment of CDI and IBD, including VOWST, SER-262, SER-287 and SER-301 (collectively, the "2016 Collaboration Products"). The 2016 License Agreement sets forth the Company's and Nestlé's respective obligations for development, commercialization, regulatory and manufacturing and supply activities for the 2016 Collaboration Products with respect to the licensed fields and the 2016 Licensed Territory.

Under the 2016 License Agreement, Nestlé agreed to pay the Company an upfront cash payment of $120,000, which the Company received in February 2016. The Company is eligible to receive up to $285,000 in development milestone payments, $375,000 in regulatory payments and up to an aggregate of $1,125,000 for the achievement of certain commercial milestones related to the sales of the 2016 Collaboration Products. Nestlé also agreed to pay the Company tiered royalties, at percentages ranging from the high single digits to high teens, of net sales of 2016 Collaboration Products in the 2016 Licensed Territory.

Under the 2016 License Agreement, the Company is entitled to receive a $20,000 milestone payment from Nestlé following initiation of a SER-287 Phase 2 study and a $20,000 milestone payment from Nestlé following the initiation of a SER-287 Phase 3 study. In November 2018, the Company entered into a letter agreement with Nestlé which modified the 2016 License Agreement to address the current clinical plans for SER-287. Pursuant to the letter agreement, the Company and Nestlé agreed that following initiation of the SER-287 Phase 2b study, the Company would be entitled to receive $40,000 in milestone payments from Nestlé, which represent the milestone payments due to the Company for the initiation of a SER-287 Phase 2 study and a Phase 3 study. The SER-287 Phase 2b study was initiated and the $40,000 of milestone payments were received in December 2018.

The 2016 License Agreement continues in effect until terminated by either party on the following bases: (i) Nestlé may terminate the 2016 License Agreement in the event of serious safety issues related to any of the 2016 Collaboration Products; (ii) the Company may terminate the 2016 License Agreement if Nestlé challenges the validity or enforceability of any of the Company's licensed patents; and (iii) either party may terminate the 2016 License Agreement in the event of the other party's uncured material breach or insolvency. Upon termination of the 2016 License Agreement, all licenses granted to Nestlé by the Company will terminate, and all rights in and to the 2016 Collaboration Products in the 2016 Licensed Territory will revert to the Company. If the Company commits a material breach of the 2016 License Agreement, Nestlé may elect not to terminate the 2016 License Agreement but instead apply specified adjustments to its payment obligations and other terms and conditions of the 2016 License Agreement.

Accounting Analysis

The Company assessed the 2016 License Agreement in accordance with Topic 606 and concluded that Nestlé is a customer. The Company identified the following promises under the contract: (i) a license to develop and commercialize the 2016 Collaboration Products in the 2016 Licensed Territory, (ii) obligation to perform research and development services, (iii) participation on a joint steering committee, and (iv) manufacturing services to provide clinical supply to complete future clinical trials. In addition, the Company identified a contingent obligation to perform manufacturing services to provide commercial supply if commercialization occurs, which is contingent upon regulatory approval. This contingent obligation is not a performance obligation at inception and has been excluded from the initial allocation as it represents a separate buying decision at market rates, rather than a material right in the contract. The Company assessed the promised goods and services to determine if they are distinct. Based on this assessment, the Company determined that Nestlé cannot benefit from the promised goods and services separately from the others as they are highly interrelated and therefore not distinct. Accordingly, the promised goods and services represent one combined performance obligation and the entire transaction price will be allocated to that single combined performance obligation.

At contract inception, the Company determined that the $120,000 non-refundable upfront amount constituted the entirety of the consideration to be included in the transaction price as the development, regulatory, and commercial milestones were fully constrained. During the year ended December 31, 2016, the Company received $10,000 from Nestlé in connection with the initiation of the Phase 1b study for SER-262 in CDI. During the year ended December 31, 2017, the Company received $20,000 from Nestlé in connection with the initiation of the Phase 3 study for VOWST, then SER-109. During the year ended December 31, 2018, the Company received $40,000 from Nestlé in connection with the initiation of the Phase 2b study for SER-287. During the year ended December 31, 2020, the Company received $10,000 from Nestlé in connection with the initiation of the Phase 1b SER-301 study. As of June 30, 2024, the aggregate amount of the transaction price allocated to the performance obligation of the 2016 License Agreement was approximately $200,000.

During the three and six months ended June 30, 2024 and 2023, using the cost-to-cost method, which best depicts the transfer of control to the customer, the Company recognized $0, $0, $620 and $(1,024), of collaboration revenue – related party, respectively.

As of both June 30, 2024 and December 31, 2023, there was $95,364 of deferred revenue related to the unsatisfied portion of the performance obligation under the 2016 License Agreement. As of June 30, 2024 and December 31, 2023, the deferred revenue is classified as current or non-current in the condensed consolidated balance sheets based on the Company's estimate of revenue that will be recognized within the next 12 months, which is determined by the cost-to-cost method which measures the extent of progress towards completion based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the performance obligation. All costs associated with the 2016 License Agreement are recorded in research and development expense in the condensed consolidated statements of operations and comprehensive loss.

Contract Balances from Contracts with Customers

The following tables present changes in the Company's contract liabilities during the six months ended June 30, 2024 and 2023 (in thousands):

	Balance as of December 31, 2023	Additions	Deductions	Balance as of June 30, 2024
Six Months Ended June 30, 2024				
Contract liabilities:				
Deferred revenue - related party	$ 95,364	—	—	$ 95,364

	Balance as of December 31, 2022	Additions	Deductions	Balance as of June 30, 2023
Six Months Ended June 30, 2023				
Contract liabilities:				
Deferred revenue - related party	$ 96,689	1,644	(2,595)	$ 95,738

During the three and six months ended June 30, 2024 and 2023 the Company recognized the following revenues as a result of changes in the contract liability balances in the respective periods (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue recognized in the period from:				
Amounts included in the contract liability at the beginning of the period	$ —	$ 1,473	$ —	$ 951

When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded. Revenue is recognized from the contract liability over time using the cost-to-cost method. During the three months ended March 31, 2023, the Company's estimate of total costs expected to be incurred increased, resulting in a reversal of revenue based on its cost-to-cost methodology.

14. Collaboration Profit and Loss

License Agreement with NHSc Rx License GmbH (Nestlé)

Accounting Analysis

The 2021 License Agreement represents a separate contract between Nestlé and the Company. The 2021 License Agreement is within the scope of Topic 808, and has elements that are within the scope of Topic 606 (see Note 13, *Revenue from Contracts with Customers)* and Topic 808.

The Company considers the collaborative pre-launch activities and commercialization activities to be separate units of account within the scope of Topic 808 and are not performance obligations under Topic 606. The Company and Nestlé were both active participants in the pre-launch activities and commercialization activities and were exposed to significant risks and rewards that were dependent on the commercial success of the activities in the arrangement. The amount allocated to the Topic 808 unit of accounting relates to the pre-launch activities performed prior to the first commercial sale of VOWST and was determined to be $35,500 based on standalone selling price.

The Company recorded the $35,500 in total liabilities on its consolidated balance sheets at the inception of the arrangement. On a quarterly basis, the Company and Nestlé provided financial information about the pre-launch activities performed by both parties. The Company reduced the $35,500 liability as the pre-launch activities were performed and it made payments to Nestlé for the pre-launch costs Nestlé incurred. As of both June 30, 2024 and December 31, 2023, there was $10,064 included in accrued expenses and other current liabilities which represents costs incurred by Nestlé for pre-launch activities that have not yet been reimbursed by the Company.

The cost associated with pre-launch activities performed by the Company is recorded within total operating expenses in the Company's condensed consolidated statements of operations and comprehensive loss. In the three and six months ended June 30, 2024 and 2023, the Company recognized $0, $0, $645, and $1,446, respectively, in research and development expenses and $0, $0, $1,539, and $4,242 respectively, in general and administrative expenses associated with pre-launch activities performed. The pre-launch activities were completed prior to the first commercial sale of VOWST, which occurred in June 2023.

Under the 2021 License Agreement with Nestlé, beginning with the first commercial sale of VOWST, which occurred in June 2023, net sales of VOWST are recorded by Nestlé and include gross sales net of discounts, rebates, allowances, and other applicable deductions. These amounts include the use of estimates and judgments, which could be adjusted based on actual results in the future. The Company records its share of the profits or losses from the sales of VOWST, including commercial and medical affairs expenses incurred by the Company, on a net basis, as collaboration (profit) loss sharing - related party. This treatment is in accordance with the Company's revenue recognition and collaboration policy, given that Nestlé and the Company are both active participants in commercialization activities and are exposed to significant risks and rewards that are dependent on the commercial success of the activities in the 2021 License Agreement. Nestlé provides the Company with reporting related to net sales of VOWST in accordance with U.S. generally accepted accounting principles in order to calculate and record collaboration profit or loss.

The collaboration (profit) loss sharing - related party line item also includes the Company's profit on the transfer of VOWST inventory to Nestlé, which represents the excess of the supply price paid by Nestlé over the Company's cost to manufacture VOWST, subject to a supply price cap applicable to product manufactured prior to commercial launch.

The collaboration (profit) loss sharing - related party line item also includes the collaboration loss related to pre-launch activities, which were completed prior to the first commercial sale of VOWST.

The components of the collaboration profit (loss) sharing for the three and six months ended June 30, 2024 are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Share of VOWST net loss	$ 6,638	$ 2,141	$ 13,766	$ 2,141
Profit on transfer of VOWST inventory to Nestlé	(9,227)	(1,273)	(13,937)	(1,273)
Collaboration (profit)/loss related to pre-launch activities	—	1,238	—	4,845
Total collaboration (profit) loss sharing - related party	$ (2,589)	$ 2,106	$ (171)	$ 5,713

15. 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 June 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 June 30, 2024 or December 31, 2023.

16. 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 six months ended June 30, 2024 and 2023. Management has considered the Company’s history of cumulative net losses incurred since inception, its early stage of commercialization of VOWST, and its projection of book and tax losses for the twelve months ending December 31, 2024. 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 June 30, 2024 and December 31, 2023, and has not recorded any income taxes for the three and six months ended June 30, 2024 and 2023. Management reevaluates the positive and negative evidence at each reporting period.

17. Related Party Transactions

As described in Notes 13 and 14, in July 2021, the Company entered into the 2021 License Agreement with NHSc Pharma Partners, succeeded by NHSc Rx License GmbH (together with SPN, their affiliates, and their subsidiaries, “Nestlé”). NHSc Rx License GmbH is an affiliate of one of the Company’s significant stockholders, SPN. During the three and six months ended June 30, 2024 and 2023, the Company recognized $0, $0, $125,853, and $126,975, respectively, of related party revenue associated with the 2021 License Agreement. As of both June 30, 2024 and December 31, 2023, there was $0 of deferred revenue related to the 2021 License Agreement. As of June 30, 2024 and December 31, 2023, there was $43,075 and $28,053 included in accrued expenses related to the 2021 License Agreement, which represents amounts due to Nestlé pursuant to the 2021 License Agreement. As of June 30, 2024 and December 31, 2023, there was $7,922 and $7,730 of deferred income - related party included on the accompanying condensed consolidated balance sheets, which represents the inventory transferred to Nestlé that Nestlé has not yet sold through to customers or transferred as free goods. The Company recognizes deferred income - related party as collaboration profit upon Nestlé's sale or transfer of such inventory to third parties. During the three and six months ended June 30, 2024 and 2023, the Company paid Nestlé $0, $0, $0, and $13,419, respectively, for Nestlé’s share of the collaboration losses pursuant to the 2021 License Agreement. During the three and six months ended June 30, 2024 and 2023, the Company received $0, $8,674, $0 and $0, respectively in payments from Nestlé for the transfer of VOWST to Nestlé. As of June 30, 2024 and December 31, 2023, there is $18,601 and $8,674 in Collaboration receivable - related party due from Nestlé pursuant to the 2021 License Agreement.

As described in Note 13, *Revenue from Contracts with Customers*, in January 2016, the Company entered into the 2016 License Agreement with Nestec, Ltd, succeeded by SPN for the development and commercialization of certain product candidates in development for the treatment and management of CDI and IBD, including UC and Crohn’s disease. SPN is one of the Company’s significant stockholders. During the three and six months ended June 30, 2024 and 2023, the Company recognized $0, $0, $620, and $(1,024), respectively, of related party revenue associated with the 2016 License Agreement. As of June 30, 2024 and December 31, 2023, there was $95,364 and $95,364 of deferred revenue related to the 2016 License Agreement, which is classified as non-current in the condensed consolidated balance sheets. The Company did not make any payment to or receive any payments from Nestlé during the three and six months ended June 30, 2024 and 2023 pursuant to the 2016 License Agreement. There is no amount due from Nestlé pursuant to the 2016 License Agreement as of June 30, 2024 or December 31, 2023.

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 commercial-stage company focused on the development and commercialization of 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. Our first drug, VOWST, formerly called SER-109, was approved by the U.S. Food and Drug Administration, or FDA, on April 26, 2023, to prevent recurrence of *Clostridioides difficile* infection, or CDI, in patients 18 or older following antibacterial treatment for recurrent CDI. Our drug discovery and development pipeline includes other pre-clinical and clinical-stage assets. VOWST and 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 launched VOWST in the United States with our collaborator, Nestlé Health Science, or Nestlé, in June 2023. On August 5, 2024, we entered into an Asset Purchase Agreement, or the Purchase Agreement, with Société des Produits Nestlé S.A., or SPN, a wholly-owned subsidiary of Nestlé S.A., pursuant to which we agreed, subject to the satisfaction or waiver of the conditions set forth therein, to sell our VOWST microbiome therapeutic business to SPN and its designated affiliates (collectively, "Nestlé Health Science"), or the Transaction. The completion of the Transaction, if consummated, or the Closing, is subject to the approval of the Transaction by our stockholders, and other customary conditions. See "VOWST" below.

Following the Closing, we expect to focus on advancing SER-155 and our other wholly-owned cultivated live biotherapeutic candidates to improve patient outcomes for medically vulnerable patient populations with potential to address large commercial opportunities. We are designing live biotherapeutics 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 our SER-109 program 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 antimicrobial resistance, or AMR.

We are currently evaluating SER-155 in a Phase 1b study in patients undergoing allogeneic hematopoietic stem cell transplantation, or allo-HSCT, to prevent enteric-derived infections and resulting blood stream infections, as well as induce immune tolerance responses to reduce the incidence of graft-versus-host disease, or GvHD. 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 patients undergoing allo-HSCT.

Study cohort 1, which included 13 participants, was designed to assess safety and drug pharmacology, including the engraftment of drug bacteria in the gastrointestinal tract. In May 2023, we announced the Phase 1b cohort 1 results, including gastrointestinal microbiome data from the first 100 days, which showed the successful engraftment of SER-155 bacterial strains in all nine subjects with evaluable microbiome samples, and a substantial reduction in the cumulative incidence of pathogen domination (a biomarker associated with the risk of serious enteric infections and resulting bloodstream infections, as well as GvHD) as compared to a reference cohort of patients in this patient population. The tolerability profile observed was favorable, with no serious adverse events attributed to SER-155 administration. Enrollment in study cohort 2, which includes 45 participants, is complete as of April 2024. Study cohort 2 incorporates a randomized, double-blinded placebo-controlled 1:1 design to further evaluate safety and engraftment as well as clinical outcomes, and data readout is anticipated in September 2024.

We believe our pending clinical and drug pharmacology results, if positive, will validate the promise of live biotherapeutics to prevent poor clinical outcomes associated with the overgrowth of pathogens in the GI tract of allo-HSCT patients. Additionally, we believe the SER-155 Phase 1b program will provide important insights into the safety profile of live biotherapeutics in immunocompromised patients and additionally into mechanisms by which live biotherapeutics can modulate host immune pathways. We intend to evaluate SER-155 and other live biotherapeutic candidates in several other medically vulnerable patient populations at high risk of infections, including chronic liver disease, cancer neutropenia, and solid organ transplants.

We have progressed additional preclinical stage programs to evaluate whether live biotherapeutics may reduce the incidence of infection in indications such as chronic liver disease, cancer neutropenia, solid organ transplant, and antimicrobial resistant, or AMR, infections more broadly in high-risk settings such as intensive care units, or ICUs, and long term acute care facilities, or LTACs. 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.

Other than VOWST, our product candidates are in early-stage clinical or preclinical development. Our ability to generate collaboration profit or product revenue sufficient to achieve profitability will depend heavily on the commercial success of VOWST, as well as 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 was $73.0 million for the six months ended June 30, 2024. As of June 30, 2024, we had an accumulated deficit of $1,051.2 million.

Until the completion of the Transaction, if consummated, we plan to focus our investment on supporting commercialization of VOWST and on our SER-155 Phase 1b study. Following the completion of the Transaction, if consummated, we plan to focus on completing our SER-155 Phase 1b study and advancing our other wholly-owned live biotherapeutic candidates, which may result in increased expenses in connection with these future activities. See "Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—*We are a commercial-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*" and "Risk Factors—Risks Related to the Transaction and the Remaining Company."

In addition, if we obtain marketing approval for any more 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 June 30, 2024, we had cash and cash equivalents totaling $71.2 million. Based on our currently available cash resources, our future operating plans, and the capital expected to be obtained from the Transaction, if consummated, and considering our ongoing obligations related to the Transaction, we anticipate being able to extend our cash runway into the fourth quarter of 2025, subject to material compliance with the TSA (as defined below), to be entered into at Closing between us and SPN. Absent the Transaction, our currently available cash resources will fund our operations into the fourth quarter of 2024. 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 potential funding from the Transaction, which is subject to stockholder approval, 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 the 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*."

On February 22, 2024, our board of directors adopted a resolution to amend the Restated Certificate of Incorporation, subject to stockholder approval, to increase the number of authorized shares of our common stock from 240,000,000 shares to 360,000,000 shares, or the Share Increase Amendment. At our annual meeting of stockholders held on April 4, 2024, our stockholders approved the Share Increase Amendment. On April 5, 2024, we amended our Restated Certificate of Incorporation to reflect the Share Increase Amendment.

VOWST

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. VOWST is the first FDA-approved orally administered microbiome therapeutic, and consists of a consortium of purified Firmicutes spores designed to prevent recurrent CDI in patients with a history of CDI by modulating the microbiome to a state that resists *C. difficil*e germination and growth. The VOWST manufacturing purification process is designed to remove unwanted microbes in an effort to reduce the risk of pathogen transmission beyond donor screening alone. We estimate that there were approximately 156,000 recurrent CDI cases in the United States during 2023 and that this number will grow at an annual rate of 2%.

We launched VOWST in the United States with our collaborator, Nestlé Health Science, in June 2023. Under the terms of the 2021 License Agreement, Nestlé Health Science assumed the role of lead commercialization party. We received an upfront license payment of $175 million in July 2021 and an additional $125 million in May 2023 following FDA approval of VOWST. The agreement also includes sales target milestones which, if achieved, could total up to $225 million. We were responsible for development and pre-commercialization costs in the United States. Following first commercial sale of VOWST, which occurred on June 2, 2023, we are entitled to share equally in its commercial profits and losses.

During the quarter ended June 30, 2024, Nestlé Health Science reported $14.4 million in VOWST net sales. The total collaboration loss for the three months ended June 30, 2024 was $13.3 million. We record our 50% share of the collaboration loss, which includes commercial and medical affairs expenses incurred by us, on a net basis. Accordingly for the quarter ended June 30, 2024, our share of the VOWST net loss was $6.6 million.

On August 5, 2024, we entered into the Purchase Agreement with SPN, pursuant to which we agreed, subject to the satisfaction or waiver of the conditions set forth therein, to sell our VOWST microbiome therapeutic business, or 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, or the Product, to Nestlé Health Science, and Nestlé Health Science will assume certain liabilities from us, or the Transaction, As consideration for the Transaction, SPN has agreed to pay us, or the Transaction Consideration:

(i) a cash payment, payable upon completion of the transaction, or the Closing, of $100 million, less approximately $17.9 million owed by us to an affiliate of SPN as of March 31, 2024 under the existing license agreement between us and the SPN affiliate, less approximately CHF2.0 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 Transition Services Agreement (as described below) to be entered into at Closing between us and SPN;

(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, payable 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 the Transaction and the Remaining Company— The amount of the Transaction Consideration we will receive in the Transaction is 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 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 period from the date of Closing 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.

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, will be terminated and each of Bacthera and Seres will release one another from any and losses, liabilities or other obligations arising thereunder with respect to the period ending as of the date of the Closing, including without limitation any milestone payments required to be paid to Bacthera thereunder.

The Closing is subject to the approval of the transaction by our stockholders and other customary conditions. As a condition to Closing, we and SPN will enter into a securities purchase agreement, or the Securities Purchase Agreement, pursuant to which SPN will agree to purchase 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 will agree not to sell or transfer the Shares for a period of six months after Closing, subject to certain customary exceptions. We will agree 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 will agree to take such action within its 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 will contain customary representations and warranties and closing conditions.

As a condition to Closing, the parties intend to enter into a Transition Services Agreement, or the TSA, which will provide for services to be performed by us in order to facilitate a transition of the business associated with the VOWST Business to SPN and its affiliates. The scope of the transition services is expected to include 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 and other services, until the later of the period specified in the schedule to the TSA for each service or June 30, 2026. SPN will agree to pay us for certain fixed costs, including a monthly fixed fee for preserved raw material suspension manufacturing, and will reimburse us for the costs of any 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 SPN 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 SPN request, we will transfer the manufacturing services to a third party service provider designated by SPN. In the event of a material failure by us to maintain the manufacturing facility under the TSA, SPN 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.

As a condition to Closing, we intend to enter into a cross-license agreement with SPN under which, we will grant 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 CDI and rCDI and associated complications, or collectively, the CDI Field, the license to SPN under such Company patents and know-how would be exclusive to SPN for five years 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.

Concurrently with the execution of the Purchase Agreement, our directors and executive officers and certain stockholders affiliated with Flagship Pioneering, Inc. entered into support agreements with us and SPN, or the Support Agreements, pursuant to which, among other things and subject to the terms and conditions therein, such parties agreed, solely in their capacities as holders of shares of common stock, or collectively, the Subject Shares, to vote all Subject Shares beneficially owned by such parties at every meeting of our stockholders (including the special meeting to consider the transactions contemplated by the Purchase Agreement) (i) in favor of adopting and approving the Purchase Agreement and the transactions contemplated by the Purchase Agreement, (ii) against any proposal that would otherwise be reasonably be expected to adversely affect the transactions contemplated by the Purchase Agreement, (iii) against any Acquisition Proposal (as defined therein), and (iv) in favor of approving any proposal to adjourn or postpone the special meeting of stockholders to a later date, if there are not sufficient votes for the adoption of the Purchase Agreement on the date on which such meeting is held. In addition, each stockholder party to a Support Agreement provided an irrevocable proxy to SPN to vote such party's Subject Shares in favor of adopting and approving the Purchase Agreement and the transactions contemplated by the Purchase Agreement.

As a condition to Closing, the parties intend to enter into assignment and assumption of lease agreements, or the Assignment and Assumption Agreements. Under the Assignment and Assumption Agreements, we will assign to SPN or its designated affiliates our rights in, to and under certain real property leases, and SPN or its designated affiliates will assume the liabilities related thereto.

As a condition to Closing, the parties intend to enter 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 accept employment with SPN or one of its designated affiliates will provide 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.

Until the completion of the Transaction, if consummated, we will continue to monitor the commercialization of VOWST. Broad demand for VOWST has been observed across both recurrent patients and healthcare providers since it became commercially available in June 2023 (metrics noted below are based on data provided by Nestlé through June 30, 2024):

- In the second quarter of 2024, approximately 1,522 completed prescription enrollment forms were received for VOWST; of those, 1,169 resulted in new patient starts by June 30, 2024;
- From launch through June 30, 2024, there were 5,757 completed prescription enrollment forms received for VOWST; of those 4,265 resulted in new patient starts by June 30, 2024;
- Prescription enrollment forms were submitted by approximately 2,452 unique healthcare providers since launch, including 708 in the second quarter, with approximately 67% of enrollments from gastroenterology and the remainder from other specialties; approximately 864 HCPs have prescribed VOWST to more than one patient; and
- VOWST demand has been observed across the recurrent CDI patient pool, including first recurrence, which is the largest recurrent CDI patient segment.

During the second quarter of 2024, Nestlé Health Science continued to scale its HCP education efforts. Since the FDA approval of VOWST, Nestlé Health Science commercial customer facing field teams have been promoting VOWST and generating healthcare provider demand. Nestlé Health Science's 170 field sales representatives promoting VOWST are divided into two teams, comprised of 150 gastroenterology representatives and 20 hospital/infectious disease representatives. In the first quarter of 2024, Nestlé Health Science identified opportunities to refine the execution of these teams in terms of focusing promotional messaging on early use of VOWST in the recurrent CDI cycle and increasing the number of HCPs that the sales teams engage. We expect these efforts to accelerate demand for VOWST in the second half of 2024.

The VOWST Voyage Support Program, or VOWST Voyage, was launched upon VOWST FDA approval to provide treatment and financial support for eligible patients. The VOWST Voyage staff work with healthcare providers and patients to convert patient enrollments into new patient starts and provide a robust high-touch customer experience.

Nestlé Health Science's payer field team continues to engage payers to build coverage, which would enable eligible patients to have access to VOWST as quickly and efficiently as possible. As of June 30, 2024, coverage policies were issued for VOWST across approximately 93% of commercial and 61% of Medicare Part D covered lives, according to data provided by Nestlé Health Science. The larger health plans and Pharmacy Benefit Managers, or PBMs, have issued policies for VOWST, and the remainder of smaller plans are extending the new-to-market block phase, enabling approval of VOWST as claims arise. Approximately 61% of the 1,169 second quarter new patient starts are being reimbursed through the patient's drug benefit.

We are investing in patient financial assistance to increase access to VOWST for patients with affordability challenges due to co-pays or other cost sharing requirements imposed on them by their insurer after the prescription has been approved. We believe that providing this type of patient access early on will contribute to a positive patient and provider experience, thus increasing demand over time. In terms of free drug utilization, in the second quarter of 2024, we saw approximately 39% of new patient starts dispensed via our free drug programs, mostly for Medicare patients. We expect utilization of these programs to drop further when the benefit design changes contained in the Inflation Reduction Act, which address patient cost sharing requirements in Medicare Part D plans, go into effect in 2025.

VOWST was previously granted Breakthrough Therapy and Orphan Drug Designations by the FDA. In connection with the FDA approval of VOWST, we received seven years of orphan-drug exclusivity, which began on April 26, 2023. During that time, VOWST 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 or biologic for the same disease or condition during that time period, except under certain circumstances.

The FDA approval of VOWST was supported by the Phase 3 development program that included the ECOSPOR III and ECOSPOR IV studies. ECOSPOR III was a multicenter, randomized, placebo-controlled study that enrolled 182 patients with multiply recurrent CDI. All patients who entered ECOSPOR III must have tested positive for *C. difficile* toxin. This inclusion criterion was implemented in an effort to ensure enrollment of only patients with active infection rather than simple colonization. The study was designed to evaluate patients for 24 weeks, with the primary endpoint comparing the *C. difficile* recurrence rate in subjects who received SER-109 verses placebo at up to eight weeks after dosing.

ECOSPOR III data demonstrated that the study achieved its primary endpoint where SER-109 was superior to placebo in reducing CDI recurrence at eight weeks, reflecting a recurrence-free rate of approximately 88% at eight weeks post-treatment. SER-109 resulted in a 27% absolute reduction of recurrence of CDI compared to placebo at eight weeks post-treatment, which is a relative risk reduction of 68%. The rate of recurrence at 12 weeks in the SER-109 arm was 18.0%, compared to a rate of 46.2% in the placebo arm, representing an absolute risk reduction of 28% (relative risk 0.40; 95% CI 0.24-0.65), and thereby consistent with the results seen at eight weeks. The efficacy results remained durable through 24 weeks of follow-up, as SER-109 was observed to significantly reduced recurrence rates compared to placebo over 24 weeks, 21.3% vs. 47.3%, respectively. These data were published in the *New England Journal of Medicine* in January 2022 and in the *Journal of the American Medical Association* in October 2022.

ECOSPOR IV was an open-label single-arm study evaluating SER-109 in 263 adult subjects with recurrent CDI. The overall safety profile observed in ECOSPOR IV through 24 weeks indicated that SER-109 was well tolerated, consistent with the safety profile observed in the prior completed Phase 3 study, ECOSPOR III. The ECOSPOR IV study results contributed to the SER-109 safety database and supported product approval. These data were published in the *JAMA Network Open* in February 2023.

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, 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 reducing the risk of infection may be replicable in a range of medically compromised patients, protecting them from infections seeded by the gut microbiome 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 evaluating SER-155, an oral, live biotherapeutic product candidate, consisting of a consortium of cultivated bacteria, in a Phase 1b study in allo-HSCT recipients in an effort to reduce incidences of gastrointestinal-derived infections, and resulting bloodstream infections and GvHD. SER-155 was designed using our reverse translational development platform. 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). In December 2023, we received Fast Track Designation for SER-155 to reduce the risk of infection and GvHD in allo-HSCT patients.

Study cohort 1, which included 13 participants who received any dosing of the SER-155 regimen, with 11 of these subjects subsequently receiving an allo-HSCT, nine of whom had evaluable samples for microbiome analysis, was designed to assess safety and drug pharmacology, including the engraftment of drug bacteria in the gastrointestinal tract. In May 2023, we announced the Phase 1b cohort 1 results, including gastrointestinal microbiome data (drug pharmacology) from the first 100 days from the nine subjects who had evaluable samples for microbiome analysis. This analysis showed the successful engraftment of SER-155 bacterial strains, and a substantial reduction in the cumulative incidence of pathogen domination (a biomarker associated with the risk of serious enteric infections, and resulting bloodstream infections, as well as GvHD) as compared to a reference cohort of patients in this patient population. The tolerability profile observed was favorable, with no serious adverse events attributed to SER-155 administration. Stem cell engraftment was observed in all subjects.

In April 2024, we announced completion of enrollment in study cohort 2, which includes 45 participants. Study cohort 2 incorporates a randomized, double-blinded placebo-controlled design to further evaluate safety, engraftment, and incidence of gastrointestinal ESKAPE microbiome pathogen domination, as well as the incidence of enteric infections, enteric driven blood stream infections, and GvHD. Cohort 2 subjects are administered either SER-155 or placebo at a 1:1 ratio. The study is being conducted at a number of leading cancer centers across the U.S. The cohort 2 data readout is anticipated in September 2024.

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*. If positive, we further believe the resulting cohort 2 data, together with the cohort 1 SER-155 Phase 1b study results will provide encouraging evidence to support further development of SER-155 to potentially reduce enteric-derived infections, resulting bloodstream infections, and GvHD in individuals undergoing allo-HSCT for cancers and other serious conditions.

Other pipeline programs, including SER-147

We are advancing the SER-147 program, an oral, live biotherapeutic product candidate, consisting of a consortium of cultivated bacteria in development for the prevention of gut-seeded infections and associated downstream blood stream infections in chronic liver disease, or CLD, and other diseases, and spontaneous bacterial peritonitis infections in patients with 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).

Nasdaq Notice and Compliance

On April 19, 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 October 16, 2024, 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 October 16, 2024.

On July 26, 2024, we received a letter from Nasdaq that we had regained compliance with the Bid Price Requirement. The notification letter confirmed that, from July 12, 2024 to July 25, 2024, our minimum bid price had been $1.00 per share or higher and, accordingly, we had regained compliance with Nasdaq Listing Rule 5450(a)(1) and that the matter was now closed.

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. For example, pursuant to an exclusive license to certain intellectual property from Memorial Sloan Kettering Cancer Center, with a patent term running until at least 2035, we are responsible for paying a 2.5% royalty on net sales of VOWST, minimum annual royalties, and milestone payments. The milestone payments are based on VOWST target sales milestones, the first being $1.0 million which was payable upon the first commercial sale of VOWST and paid in July 2023, the second being $2.5 million payable upon annual VOWST sales of $100.0 million, and the last being $10.0 million payable upon annual VOWST sales of $500.0 million. 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 VOWST extend through 2034, through 2041 for SER-155, and through 2040 for SER-301. 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 31 issued U.S. patents and 1 allowed U.S. patent application.

In connection with the Transaction and pursuant to the Purchase Agreement, we expect to transfer certain patents and trademarks affiliated with the VOWST Business to SPN at Closing. In addition, as a condition to Closing, we intend to enter into a cross-license agreement, or the Cross-License Agreement, with SPN. Under the Cross-License Agreement, we will grant 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 us that is 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 Company patents and know-how would be exclusive to SPN for five years 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. We will also grant SPN an exclusive, perpetual, worldwide, fully paid-up license under 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 Product to exploit SER-262 in the CDI Field. The license to SPN would be exclusive to SPN for five years after Closing and co-exclusive between SPN and us following that five year period. SPN will grant 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 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 us, SPN, and/or their respective affiliates will terminate and be 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. For example, VOWST (which was approved by the FDA in April 2023) has a 12-year period of exclusivity in the United States. In the European Union, new molecular entities generally receive eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization.

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. Under our 2021 License Agreement with Nestlé, beginning with the first commercial sale of VOWST, which occurred in June 2023, net sales of VOWST are recorded by Nestlé and include gross sales net of discounts, rebates, allowances, and other applicable deductions. We record our share of the net profits or losses from the sales of VOWST, including our commercial and medical affairs expenses, on a net basis, pursuant to the terms of the 2021 License Agreement. See *Collaboration (Profit) Loss Sharing - related party* below, and also "–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 and 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, if consummated.

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. Prior to the commercial launch of VOWST, general and administrative expenses also included professional service fees for marketing and market access activities to commercialize VOWST.

We expect that our general and administrative expenses will decrease 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 anticipated 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.

Collaboration (Profit) Loss Sharing - related party

Under the 2021 License Agreement with Nestlé, VOWST net sales are recorded by Nestlé and include gross sales net of discounts, rebates, allowances, and other applicable deductions. These amounts include the use of estimates and judgments, which could be adjusted based on actual results in the future. We record our share of the profits or losses from the sales of VOWST, including our commercial and medical affairs expenses, on a net basis, as collaboration (profit) loss sharing - related party. This treatment is in accordance with our revenue recognition and collaboration policy, given that Nestlé and we are both active participants in commercialization activities and are exposed to significant risks and rewards that are dependent on the commercial success of the activities in the arrangement. Nestlé provides us with reporting related to net sales of VOWST in accordance with U.S. generally accepted accounting principles in order to calculate and record collaboration profit or loss.

The collaboration (profit) loss sharing - related party line item also includes our profit on the transfer of VOWST inventory to Nestlé, which represents the excess of the supply price paid by Nestlé over our cost to manufacture VOWST, subject to a supply price cap.

The collaboration (profit) loss sharing - related party line item also includes collaboration loss related to pre-launch activities, which were completed prior to the first commercial sale of VOWST in June 2023.

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.

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 six months ended June 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 six months ended June 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 June 30, 2024 and 2023

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

	Three Months Ended June 30,		
	2024	2023	Change
Revenue:			
Collaboration revenue - related party	$ —	$ 126,473	$ (126,473)
Total revenue	—	126,473	(126,473)
Operating expenses:			
Research and development	17,875	46,792	(28,917)
General and administrative	16,059	28,051	(11,992)
Collaboration (profit) loss sharing - related party	(2,589)	2,106	(4,695)
Total operating expenses	31,345	76,949	(45,604)
(Loss) income from operations	(31,345)	49,524	(80,869)
Other income (expense):			
Interest income	1,230	1,726	(496)
Interest expense	(3,447)	(3,187)	(260)
Other income (expense)	692	(1,511)	2,203
Total other expense, net	(1,525)	(2,972)	1,447
Net loss (income)	$ (32,870)	$ 46,552	$ (79,422)

Revenue

Total revenue was $0 million and $126.5 million for the three months ended June 30, 2024 and 2023, respectively. The decrease in revenue as compared to the prior period was primarily due to the milestone payment we received from our collaborator Nestlé, upon FDA approval of VOWST in the second quarter of 2023. In the current period, we did not recognize any revenue under the 2016 License Agreement. For additional information, see Note 13, *Revenue from Contracts with Customers*, to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Research and Development Expenses

	Three Months Ended June 30,		
	2024	2023	Change
Microbiome therapeutics platform and research and development operations	$ 7,184	$ 13,653	$ (6,469)
VOWST	485	6,016	(5,531)
SER-155	2,207	2,298	(91)
Early stage programs	6	523	(517)
Total direct research and development expenses	9,882	22,490	(12,608)
Personnel-related (including stock-based compensation)	7,993	24,302	(16,309)
Total research and development expenses	$ 17,875	$ 46,792	$ (28,917)

Research and development expenses were $17.9 million for the three months ended June 30, 2024 and $46.8 million for the three months ended June 30, 2023. The decrease of $28.9 million was primarily due to the following:

- a decrease in personnel-related costs of $16.3 million primarily due to a decrease of $8.2 million in salaries, bonus, employee benefits expenses, and payroll taxes as a result of the restructuring plan implemented in 2023, a decrease of $5.0 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, and a decrease of $3.1 million resulting from the capitalization of labor costs into inventory following FDA approval of VOWST;
- a decrease of $5.5 million in expenses related to our VOWST program due to a decrease in facilities, lab supplies and consumables of $1.8 million and a decrease in contract manufacturing costs of $0.8 million, as we have capitalized manufacturing and overhead costs into inventory in conjunction with the commercialization of VOWST, a $1.3 million decrease in consulting expenses, and a $1.7 million decrease in clinical trials and analytical testing costs due to reduced clinical work with respect to VOWST as a result of commercialization;
- a decrease of $6.5 million in expenses related to our microbiome therapeutics platform and research and development operations, primarily due to a decrease of $4.3 million related to the capitalization of costs that relate to VOWST manufacturing into inventory, a decrease in employee-related costs of $1.2 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 $1.0 million; and

- a decrease of $0.5 million in expenses related to our early stage programs due to the restructuring plan.

General and Administrative Expenses

	Three Months Ended June 30,		
	2024	2023	Change
Personnel related (including stock-based compensation)	$ 5,818	$ 11,110	$ (5,292)
Professional fees	4,853	11,410	(6,557)
Facility-related and other	5,388	5,531	(143)
Total general and administrative expenses	$ 16,059	$ 28,051	$ (11,992)

General and administrative expenses were $16.1 million for three months ended June 30, 2024 compared to $28.1 million for the three months ended June 30, 2023. The decrease of $12.0 million was primarily due to the following:

- a decrease in personnel related costs of $5.3 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 $6.6 million primarily due to a decrease in professional services, consulting, and recruiting fees; and
- a decrease in facility-related and other costs of $0.1 million primarily related to information technology costs.

Collaboration (Profit) Loss Sharing - related party

Collaboration (profit) loss sharing – related party resulted in $2.6 million of income to us for the three months ended June 30, 2024, compared to $2.1 million of expense for the three months ended June 30, 2023. Beginning with the commercial launch of VOWST in June 2023, we record our share of the net profits and losses from the sales of VOWST, which are recorded by Nestlé and include gross sales net of discounts, rebates, allowances, and other applicable deductions, as collaboration (profit) loss sharing - related party. Our share of VOWST net profit and loss also includes commercial and medical affairs expenses incurred by us. For the three months ended June 30, 2024 and 2023, our share of the VOWST net loss was $6.6 million and $2.1 million, respectively. We also record as collaboration (profit) loss sharing - related party our net profit on the transfer of VOWST to Nestlé. For the three months ended June 30, 2024 and 2023, these amounts were $9.2 million and $1.3 million, respectively, in net profit. For the three months ended June 30, 2023, collaboration (profit) loss sharing – related party also included $1.2 million of net loss related to pre-launch expenses.

The components of the collaboration (profit) loss sharing - related party are as follows (in thousands):

	Three Months Ended June 30,	
	2024	2023
Share of VOWST net loss	$ 6,638	$ 2,141
Profit on transfer of VOWST inventory to Nestlé	(9,227)	(1,273)
Collaboration (profit)/loss related to pre-launch activities	—	1,238
Total collaboration (profit) loss sharing - related party	$ (2,589)	$ 2,106

Other Expense, Net

Other expense, net for the three months ended June 30, 2024 and 2023 was $1.5 million and $3.0 million, respectively. The decrease in other expense, net was primarily due to an increase in other income of $2.2 million due to $0.7 million of sublease income recorded in the three months ended June 30, 2024 and the loss on extinguishment of the Hercules credit facility recorded in the three months ended June 30, 2023. For more information, see Note 9, *Notes Payable*, to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report. This increase was partially offset by a decrease in interest income of $0.5 million and an increase in interest expense of $0.3 million as a result of higher interest rates and a higher borrowing base as compared to the same period in the prior year.

Comparison of Six Months Ended June 30, 2024 and 2023

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

Revenue

	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023	Change
		(in thousands)	
Revenue:			
Collaboration revenue - related party	$ —	$ 125,951	$ (125,951)
Total revenue	—	125,951	(125,951)
Operating expenses:			
Research and development	39,577	90,761	(51,184)
General and administrative	31,525	50,521	(18,996)
Collaboration (profit) loss sharing - related party	(171)	5,713	(5,884)
Total operating expenses	70,931	146,995	(76,064)
Loss from operations	(70,931)	(21,044)	(49,887)
Other income (expense):			
Interest income	2,878	2,758	120
Interest expense	(8,110)	(5,135)	(2,975)
Other income (expense)	3,160	(1,201)	4,361
Total other expense, net	(2,072)	(3,578)	1,506
Net loss	$ (73,003)	$ (24,622)	$ (48,381)

Total revenue was $0 million and $126.0 million for the six months ended June 30, 2024 and 2023, respectively. The change in revenue as compared to the prior period was primarily due to the milestone payment received from our collaborator Nestlé, upon FDA approval of VOWST in the second quarter of 2023. In the current period, we did not recognize any revenue under the 2016 License Agreement with Nestlé. For additional information, see Note 13, *Revenue from Contracts with Customers*, to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Research and Development Expenses

	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023	Change
		(in thousands)	
Microbiome therapeutics platform and research and development operations	$ 16,700	$ 26,770	$ (10,070)
VOWST	1,061	15,057	(13,996)
SER-155	4,607	3,643	964
Early stage programs	91	826	(735)
Total direct research and development expenses	22,459	46,296	(23,837)
Personnel-related (including stock-based compensation)	17,118	44,465	(27,347)
Total research and development expenses	$ 39,577	$ 90,761	$ (51,184)

Research and development expenses were $39.6 million for the six months ended June 30, 2024 and $90.8 million for the six months ended June 30, 2023. The decrease of $51.2 million was primarily due to the following:

- a decrease in personnel-related costs of $27.3 million primarily due to a decrease of $14.9 million in salaries, bonus, and employee benefits expenses as a result of the restructuring plan implemented in 2023, a decrease of $8.7 million resulting from the capitalization of labor costs into inventory following FDA approval of VOWST, and a decrease of $5.1 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 $1.4 million in payroll taxes related to tax credits we received during the three months ended March 31, 2023;
- a decrease of $14.0 million in expenses related to our VOWST program due to a decrease in facilities, lab supplies and consumables of $4.9 million and a decrease in contract manufacturing costs of $4.1 million, as we have capitalized manufacturing and overhead costs into inventory in conjunction with the commercialization of VOWST, a $2.8 million decrease in consulting expenses, and a $2.2 million decrease in clinical trials and analytical testing costs due to reduced clinical work with respect to VOWST as a result of commercialization;
- a decrease of $10.1 million in expenses related to our microbiome therapeutics platform and research and development operations, primarily due to a decrease of $7.8 million related to the capitalization of costs that relate to VOWST manufacturing into inventory, a decrease in employee-related costs of $2.4 million primarily due to a reduction in the use of contractors following the implementation of the restructuring plan, a decrease in consulting expenses of $1.7 million,

and a decrease of $0.8 million in clinical trial, analytical and other manufacturing costs, partially offset by $2.7 million of impairment charges related to our idled donor collection facility in Cambridge, Massachusetts; and

- a decrease of $0.7 million in expenses related to our early stage programs due to the restructuring plan;

partially offset by:

- an increase of $1.0 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

	Six Months Ended June 30, 2024	2023	Change
		(in thousands)	
Personnel related (including stock-based compensation)	$ 12,582	$ 19,800	$ (7,218)
Professional fees	7,770	19,300	(11,530)
Facility-related and other	11,173	11,421	(248)
Total general and administrative expenses	$ 31,525	$ 50,521	$ (18,996)

General and administrative expenses were $31.5 million for the six months ended June 30, 2024 compared to $50.5 million for the six months ended June 30, 2023. The decrease of $19.0 million was primarily due to the following:

- a decrease in personnel related costs of $7.2 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 $11.5 million primarily due to a decrease in professional services, consulting, and recruiting fees; and
- a decrease in facility-related and other costs of $0.2 million primarily related to information technology costs, laboratory and office rent expenses, license costs and office supplies.

Collaboration (Profit) Loss Sharing - related party

Collaboration (profit) loss sharing – related party resulted in $0.2 million of income to us for the six months ended June 30, 2024, compared to $5.7 million of expense for the six months ended June 30, 2023. Beginning with the commercial launch of VOWST in June 2023, we record our share of the net profits and losses from the sales of VOWST, which are recorded by Nestlé and include gross sales net of discounts, rebates, allowances, and other applicable deductions, as collaboration (profit) loss sharing - related party. Our share of VOWST net profits and loss also includes commercial and medical affairs expenses incurred by us. For the six months ended June 30, 2024 and 2023, our share of the VOWST net loss was $13.8 million and $2.1 million, respectively. We also record as collaboration (profit) loss sharing - related party our net profit on the transfer of VOWST to Nestlé. For the six months ended June 30, 2024 and 2023, these amounts were $13.9 million and $1.3 million, respectively, in net profit. For the six months ended June 30, 2023, collaboration (profit) loss sharing – related party also included $4.8 million of net loss related to pre-launch expenses.

The components of the collaboration (profit) loss sharing - related party are as follows (in thousands):

	Six Months Ended June 30, 2024	2023
Share of VOWST net loss	$ 13,766	$ 2,141
Profit on transfer of VOWST inventory to Nestlé	(13,937)	(1,273)
Collaboration (profit)/loss related to pre-launch activities	-	4,845
Total collaboration (profit) loss sharing - related party	$ (171)	$ 5,713

Other Expense, Net

Other expense, net for the six months ended June 30, 2024 and 2023 was $2.1 million and $3.6 million, respectively. The decrease in other expense, net was primarily due to an increase in interest income of $0.1 million and an increase in other income of $4.4 million primarily due to $2.0 million of foreign currency gains and $1.1 million of sublease income, partially offset by $0.3 million of loss on disposal of fixed assets. Additionally, during the six months ended June 30, 2023, we recognized $1.6 million of loss on extinguishment of the Hercules credit facility, which resulted in relatively higher other income during the six months ended June 30, 2024. This increase was partially offset by an increase in interest expense of $3.0 million as a result of higher interest rates and a higher borrowing base as compared to the same period in the prior year.

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, subject to the satisfaction or waiver of the conditions set forth therein, 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 will assume certain liabilities from us. As consideration for the Transaction, SPN has agreed to pay us:

(i) a cash payment, payable 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 existing license agreement between us and the SPN affiliate, less approximately CHF2.0 million in satisfaction of fees due under an existing manufacturing agreement between us and Bacthera AG;

(ii) cash installment payments of $50 million on January 15, 2025 and $25 million on July 1, 2025 (the "Installment Payments"), conditioned on our material compliance with obligations under the Transition Services Agreement (as described below) to be entered into at Closing between us and SPN;

(iii) prepayment of the $60 million milestone payment tied to the achievement of worldwide annual net sales of the Product of $150 million (the "First Sales Milestone"), payable 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 (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 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.

The Closing is subject to the approval of the transaction by our stockholders and other customary conditions. As a condition to Closing, we and SPN will enter into the Securities Purchase Agreement, pursuant to which SPN will agree to purchase 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 million.

On February 22, 2024, our board of directors adopted a resolution to amend the Restated Certificate of Incorporation, subject to stockholder approval, to increase the number of authorized shares of our common stock from 240,000,000 shares to 360,000,000 shares, or the Share Increase Amendment. At our annual meeting of stockholders held on April 4, 2024, our stockholders approved the Share Increase Amendment. On April 5, 2024, we amended our Restated Certificate of Incorporation to reflect the Share Increase Amendment. Our board of directors recommended that our stockholders approve the Share Increase Amendment because they believed it was in the best interests of us and our stockholders to increase our authorized shares of common stock in order to have additional shares available for use as our board of directors deems appropriate or necessary. As such, the primary purpose of the Share Increase Amendment was to provide us with greater flexibility with respect to managing our common stock in connection with such corporate purposes as may, from time to time, be considered advisable by our board of directors. These corporate purposes could include, without limitation, financing activities, public or private offerings of common stock, stock dividends or splits, conversions of convertible securities, issuance of options and other equity awards pursuant to our incentive plans, establishing a strategic relationship with a corporate collaborator and acquisition transactions.

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 June 30, 2024, we have sold 23,732,829 shares of common stock under the Sales Agreement, at an average price of approximately $1.80 per share, raising aggregate net proceeds of approximately $41.0 million after deducting an aggregate commission of approximately 3% and other issuance costs.

As of June 30, 2024, we had cash and cash equivalents totaling $71.2 million and an accumulated deficit of $1,051.2 million. For the six months ended June 30, 2024, we incurred a net loss of $73.0 million, and used cash in operations of $75.0 million. We may seek to raise additional capital through financing or other transactions, including our at-the-market equity offering. 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 expect that our operating losses and negative cash flows will continue for the foreseeable future.

Under applicable accounting standards, we have the responsibility to evaluate whether conditions or events raise substantial doubt about our ability to meet our future financial obligations as they become due within 12 months after the date the consolidated financial statements are issued. The receipt of potential funding from the Transaction, which is subject to stockholder approval, and the ability to obtain sufficient additional equity or debt financing with terms favorable or acceptable to us cannot be considered probable, as these events are outside of our control. See "Risk Factors—Risks Related to the Transaction and the Remaining Company." 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.

Restructuring Plan

In November 2023, we announced a restructuring plan to prioritize the commercialization of VOWST and the completion of the SER-155 Phase 1b study, while reducing costs and supporting longer-term business sustainability. The restructuring plan included (i) a reduction of our 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. The restructuring plan was substantially implemented around the end of fiscal 2023. In connection with the restructuring plan, for the year ended December 31, 2023, we incurred approximately $5.6 million in restructuring costs, primarily related to the workforce reduction, of which $5.3 million are expected to result in cash expenditures, and the remaining $0.3 million relates to stock-based compensation expense associated with the acceleration of unvested equity awards. These costs were incurred in the fourth quarter of 2023. See Note 12, *Restructuring*, to our condensed consolidated financial statements included elsewhere in this Quarterly Report. The restructuring plan was expected to result in savings of approximately $75.0 million to $85.0 million in 2024, including approximately $35.0 million from the reduction in workforce. We are on track to achieve the estimated savings based on actual results for the first half of 2024 as compared to expenses incurred in the periods immediately prior to the restructuring.

The foregoing estimates are based upon current assumptions and expectations but are subject to known and unknown risks and uncertainties. Accordingly, we may not be able to fully realize the cost savings and benefits initially anticipated from the restructuring plan, and the expected costs may be greater than expected. See "Risk Factors—Risks Related to Our Operations—*We may be unable to realize expected benefits from our restructuring plan and our business might be adversely affected.*"

Collaboration and Manufacturing Agreements

License Agreement with Société des Produits Nestlé S.A. (Nestlé)

In January 2016, we entered into the 2016 License Agreement with Nestec, Ltd., as succeeded by SPN, or, together with NHSc Rx License GmbH, their affiliates, and their subsidiaries, Nestlé, for the development and commercialization of certain of our product candidates in development for the treatment and management of CDI and IBD, including UC and Crohn's disease. In exchange for the license, Nestlé agreed to pay us an upfront cash payment of $120.0 million, which we received in February 2016. Nestlé has also agreed to pay us tiered royalties, at percentages ranging from the high single digits to high teens, of net sales of certain products based on our microbiome technology that are being developed for the treatment of CDI and IBD, including VOWST, SER-262, SER-287 and SER-301, or collectively, the 2016 Collaboration Products, in markets outside of the United States and Canada, or the 2016 Licensed Territory. We are eligible to receive up to $285.0 million in development milestone payments, $375.0 million in regulatory payments and up to an aggregate of $1.1 billion for the achievement of certain commercial milestones related to the sales of 2016 Collaboration Products. The full potential value of the up-front payment and milestone payments payable by Nestlé is over $1.9 billion, assuming all products receive regulatory approval and are successfully commercialized. In September 2016, we received a

$10.0 million milestone payment associated with the initiation of the Phase 1b clinical study for SER-262 in CDI. In June 2017, we initiated a Phase 3 clinical study of VOWST (ECOSPOR III) in patients with multiply recurrent CDI. In July 2017, we received $20.0 million based on the achievement of this milestone under the 2016 License Agreement. In November 2018, we executed a letter agreement with Nestlé, or the Letter Agreement, modifying certain terms of the 2016 License Agreement. Under the Letter Agreement, Nestlé agreed to pay us the $20.0 million Phase 3 milestone payment upon commencement of the Phase 2b study for SER-287. In December 2018, we received $40.0 million in milestone payments in connection with the commencement of the Phase 2b study for SER-287. In August 2020, we received $10.0 million from Nestlé in connection with the initiation of the Phase 1b SER-301 study. To date, we have received $80.0 million in development milestones under the 2016 License Agreement with Nestlé.

For the development of 2016 Collaboration Products for IBD under a global development plan, we agreed to pay the costs of clinical trials of such products up to and including Phase 2 clinical trials, and 67% of the costs for Phase 3 and other clinical trials of such products, with Nestlé bearing the remaining 33% of such costs. For other clinical development of 2016 Collaboration Products for IBD, we agreed to pay the costs of such activities to support approval in the United States and Canada.

With respect to development of 2016 Collaboration Products for CDI under a global development plan, we agreed to pay all costs of Phase 2 clinical trials for VOWST and for Phase 3 clinical trials for VOWST. We agreed to bear all costs of conducting any Phase 1 or Phase 2 clinical trials under a global development plan for 2016 Collaboration Products other than VOWST for CDI. We agreed to pay 67% and Nestlé agreed to pay 33% of other costs of Phase 3 clinical trials conducted for 2016 Collaboration Products other than VOWST for CDI under a global development plan. For other clinical development of 2016 Collaboration Products for CDI, we agreed to pay costs of such development activities to support approval in the United States and Canada, and Nestlé agreed to bear the cost of such activities to support approval of 2016 Collaboration Products in the 2016 Licensed Territory.

The 2016 License Agreement continues in effect until terminated by either party on the following bases: (i) Nestlé may terminate the 2016 License Agreement in the event of serious safety issues related to any of the 2016 Collaboration Products; (ii) we may terminate the 2016 License Agreement if Nestlé challenges the validity or enforceability of any of our licensed patents; and (iii) either party may terminate the 2016 License Agreement in the event of the other party's uncured material breach or insolvency. Upon termination of the 2016 License Agreement, all licenses granted to Nestlé by us will terminate, and all rights in and to the 2016 Collaboration Products in the 2016 Licensed Territory will revert to us. If we commit a material breach of the 2016 License Agreement, Nestlé may elect not to terminate the 2016 License Agreement but instead apply specified adjustments to its payment obligations and other terms and conditions of the 2016 License Agreement.

License Agreement with NHSc Rx License GmbH (Nestlé)

On July 1, 2021, we entered into a License Agreement, or the 2021 License Agreement, with NHSc Pharma Partners, succeeded by NHSc Rx License GmbH, or, together with Société des Produits Nestlé S.A, their affiliates, and their subsidiaries, Nestlé. Pursuant to the 2021 License Agreement, we granted to Nestlé, under certain of our patent rights and know how, a co-exclusive, sublicensable (under certain circumstances) license to develop, commercialize and conduct medical affairs activities for (i) therapeutic products based on our microbiome technology (including VOWST) that are developed by us or on our behalf for the treatment of CDI and recurrent CDI, as well as any other indications pursued for the products upon mutual agreement of the parties, or the 2021 Field, in the United States and Canada, or the 2021 Licensed Territory, and (ii) VOWST and any improvements and modifications thereto developed pursuant to the terms of the 2021 License Agreement, or the 2021 Collaboration Products, for any indications in the 2021 Licensed Territory.

The 2021 License Agreement sets forth the parties' respective obligations for development, regulatory, commercialization, medical affairs, and manufacturing and supply activities for the 2021 Collaboration Products with respect to the 2021 Field and the 2021 Licensed Territory. Pursuant to the 2021 License Agreement, we were responsible for, and used commercially reasonable efforts in, conducting development of VOWST in the 2021 Field in the United States until first regulatory approval for VOWST was obtained in the 2021 Field in the United States and in accordance with a development and regulatory activity plan, at our cost, subject to certain exceptions specified in the 2021 License Agreement. We are also responsible for all regulatory affairs related to the 2021 Collaboration Products in the 2021 Field in the 2021 Licensed Territory, at our cost, except that expenses incurred for regulatory activities approved by a joint steering committee pursuant to a life cycle management plan for the 2021 Collaboration Products are shared equally between the parties. We are now solely responsible for manufacturing and supplying VOWST for development in the 2021 Field in the 2021 Licensed Territory.

Nestlé has the sole right to commercialize VOWST in the 2021 Licensed Territory in accordance with a commercialization plan, subject to our right to elect to provide up to a specified percentage of all promotional details for a certain target audience. Each party will use commercially reasonable efforts to commercialize VOWST in the 2021 Licensed Territory in accordance with the commercialization plan. Both parties will perform medical affairs activities for VOWST in the 2021 Licensed Territory in accordance with a medical affairs plan. We are solely responsible for the manufacturing and supply of VOWST for commercialization under a supply agreement that has been executed between the parties. We were responsible for commercialization and medical affairs activities costs incurred by the parties until first commercial sale of the first 2021 Collaboration Product, or VOWST, in the 2021

Licensed Territory and in accordance with a pre-launch plan, up to a specified cap. Since the first commercial sale of VOWST in June 2023, we are entitled to share equally in its commercial profits and losses.

In exchange for the grant of the licenses under the 2021 License Agreement, Nestlé agreed to pay us a non-refundable, non-creditable and non-cancelable upfront payment of $175.0 million, which was received in July 2021. Nestlé also agreed to pay us an additional $125.0 million due upon FDA approval of VOWST, which we received in May 2023, $10.0 million upon Canadian regulatory approval of VOWST, and sales target milestones payments totaling up to $225.0 million.

The 2021 License Agreement continues in effect until all development and commercialization activities for VOWST in the 2021 Licensed Territory have permanently ceased. The 2021 License Agreement may be terminated by either party upon sixty days' written notice for the other party's material breach that remains uncured during such sixty-day period, or immediately upon written notice for the other party's insolvency. Nestlé may also terminate the 2021 License Agreement at-will with twelve months' prior written notice, effective only on or after the third anniversary of first commercial sale of VOWST in the 2021 Licensed Territory. We may also terminate the 2021 License Agreement immediately upon written notice if Nestlé challenges any licensed patent in the 2021 Licensed Territory.

Upon termination of the 2021 License Agreement, all licenses granted to Nestlé by us will terminate. If we commit a material breach of the 2021 License Agreement, Nestlé may elect not to terminate the 2021 License Agreement but instead apply specified adjustments to the payment terms and other terms and conditions of the 2021 License Agreement. The 2021 License Agreement contains customary representations and warranties by the parties, intellectual property provisions including ownership, patent prosecution, enforcement and defense, certain indemnification rights in favor of each party, and customary confidentiality provisions and limitations of liability.

Long Term Manufacturing Agreement with Bacthera

In November 2021, we entered into a Long Term Manufacturing Agreement with BacThera AG, or Bacthera, a joint venture between Chr. Hansen and a Lonza Group affiliate, which was amended on December 14, 2022, or the Bacthera Agreement. The Bacthera Agreement governs the general terms under which Bacthera, or one of its affiliates, will (i) construct a dedicated full-scale production suite for us at Bacthera's Microbiome Center of Excellence in Visp, Switzerland; and (ii) provide manufacturing services to us for VOWST and other products, as agreed to by the parties.

Under the terms of the Bacthera Agreement, we agreed to pay Bacthera a total of at least 256 million CHF (or approximately $283 million using the USD/CHF exchange rate in effect as of June 30, 2024) for the initial term of the agreement, inclusive of the construction fees and annual operating fees. Bacthera is funding the majority of the construction costs and will own and control the manufacturing suite during construction. The construction fees that we are responsible for represent a small percentage of the overall construction costs and are payable upon the achievement of certain milestones related to the construction of the dedicated manufacturing suite. The annual operating fee includes the cost of a baseline annual batch production volume. We have also agreed to pay certain other ancillary fees and a per-batch fee in excess of the baseline batches. These fees are subject to adjustment during construction for certain items outside of Bacthera's control and annually against an agreed index. We will supply the active pharmaceutical ingredients to Bacthera to enable it to perform the services and pay for certain other raw materials and manufacturing components, which will be acquired by Bacthera. See also *Bacthera Long Term Manufacturing Agreement* below and *Risk Factors—Risks Related to our Dependence on Third Parties and Manufacturing—We rely on third parties for certain aspects of the manufacture of our product and 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 and product candidates or that such quantities may not be available at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts*.

The Bacthera Agreement has an initial term that continues until the tenth anniversary of the earlier of (a) successful completion of construction and demonstration of Bacthera's readiness for commercial production or (b) the commencement of manufacturing. The initial term is subject to renewals, which could extend the term to 16 years, and additional three-year terms thereafter. Each party has the ability to terminate the Bacthera Agreement upon the occurrence of certain customary conditions. We may also terminate the Bacthera Agreement for convenience after a defined period. In the event of a termination, we have certain financial obligations that would apply, and Bacthera has agreed to grant a license to Bacthera-developed manufacturing know how, if any, and provide technical assistance to us, so that we could transfer the manufacturing operations to ourselves or a third party. The Bacthera Agreement also contains representations, warranties and indemnity obligations as well as limitations of liability that are customary for agreements of this type.

Concurrently with the execution of the Purchase Agreement, we, SPN and Bacthera entered into an Assignment and Termination of Manufacturing Agreement, or the Termination of Bacthera Agreement, pursuant to which the parties agreed that concurrently with the Closing, we will assign to SPN the Bacthera Agreement, and, immediately thereafter, the Bacthera Agreement will be terminated by mutual agreement, upon the terms and subject to the conditions set forth therein. Pursuant to the Termination of Bacthera Agreement, concurrently with the Closing, SPN will pay a specified amount to Bacthera in full and final settlement of all outstanding liabilities owed to Bacthera pursuant to the Bacthera Agreement. See Risk Factors— Risks Related to the Transaction and the Remaining Company— *The completion of the Transaction (as defined below) is subject to conditions, some or all of which may* *not be satisfied, or completed on a timely basis, if at all. Failure to complete, or unexpected delays in completing, the Transaction or any termination of the Purchase Agreement would have an adverse effect on the Company, its financial condition and results of operations*.

Indebtedness

Oaktree Credit Agreement

On April 27, 2023, or the Oaktree Closing Date, we entered into the Oaktree Credit Agreement, among the Company, the subsidiary guarantors from time to time party thereto, the Oaktree Lenders, and the Agent. The Oaktree Credit Agreement establishes a term loan facility of $250.0 million, consisting of (i) $110.0 million, or the Tranche A Loan, funded on the Closing Date, (ii) $45.0 million, or the Tranche B Loan, that the Company may borrow subject to certain conditions, (iii) $45.0 million, or the Tranche C Loan, that the Company may borrow subject to certain conditions, and (iv) $50.0 million, or the Tranche D Loan, available in Oaktree's sole discretion. The Tranche B Loan may be drawn by the Company until September 30, 2024, if VOWST net sales for the trailing six consecutive months are at least $35 million and at least 4.5% greater in the calendar quarter prior to the Applicable Funding Date (as defined in the Oaktree Credit Agreement) over the calendar quarter immediately preceding it. The Tranche C Loan may be drawn until September 30, 2025, if VOWST net sales for the trailing 12 consecutive months are at least $120 million and at least 4.5% greater in each of the two calendar quarters prior to the Applicable Funding Date relative, in each case, to the calendar quarter immediately preceding it. The Oaktree Term Loan has a maturity date of April 27, 2029, or the Oaktree Maturity Date. Of the $110.0 million Tranche A Loan advanced by the Lenders at closing, approximately $53.4 million repaid the Company's existing credit facility with Hercules. After deducting other transaction expenses and fees, the Company received net proceeds of approximately $50.4 million.

Borrowings under the Oaktree Term Loan bear interest at a rate per annum equal to the three-month term Secured Overnight Financing Rate (subject to a 2.500% floor and a 5.000% cap), plus an applicable margin of 7.875%, payable quarterly in arrears. If certain VOWST net sales targets are met, the applicable margin will be reduced from 7.875% to 7.50% through the Oaktree Maturity Date. We are required to make quarterly interest-only payments on the Oaktree Term Loan for the first three years after the Oaktree Closing Date. Beginning on June 30, 2026, we will be required to make quarterly payments of interest, plus repay 7.5% of the outstanding principal of the Oaktree Term Loan in quarterly installments until the Oaktree Maturity Date, unless the interest only period is extended based upon the achievement of certain VOWST net sales targets.

We are obligated to pay the Oaktree Lenders an exit fee equal to 1.50% of the aggregate amount of the Oaktree Term Loan funded, such exit fee to be due and payable upon the earliest to occur of (1) the Oaktree Maturity Date, (2) the acceleration of the outstanding Oaktree Term Loan, and (3) the prepayment of the outstanding Oaktree Term Loan. We may voluntarily prepay the outstanding Oaktree Term Loan, subject to a customary make-whole for the first two years following the Oaktree Closing Date plus 4.0% of the principal amount of the Oaktree Term Loan prepaid, and thereafter a prepayment premium equal to (i) 4.0% of the principal amount of the Oaktree Term Loan prepaid, if prepaid after the second anniversary of the Oaktree Closing Date through and including the third anniversary of the Oaktree Closing Date, (ii) 2.0% of the principal amount of the Oaktree Term Loan if prepaid after the third anniversary of the Oaktree Closing Date through and including the fourth anniversary of the Oaktree Closing Date, (iii) 1.0% of the principal amount of the Oaktree Term Loan if prepaid after the fourth anniversary of the Oaktree Closing Date through and including the fifth anniversary of the Oaktree Closing Date, with no prepayment premium due after the fifth anniversary of the Oaktree Closing Date through the Oaktree Maturity Date.

Our obligations under the Oaktree Credit Agreement and the other Loan Documents (as defined in the Oaktree Credit Agreement) will be guaranteed by any of our domestic subsidiaries that become Guarantors (as defined in the Oaktree Credit Agreement), subject to certain exceptions. Our and our Guarantors', or collectively, the Loan Parties, respective obligations under the Oaktree Credit Agreement and the other Loan Documents are secured by first priority security interests in substantially all assets of the Loan Parties, including intellectual property, subject to certain customary thresholds and exceptions. As of June 30, 2024, there were no Guarantors.

The Oaktree Credit Agreement contains customary representations, warranties and affirmative and negative covenants, including a financial covenant requiring us to maintain certain levels of cash and cash equivalents in accounts subject to a control agreement in favor of the Agent of at least $30.0 million at all times commencing from 30 days after the Oaktree Closing Date and decreasing to $25.0 million of cash and cash equivalents in such controlled accounts after we borrow any Tranche B Loan. As of June 30, 2024, we were in compliance with all financial covenants pursuant to the Oaktree Credit Agreement.

In addition, the Oaktree Credit Agreement contains certain events of default that entitle the Agent to cause our indebtedness under the Oaktree Credit Agreement to become immediately due and payable, and to exercise remedies against the Loan Parties and the collateral securing the Oaktree Term Loan, including cash. Under the Oaktree Credit Agreement, an event of default will occur if, among other things, we fail to make payments under the Oaktree Credit Agreement (subject to specified periods), we or our subsidiaries breach any of the covenants under the Oaktree Credit Agreement (subject to specified cure periods with respect to certain breaches), a material adverse change occurs, we, our subsidiaries or our or their respective assets become subject to certain legal proceedings, such as bankruptcy proceedings, we and/or our subsidiaries are unable to pay our or their debts as they become due or default on contracts with third parties which would permit the holder of indebtedness in excess of a certain threshold to accelerate the maturity of such indebtedness or that could cause a material adverse change. Upon the occurrence and for the duration of an event of default, an additional default interest rate equal to 2.0% per annum may apply to all obligations owed under the Oaktree Credit Agreement.

On the Oaktree Closing Date, we issued to the Oaktree Lenders of such Tranche A Loan warrants to purchase 647,589 shares (subject to certain adjustments) of our common stock, or the 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, we are required to issue to the Oaktree Lenders of the Oaktree Term Loan 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, or the Tranche B Warrant, and the Tranche C Warrant, respectively, and together the Additional Warrants. The Additional Warrants will be immediately exercisable upon issuance, and the exercise period will expire seven years from the date of issuance. As of June 30, 2024, given the anticipated Transaction and expected 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.

On May 1, 2024, we received a Notice of Default and Reservation of Rights (the "Notice") from the Agent under the Oaktree Credit Agreement.

The Notice specified that in the Agent's view, one or more events of default have occurred under the Oaktree Credit Agreement due to (a) our non-payment of a milestone payment to Bacthera under the Bacthera Agreement which the Agent characterized as "Indebtedness" that would not be permitted under the Oaktree Credit Agreement and (b) our failure to deliver written notice to the Agent regarding such non-payment.

Under the Bacthera Agreement, approximately $28.1 million would be due to Bacthera upon their substantial completion of our dedicated production suite. However, we have identified certain incomplete elements of the project required to satisfy the "Substantial Completion" criteria as set forth in the Bacthera Agreement. We believe that it is probable that these elements can be completed in 2024 and discussions with Bacthera are continuing to align on the steps necessary to complete those steps and the related timing of any milestone payment. See "*Bacthera Long Term Manufacturing Agreement*" below.

We have responded by letter to the Notice, advising the Agent that no default or event of default under the Oaktree Credit Agreement has occurred or is continuing, because the payment under the Bacthera Agreement is not due, and, as a result, no notice of non-payment was required. Moreover, even if the payment were due, we do not believe such payment would constitute Indebtedness (as defined in the Oaktree Credit Agreement).

Based on the above, we believe that we are not in default under the Oaktree Credit Agreement, and that the Agent does not have the right to accelerate the indebtedness or otherwise pursue remedies thereunder. If the Agent were to pursue any such actions, we intend to vigorously defend ourselves against them and to pursue any counterclaims available to us. We are attempting to resolve this matter with the Agent consensually. The Bacthera Agreement is being assigned and terminated as part of the Transaction. Pursuant to the termination of the Bacthera Agreement, SPN will pay a termination payment to Bacthera in full and final settlement of all outstanding liabilities owed to Bacthera.

The outstanding indebtedness under the Oaktree Credit Agreement, including accrued and unpaid interest, prepayment fees, and exit fees, will be repaid concurrent with the closing of the Transaction with Nestlé, as we are obligated to use the proceeds from the completion of the Transaction to fully retire our senior secured debt facility with Oaktree.

Cash Flows

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

	Six Months Ended June 30,	
	2024	2023
	(in thousands)	
Cash used in operating activities	$ (75,047)	$ (10,600)
Cash provided by investing activities	1,240	13,256
Cash provided by financing activities	18,762	63,833
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (55,045)	$ 66,489

Operating Activities

During the six months ended June 30, 2024, operating activities used $75.0 million of cash, primarily due to a net loss of $73.0 million and changes in our operating assets and liabilities of $25.8 million, partially offset by non-cash charges of $23.7 million. Non-cash charges consisted of stock-based compensation expense of $12.0 million, $4.8 million related to the amortization of right-of-use assets, $3.0 million of depreciation and amortization, $1.0 million of amortization of debt issuance costs, $0.3 million loss on disposal of fixed assets, and $3.3 million of impairment charges related to our long-lived assets. These are partially offset by a $0.5 million decrease in the fair value of the Additional Warrants. Changes in our operating assets and liabilities during the six months ended

June 30, 2024 consisted of a decrease in operating lease liabilities of $2.3 million, and an increase in inventories of $23.4 million related to the capitalization of VOWST manufacturing costs during the period, an increase in collaboration receivable - related party of $9.9 million, partially offset by an increase in accrued expenses and other current and long-term liabilities of $5.8 million, a decrease in prepaid expenses and other current and other non-current assets of $2.5 million, an increase in deferred income - related party of $0.2 million, and an increase in accounts payable of $1.2 million.

During the six months ended June 30, 2023, operating activities used $10.6 million of cash, primarily due to a net loss of $24.6 million and changes in our operating assets and liabilities of $20.8 million, partially offset by non-cash charges of $34.8 million. Non-cash charges consisted of stock-based compensation expense of $20.3 million, loss sharing under the 2021 License Agreement with Nestlé of $5.7 million, $4.2 million related to the amortization of right-of-use assets, $2.9 million of depreciation and amortization, and $1.6 million of loss from the extinguishment of the Hercules credit facility. Changes in our operating assets and liabilities during the six months ended June 30, 2023 consisted of a decrease in accrued expenses and other current and long-term liabilities of $9.7 million, primarily due to a payment of $13.4 million to Nestlé for its share of collaboration expenses under the 2021 License Agreement, a decrease in accounts payable of $3.1 million, a decrease in deferred revenue of $1.0 million, a decrease in operating lease liabilities of $0.6 million, an increase in inventories of $5.3 million and an increase in collaboration receivable - related party of $7.6 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 $3.6 million and an increase in deferred income - related party of $2.8 million.

Investing Activities

During the six months ended June 30, 2024, net cash provided by investing activities was $1.2 million, consisting of 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 $0.2 million of purchases of property and equipment.

During the six months ended June 30, 2023, net cash provided by investing activities was $13.3 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 $5.3 million.

Financing Activities

During the six months ended June 30, 2024, net cash provided by financing activities was $18.8 million, consisting of $18.4 million from the issuance of common stock under our at the market equity program, net of issuance costs and $0.4 million in connection with the issuance of common stock under our 2015 Employee Stock Purchase Plan, or ESPP.

During the six months ended June 30, 2023, net cash provided by financing activities was $63.8 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 $0.4 million from the issuance of common stock associated with the exercise of stock options, and $1.2 million in connection with the issuance of common stock under our 2015 Employee Stock Purchase Plan, or ESPP.

Funding Requirements

Our expenses may increase in connection with our ongoing commercialization activities, 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:

- commercialize and manufacture VOWST for adult patients with recurrent CDI with our collaborator, as adjusted if and upon the Closing of the Transaction;
- continue the clinical development of SER-155 to potentially reduce incidences of gastrointestinal infections, resulting bloodstream infections, and GvHD in patients receiving allo-HSCT;
- 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 have obtained or in the future for which we may obtain regulatory approval;
- perform our obligations under our agreements with our 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 timing and completion of the Transaction;
- the significant costs, fees and expenses related to the Transaction;
- the success of our restructuring plan, announced in November 2023, including its anticipated benefits, which has been substantially implemented;
- the cost of manufacturing VOWST and our product candidates;
- our share of the profits and losses from commercial sales of VOWST pursuant to the 2021 License Agreement;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates and research activities;
- the costs, timing and revenue, if any, of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for our current or future product candidates and achieve product sales. In addition, VOWST and 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 included and our Oaktree Term Loan includes, 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 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 potential funding from the Transaction, which is subject to stockholder approval, 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, our future operating plans, and the capital expected to be obtained from the Transaction, if consummated, and considering our ongoing obligations related to the Transaction, we anticipate being able to extend our cash runway into the fourth quarter of 2025, subject to material compliance with the TSA. Absent the Transaction, our currently available cash resources will fund our operations into the fourth quarter of 2024.

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 below.

Asset Purchase Agreement

On August 5, 2024, we entered into the Purchase Agreement with SPN, pursuant to which we agreed, subject to the satisfaction or waiver of the conditions set forth therein, to sell the VOWST Business to Nestlé Health Science and Nestlé Health Science will assume certain liabilities from us, for the Transaction Consideration. Following the Closing, we expect to focus on advancing SER-155 and our other wholly-owned cultivated live biotherapeutic candidates to improve patient outcomes for medically vulnerable patient populations with potential to address large commercial opportunities. The Closing is subject to the approval of the Transaction by our stockholders, and other customary conditions. See *Overview – VOWST* for further details.

Bacthera Long Term Manufacturing Agreement

Our remaining commitments due under the Bacthera Agreement, inclusive of construction fees and annual operating fees, and using the USD/CHF exchange rate in effect as of June 30, 2024, total $270.4 million. Under the Bacthera Agreement, $28.1 million is due upon substantial completion of our dedicated production suite, which we believed had occurred in late 2023. Recent discussions between us and Bacthera have identified certain elements of the production suite construction currently missing that would be required to satisfy the substantial completion criteria as defined in the Bacthera Agreement. The Company believes that it is probable that these elements can be completed in 2024 and discussions with Bacthera are continuing in order to align on the steps necessary to remediate and the related timing of any milestone payment. Concurrently with the execution of the Purchase Agreement, we, SPN and Bacthera entered into an Assignment and Termination of Manufacturing Agreement (the "Termination of Bacthera Agreement"), pursuant to which the parties agreed that concurrently with the Closing, we will assign the Bacthera Agreement to SPN, and, immediately thereafter, the Bacthera Agreement will be terminated by mutual agreement, upon the terms and subject to the conditions set forth therein. Pursuant to the Termination of Bacthera Agreement, concurrently with the Closing, SPN will pay a specified amount to Bacthera in full and final settlement of all outstanding liabilities owed to Bacthera pursuant to the Bacthera Agreement. See *Risk Factors—Risks Related to our Dependence on Third Parties and Manufacturing—We rely on third parties for certain aspects of the manufacture of our product and 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 and product candidates or that such quantities may not be available at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts* and *— Risks Related to the Transaction and the Remaining Company— The completion of the Transaction (as defined below) is subject to conditions, some or all of which may not be satisfied, or completed on a timely basis, if at all. Failure to complete, or unexpected delays in completing, the Transaction or any termination of the Purchase Agreement would have an adverse effect on the Company, its financial condition and results of operations*.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Fluctuation Risk

We are exposed to market risk related to changes in interest rates.

As of June 30, 2024, we had outstanding borrowings under the Oaktree Term Loan. Borrowings under the Oaktree Term Loan bear interest at a rate per annum equal to three-month term Secured Overnight Financing Rate (subject to a 2.500% floor and a 5.000% cap), plus an applicable margin of 7.875%, payable quarterly in arrears. An immediate 10% change in the Secured Overnight Financing Rate would not have a material impact on our debt-related obligations, financial position or results of operations.

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

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended June 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors

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

Risks Related to The Transaction and the Remaining Company

The completion of the Transaction (as defined herein) is subject to conditions, some or all of which may not be satisfied, or completed on a timely basis, if at all. Failure to complete, or unexpected delays in completing, the Transaction or any termination of the Purchase Agreement would have an adverse effect on the Company, its financial condition and results of operations.

On August 5, 2024, we and SPN entered into an Asset Purchase Agreement (the "Purchase Agreement"), pursuant to which we have agreed to sell our VOWST microbiome therapeutic business, including all inventory and equipment, certain patent rights, 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 (the "VOWST Business"), to SPN (the "Transaction"). The completion of the Transaction is subject to a number of conditions, including the approval of the Transaction by our stockholders, which make the completion and timing of the Transaction uncertain. The failure to satisfy all of the required conditions could delay the completion of the Transaction for a significant period of time or prevent it from occurring at all. There can be no assurance that the conditions to the completion of the Transaction will be satisfied or waived or that the Transaction will be completed.

In addition, either we or SPN may terminate the Purchase Agreement under certain circumstances, including if the Transaction is not completed by February 6, 2025. In certain circumstances, upon termination of the Purchase Agreement, we would be required to pay $4.7 million to SPN for the reimbursement of expenses.

If the Transaction is not completed, we would be adversely affected and, without realizing any of the benefits of having completed the Transaction, will be subject to a number of risks, including the following:

- the trading price of our common stock could decline;
- if the Purchase Agreement is terminated and our board of directors seeks another strategic transaction, our stockholders cannot be certain that we will be able to find a party willing to enter into a transaction on terms equivalent to or more attractive than the terms that SPN has agreed to in the Purchase Agreement;
- time and resources, financial and otherwise, committed by our management to matters relating to the Transaction could otherwise have been devoted to pursuing other beneficial opportunities;
- failure to receive the Transaction Consideration could adversely impact our liquidity;
- we would be unable to use the Transaction Consideration to fully repay the indebtedness under the Oaktree Credit Agreement, leaving the matter of the defaults alleged by Oaktree, and our belief that it is not in default, unresolved;
- the obligation to pay an approximately $28 million milestone payment that will be due to Bacthera upon Bacthera's substantial completion of our dedicated production suite would not be assumed by SPN, we will remain obligated to make this milestone payment to Bacthera upon their substantial completion of the project, and Bacthera may allege claims of non-performance by us or may seek to collect this milestone payment from us even though we believe the "substantial completion" criteria set forth in the Bacthera Agreement have not been satisfied as of the date of this quarterly report;
- we may experience negative reactions from the financial markets or from its customers, suppliers, partners or employees; and
- we will generally be required to pay its expenses relating to the Transaction, such as legal, accounting and financial advisory fees, whether or not the Transaction is completed.

In addition, if the Transaction is not completed, we could be subject to litigation related to any failure to complete the Transaction. Any of these risks could materially and adversely impact our business, financial condition, results of operations and the trading price of shares of our common stock.

Similarly, delays in the completion of the Transaction could, among other things, result in additional transaction costs, loss of revenue or other negative effects associated with delay and uncertainty about completion of the Transaction and could materially and adversely impact our business, financial condition, results of operations and the trading price of shares of our common stock.

The amount of the Transaction Consideration we will receive in the Transaction is subject to various risks and uncertainties.

In connection with the Transaction, SPN will assume certain liabilities with respect to the VOWST Business and pay to us:

- a cash payment, payable upon Closing, of $100 million, less approximately $17.9 million owed by us to SPN as of March 31, 2024 under the existing license agreement between us and the SPN affiliate, less approximately CHF2.0 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 Transition Services Agreement to be entered into at Closing between us and SPN;
- 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, payable 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 (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.

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 Transition Services Agreement 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 (as defined herein), we will be entitled to receive 50% of all net profit and will bear 50% of all net loss, as applicable (the “Profit Sharing Payments”). 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.

The Purchase Agreement contains provisions that limit our ability to pursue alternatives to the Transaction, which could discourage a third party from making a favorable alternative transaction proposal, and provides that, in specified circumstances, we would be required to reimburse SPN for certain of its expenses.

The Purchase Agreement contains non-solicitation provisions that make it substantially more difficult for us to sell our assets or engage in an acquisition of the Company with a party other than SPN. Specifically, we agreed, subject to certain exceptions with respect to unsolicited bids and the exercise of fiduciary duties by our board of directors, not to directly or indirectly solicit a proposal for an alternative transaction from a third party or to enter into discussions concerning, or provide confidential information in connection with any submission, announcement, proposal or offer that would reasonably be expected to lead to a proposal for an alternative transaction from a third party.

These non-solicitation provisions, among others contained in the Purchase Agreement, could discourage a third party that might have an interest in acquiring all or substantially all of our assets or our common stock from considering or proposing such an acquisition, even if that party were prepared to pay consideration with a higher value than the consideration paid by SPN.

In certain circumstances, upon termination of the Purchase Agreement, we would be required to pay $4.7 million to SPN for the reimbursement of expenses.

We will incur significant expenses in connection with the Transaction, regardless of whether the Transaction is completed.

We expect to incur significant expenses related to the Transaction. These expenses include, but are not limited to, financial advisory and opinion fees and expenses, legal fees, accounting fees and expenses, certain employee expenses, filing fees, printing expenses and other related fees and expenses. Many of these expenses will be payable by us regardless of whether the Transaction is completed.

Further, if the Transaction is completed, we will enter into the TSA, which will provide for services to be performed by us in order to facilitate a smooth transition of the business associated with the VOWST Business to Nestlé. Performance of our obligations under the TSA will incur significant financial costs and the focus and attention of our management and employee resources may be diverted from our remaining business.

The announcement and pendency of the Transaction, whether or not consummated, may adversely affect our business and operations.

The announcement and pendency of the Transaction, whether or not consummated, may adversely affect the trading price of our common stock as well as our relationships with existing or potential suppliers, customers, vendors, distributors, licensors, licensees, collaboration partners and other business partners, and may have an adverse effect on the business, financial condition and results of operations of the Company. The pending Transaction may cause such counterparties to seek to change existing business relationships with the Company or the VOWST Business, to forego new relationships or to enter into alternative agreements with our competitors because business partners may perceive that such new relationships are likely to be more stable.

In addition, current and prospective employees of the Company, including of the VOWST Business, may feel uncertain about their roles within the Company or the VOWST Business prior to and following the completion of Transaction, which may have an adverse effect on our ability to attract or retain key management personnel or other key employees. If key employees depart, the business of the Company, its financial condition and its results of operations may be adversely impacted.

The focus and attention of our management and employee resources may also be diverted from operational matters during the pendency of the Transaction to focus on integration matters and the consummation of the Transaction.

Lawsuits may be filed against us challenging the Transaction and an adverse ruling in any such lawsuit may prevent the Transaction from being completed or from being completed within the expected time frame.

One of the conditions to the completion of the Transaction is the absence of any judgment or law issued or enacted by any governmental entity of competent jurisdiction, in each case that has been entered and remains in effect that prevents, enjoins, renders illegal or prohibits the consummation of the Transaction. Accordingly, if litigation is filed challenging the Transaction and a plaintiff is successful in obtaining an order enjoining completion of the Transaction, then such order may prevent the Transaction from being completed or from being completed within the expected time frame.

We may not be able to realize the anticipated benefits of the Transaction.

We may not be able to realize the anticipated benefits from the Transaction, including potentially deploying the proceeds from the Transaction to advance 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.

We may also face new challenges operating as a smaller company as a result of the completion of the Transaction, including:

- maintaining employee morale and retaining key management and other employees;
- retaining existing business and operational relationships, including with third parties, employees and other counterparties, as may be impacted by contracts containing consent and/or other provisions that may be triggered by the Transaction, or with counterparties that otherwise prefer to transact with larger companies (or will only transact with smaller companies on less favorable terms); and
- raising capital on favorable terms in debt or equity markets.

Following the Transaction, we will be a smaller, less diversified company.

If consummated, the Transaction will result in the Company being a smaller, less diversified company with a more limited remaining business concentrated on SER-155, which is currently being evaluated in a Phase 1b study in patients undergoing allogeneic hematopoietic stem cell transplantation to reduce the incidence of graft-versus-host disease, 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 revenues, costs and cash flows will diminish 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.

In addition, we will need to secure additional funding to maintain operations beyond our current cash runway, which, with the cash payable upon Closing and the Installment Payments expected to be obtained from the Transaction, if consummated, we anticipate being able to extend into 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 will have broad discretion as to the use of the proceeds from the Transaction, and may not use the proceeds effectively.

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

Risks Related to Our Financial Position and Need for Additional Capital

We are a commercial-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 $73.0 million for the six months ended June 30, 2024. As of June 30, 2024, we had an accumulated deficit of $1,051.2 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 collaboration agreements, and loan facility. We have devoted substantially all of our financial resources and efforts to developing our microbiome therapeutics platform, identifying potential product candidates and conducting preclinical studies and clinical trials. We have only had one product, VOWST, which was approved for marketing in the United States to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI on April 26, 2023, and launched in June 2023. 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 supporting commercialization of VOWST and on our SER-155 Phase 1b study until the completion of the Transaction, if consummated, and on completing our SER-155 Phase 1b study and advancing our other wholly-owned cultivated live biotherapeutic candidates following the completion of the Transaction, if consummated, our expenses may increase substantially in connection with our ongoing and future activities, particularly if and as we:

- commercialize and manufacture VOWST for adult patients with recurrent CDI with our collaborator Nestlé, as adjusted if and upon the Closing of the Transaction;
- continue the clinical development of SER-155 to potentially reduce incidences of gastrointestinal infections, resulting bloodstream infections, and GvHD in patients receiving allo-HSCT;
- 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 our agreements with our 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 commercialization efforts, diversify our product offerings or even continue our 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, our future operating plans, and the capital expected to be obtained from the Transaction, if consummated, and considering our ongoing obligations related to the Transaction, we anticipate being able to extend our cash runway into the fourth quarter of 2025, subject to material compliance with the TSA, and we will require additional funding at that time. See "Risk Factors—Risks Related to the Transaction and Remaining Company." Because the ability to obtain sufficient capital from the Transaction, if consummated, or additional equity or debt 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 six months ended June 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 will need additional funding in order to complete development of our product candidates and commercialize VOWST and 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 commercialization efforts.

Our expenses may increase in connection with our ongoing activities, particularly if and as we scale up manufacturing operations and continue the commercialization of VOWST (until the completion of the Transaction, if consummated), continue the SER-155 Phase 1b study, 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 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 timing and completion of the Transaction;
- the success of our restructuring plan, announced in November 2023, including its anticipated benefits, which has been substantially implemented;
- the cost of manufacturing VOWST and our product candidates;
- our share of the profits and losses from commercial sales of VOWST pursuant to the 2021 License Agreement;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates and research activities;
- the costs, timing and revenue, if any, of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;

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

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 products or 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 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 the commercialization of VOWST (until the completion of the Transaction, if consummated) 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.

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 approved by the FDA in April 2023, we have not yet demonstrated our ability to obtain regulatory approvals. Moreover, with the recent approval of VOWST, 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 our restructuring plan announced in November 2023 and substantially implemented by December 31, 2023, 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

Other than VOWST, 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. Other than VOWST, which launched in the United States in June 2023, we are at an early stage of development of our product candidates and our platform has not yet, and may never, lead to other approvable or marketable drugs. We are developing additional product candidates that we intend to develop 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 and 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 products, 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 products and 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 products, 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 products following approval; and
- maintaining and growing an organization of scientists and business people who can develop and commercialize our products and technology.

If we or our collaborators do not successfully develop and commercialize our products or 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.

VOWST and our product candidates are based on microbiome therapeutics, which is a novel approach to therapeutic intervention.

VOWST and our product candidates are based on microbiome therapeutics, 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 microbiome therapeutics, which could result in a longer than expected regulatory review process, increase our expected development costs and delay or prevent commercialization of our product candidates.

Our reverse translational microbiome therapeutics platform relies on third parties for biological materials, including human stool. Some biological materials have not always met our expectations or requirements, and any disruption in the supply of these biological materials could materially adversely affect our business. For example, if any supplied biological materials are contaminated with disease organisms, we would not be able to use such biological materials. Although we have control processes and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. Improper storage of these materials, by us or any third-party suppliers, may require us to destroy some of our materials or products, which could delay the development or commercialization of VOWST (until the completion of the Transaction, if consummated) or 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 commercialization of our product candidates.

Other than VOWST, which received FDA approval in April 2023 to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI, 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 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 our 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 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 our collaborators from commercializing the product candidate in that jurisdiction and may affect our plans for commercialization in other jurisdictions as well. Other than FDA approval for VOWST in the United States to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI, 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 commercialization of our product candidates. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent 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 designation 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.

Prior to receiving FDA approval for VOWST, we received Breakthrough Therapy designation for SER-109 for treatment of CDI, and we may seek a Breakthrough Therapy designation for other 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 products and 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. In connection with VOWST's approval, we received a seven year period of exclusivity to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI, which period began on April 26, 2023.

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

The collaboration and license agreements with Société des Produits Nestlé S.A. ("SPN") and NHSc Rx License GmbH (collectively, and together with their affiliates and subsidiaries, "Nestlé") are important to our business. If we or Nestlé fail to adequately perform under these agreements, or if we or Nestlé terminate the agreements, the development and commercialization of our CDI and IBD product candidates and/or VOWST could be adversely affected, delayed or terminated and our business would be adversely affected.

In January 2016, we entered into a Collaboration and License Agreement with Nestlé, or the 2016 License Agreement. The 2016 License Agreement may be terminated:

- by Nestlé in the event of serious safety issues related to VOWST, SER-287, SER-301 or other specific products added under the 2016 License Agreement, or, collectively, the 2016 Collaboration Products;
- by us if Nestlé challenges the validity or enforceability of any of our licensed patents; and
- by either Nestlé or us in the event of the other party's uncured material breach or insolvency.

Upon termination of the 2016 License Agreement, all licenses granted to Nestlé by us will terminate, and all rights in and to the 2016 Collaboration Products held by Nestlé will revert to us. If we commit a material breach of the 2016 License Agreement, Nestlé may elect not to terminate the 2016 License Agreement but instead apply specified adjustments to its payment obligations and other terms and conditions of the 2016 License Agreement. If Nestlé were to make such adjustments, the funding from and benefits of the 2016 License Agreement could be diminished, which could adversely affect our financial condition. Unless the 2016 License Agreement is terminated by us for Nestlé's uncured material breach, upon termination of the 2016 License Agreement, Nestlé will be eligible to receive post-termination royalties from us until Nestlé has recouped certain development costs related to the 2016 Collaboration Products and specified percentages of any milestone payments paid to us under the 2016 License Agreement prior to termination, which could have a material adverse effect on our business.

In July 2021, we entered into a License Agreement with Nestlé, or the 2021 License Agreement. The 2021 License Agreement may be terminated:

- by Nestlé with twelve months' prior written notice, effective only on or after the third anniversary of first commercial sale of VOWST and any improvements and modifications thereto developed pursuant to the terms of the 2021 License Agreement, or the 2021 Collaboration Products;
- by us if Nestlé challenges the validity or enforceability of any of our licensed patents; and
- by either Nestlé or us in the event of the other party's uncured material breach or insolvency.

Upon termination of the 2021 License Agreement, all licenses granted to Nestlé by us will terminate. If we commit a material breach of the 2021 License Agreement, Nestlé may elect not to terminate the 2021 License Agreement but instead apply specified adjustments to the payment terms and other terms and conditions of the agreement. If Nestlé were to make such adjustments, the funding from and benefits of the 2021 License Agreement could be diminished, which could adversely affect our financial condition. In the event we materially breach the 2021 License Agreement or file for bankruptcy, the share of profits and milestones due to us will be reduced by a specified percentage until Nestlé has recouped twice the losses caused by our material breach or bankruptcy.

Termination of these agreements could cause significant delays in our product development and commercialization efforts that could prevent us from commercializing our CDI and IBD products and product candidates without first expanding our internal capabilities or entering into another agreement with a third party. Any alternative collaboration or license could also be on less favorable terms to us. In addition, under the agreements, Nestlé agreed to provide funding for certain clinical development activities. If either of the agreements were terminated, we may need to refund those payments and seek additional financing to support the research and development or commercialization of any terminated products or discontinue any terminated products or product candidates, which could have a material adverse effect on our business.

Under the collaboration and license agreements, we are dependent upon Nestlé to successfully commercialize any applicable collaboration products both outside and within the United States and Canada, as applicable. For example, we must work closely with Nestlé to supply VOWST to them and coordinate scientific messaging. To optimize the commercial potential of VOWST, we must execute these plans effectively and collaboratively. We cannot directly control Nestlé's commercialization activities or the resources it allocates to our product candidates. Our interests and Nestlé's interests may differ or conflict from time to time, or we may disagree with Nestlé's level of effort or resource allocation. Nestlé may internally prioritize our product candidates differently than we do or it may not allocate sufficient resources to effectively or optimally commercialize them. If these events were to occur, our business would be adversely affected.

We rely on Nestlé to provide information related to the commercialization of VOWST so that we can make strategic decisions and projections, and we may provide this data, or statements based upon this data, to investors. If the data Nestlé provides us is inaccurate or incomplete, it may adversely affect our financial statements, business operations, the commercial success of VOWST or our stock price.

Under the 2021 License Agreement, VOWST net sales are recorded by Nestlé and include gross sales net of discounts, rebates, allowances, and other applicable deductions. We rely on Nestlé to provide reporting related to net sales of VOWST in accordance with U.S. generally accepted accounting principles in order to calculate and record collaboration profit or loss. We also rely on Nestlé to provide timely, accurate and complete information related to the commercialization of VOWST, including data on prescribers, prescriptions and new patient starts. We use the information provided to us by Nestlé to report our results of operations, to plan for our future operations, and to make strategic decisions and projections, which may prove to be inaccurate or suboptimal. We base some of our strategic decisions and projections on the data Nestlé provides and we may provide this information to investors and analysts who may make their own predictions and estimates, all of which may prove to be inaccurate. Any failure by Nestlé to provide accurate and complete information related to the commercialization of VOWST, or to provide it on a timely basis, could adversely impact our financial statements, business operations, the commercial success of VOWST or our stock price.

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 commercialization of our products, producing additional losses and depriving us of potential product revenue.

We rely on third parties for certain aspects of the manufacture of our product and 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 and product candidates or that such quantities may not be available at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We rely, and expect to continue to rely, on third parties, including GenIbet and Bacthera, for certain aspects of materials supply for our product candidates in preclinical and clinical testing, as well as for commercial manufacture of VOWST and 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 commercialization efforts. For example, VOWST and certain of our product candidates rely on human stool from third-party donors. If we do not obtain an adequate supply of donor-derived material to meet clinical or commercial demand, our ability to manufacture VOWST and our product candidates may be delayed or adversely impacted.

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. Some of the contract manufacturers we rely on to produce VOWST or our product candidates have never produced any other FDA-approved therapeutic. One of the contract manufacturers on which we rely, Bacthera, is constructing a dedicated production suite to manufacture VOWST and our product candidates. We initially believed this dedicated production suite was substantially completed in late 2023, however, recent discussions between us and Bacthera have identified certain elements of the production suite construction currently missing that would be required to satisfy the substantial completion criteria as defined in the Bacthera Agreement. We believe that it is probable that the missing elements can be remediated during the year ending December 31, 2024 and discussions with Bacthera are continuing in order to align on the steps necessary to complete that remediation and the related timing of the milestone payment. However, we cannot provide assurance that these discussions will be successful. Moreover, upon completion, the dedicated production suite may not be approved by the FDA for the manufacture of VOWST. In addition, upon consummation of the Transaction, the liabilities constituting the substantial completion milestone payment will be assumed by Nestlé and Nestlé will be obligated to make this milestone payment to Bacthera upon their substantial completion of the project. 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. 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 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, such as Bacthera, 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 commercialization efforts.

Other than the manufacture of VOWST after its recent FDA approval, we have very little 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 and Waltham, Massachusetts locations where we conduct process development, scale-up activities and a portion of the manufacture of microbiome therapeutics 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. The FDA inspected our Cambridge and Waltham facilities in December 2022 and closed the inspections without issue. We currently intend to rely in part on third-party manufacturers for portions of the commercial manufacturing of VOWST and may establish a manufacturing facility for VOWST or 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. 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.

In addition, some of our product candidates require donor material, of which we may not be able to collect sufficient quantities for commercial-scale or other manufacturing.

Risks Related to Commercialization of Our Products, Product Candidates and Other Legal Matters

We depend heavily on the commercial success of VOWST, which was approved for marketing by the FDA in April 2023 and launched in the United States in June 2023. There is no assurance that our commercialization efforts, or those of our collaborators, in the United States with respect to VOWST will be successful or that we will be able to generate collaboration profit at the levels or within the timing we expect, or at the levels or within the timing necessary to support our goals for VOWST.

Our business currently depends heavily on our ability to successfully commercialize VOWST in the United States in its approved indication with our collaborator, Nestlé. We may never be able to successfully commercialize VOWST or meet our expectations with respect to collaboration profit. There is no guarantee that the infrastructure, systems, processes, policies, personnel, relationships and materials we have built in preparation for the launch and commercialization of VOWST in the United States will be sufficient for us to achieve success at the levels we expect. Additionally, healthcare providers may not accept a new treatment paradigm for patients with recurrent CDI. We may also encounter challenges related to reimbursement of VOWST, even if we have positive early indications from payors, including potential limitations in the scope, breadth, availability, or amount of reimbursement covering VOWST. Similarly, healthcare organizations or patients may determine that the financial burdens of treatment are not acceptable. Our results may also be negatively impacted if we encounter deficiencies or inefficiencies in our infrastructure or processes. Any of these issues could impair our ability to successfully commercialize VOWST or to generate substantial collaboration profit or to meet our expectations with respect to the amount or timing of collaboration profit. Any issues or hurdles related to our commercialization efforts may materially adversely affect our business, results of operations, financial condition and prospects. There is no guarantee that we will be successful in our commercialization efforts with respect to VOWST, or that we will generate significant collaboration profit from VOWST or any product candidate or become profitable.

Even though VOWST has received FDA approval and even if any of our product candidates receive marketing approval, VOWST and 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.

Even though VOWST has received FDA approval to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI, and even if any of our product candidates receive marketing approval, VOWST or our product candidates may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current CDI treatment involves the use of antibiotics alone, which are well established in the medical community or the use of FMT, and physicians may continue to rely on these treatments or the treatments of our competitors. If VOWST or our product candidates (if and when they are approved) do not achieve an adequate level of acceptance, we or our collaborators may not generate significant collaboration profit and we may not become profitable. The degree of market acceptance of VOWST or 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 together with other medications;
- interactions of our products with other medicines patients are taking; and
- the ability of patients to take our products.

If we or our collaborators are unable to establish effective sales, marketing and distribution capabilities or enter into agreements with third parties with such capabilities, we or our collaborators may not be successful in commercializing VOWST or 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 VOWST or for any other product for which we obtain marketing approval, we will need to establish a sales and marketing organization and/or we will need our collaborator Nestlé to perform sales and marketing functions and they may not be successful in doing so.

In July 2021, we entered into the 2021 License Agreement with Nestlé, pursuant to which we granted Nestlé, under certain of our patent rights and know how, a co-exclusive, sublicensable (under certain conditions) license to develop, commercialize and conduct medical affairs activities for the 2021 Collaboration Products, including VOWST, in the United States and Canada. Under the 2021 License Agreement, Nestlé has the sole right to commercialize VOWST in the 2021 Licensed Territory in accordance with a commercialization plan, subject to our right to elect to provide up to a specified percentage of all promotional details for a certain target audience. Each party will use commercially reasonable efforts to commercialize VOWST in the 2021 Licensed Territory in accordance with the commercialization plan. Both parties will perform medical affairs activities for VOWST in the 2021 Licensed Territory in accordance with a medical affairs plan. We were responsible for commercialization and medical affairs activities costs incurred by the parties until first commercial sale of the first 2021 Collaboration Product, or VOWST, in the 2021 Licensed Territory and in accordance with a pre-launch plan, up to a specified cap. Since the first commercial sale of VOWST in June 2023, we are entitled to share equally in its commercial profits and losses.

In the future, we expect to build a focused sales and marketing infrastructure, or certain components of such infrastructure, if we were to market or co-promote VOWST and 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 any product launch. 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 our collaborators cannot retain or reposition sales and marketing personnel.

Factors that may inhibit efforts to commercialize our products 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, including Nestlé, to sell, market and distribute VOWST and 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 product revenue or collaboration profit and 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 products 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 and our collaborators face competition with respect to VOWST and our other 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 reducing CDI and other 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. For example, FMT is a procedure that has resulted in reports of high success rates for recurrent CDI. 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 VOWST or 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 continue to commercialize VOWST or 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 products may be difficult. We cannot be certain if and when we will obtain an adequate level of reimbursement for our products 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 VOWST or any product candidate for which we obtain marketing approval, and the 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 VOWST or any other 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 VOWST or any other 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 any product candidates or products;
- 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 any products that we develop.

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, increase commercialization of VOWST (until the completion of the Transaction, if consummated), or if we commence commercialization of our product candidates. 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 VOWST or our product candidates.

Because we have received FDA approval of VOWST to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI, and 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.

VOWST qualified, and 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 products. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products 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 products 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 or our collaborators may not obtain approvals for VOWST or 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 products in any market.

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

VOWST and 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 our collaborators 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. For example, the FDA-approved label for VOWST includes certain warnings and precautions regarding transmissible infectious agents and the potential presence of food allergens.

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. For example, the FDA-approved label for VOWST includes a limitation of use that VOWST is not indicated for the treatment of CDI.

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 our 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 our collaborators later discover previously unknown problems with our products, 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 our collaborators, including requiring withdrawal of the product from the market. Any failure by us or our collaborators to comply with applicable regulatory requirements may yield various results, including:

- litigation involving patients taking our products;
- 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;
- 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 our collaborators are found to have improperly promoted off-label uses of approved products, including VOWST or 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 VOWST and 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. The current FDA-approved indication for VOWST is limited to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI. Physicians may nevertheless prescribe VOWST or 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 our 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 VOWST or 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 our 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 VOWST and any product candidates for which we obtain marketing approval. Our and our 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 VOWST and 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 our or our 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 our 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 products and 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 VOWST and 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 products at what we consider to be a fair or competitive price, generate revenue, attain profitability, or commercialize VOWST or 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 products 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 VOWST or 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 products 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 products, 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 products. 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 and options to obtain 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 31 issued U.S. patents and 1 allowed U.S. patent application, 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, given that VOWST is a complex composition with some variation from lot-to-lot and that, likewise, third-party compositions may have similar complexity and variability, it is possible that a patent claim may provide coverage for some but not all lots of a product, product candidate or third-party product. 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 products or 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 products, 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 products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products 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 VOWST or 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 products.

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 our collaborators, to develop, manufacture, market and sell VOWST and 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. While no such litigation has been brought against us and we have not been held by any court to have infringed a third party's intellectual property rights, we cannot guarantee that our technology, VOWST or our product candidates, or use of VOWST or our products do not infringe third-party patents. In addition, in connection with the Transaction and pursuant to the Purchase Agreement, we expect to transfer certain patents and trademarks affiliated with the VOWST Business to Nestlé at Closing. If there are any issues related to enforcing our patents or trademarks, it could impact the Closing of the Transaction.

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 VOWST or 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, VOWST, 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 VOWST or 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, VOWST or our product candidates or the use of VOWST or our product candidates. We are aware of several pending patent applications containing one or more claims that could be construed to cover VOWST, 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 VOWST, 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 VOWST, 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 VOWST, 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 VOWST, 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 VOWST, 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 VOWST or 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 VOWST or 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 VOWST or 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 VOWST or 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 VOWST or one of our product candidates, the defendant could counterclaim that the patent covering VOWST or 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 VOWST or 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 products 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 products, 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

The terms of the Oaktree Credit Agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

On April 27, 2023, we entered into the Oaktree Credit Agreement, which establishes a term loan facility of $250.0 million, consisting of (i) the Tranche A Loan, funded on the Oaktree Closing Date, (ii) the Tranche B Loan, that we may borrow subject to certain conditions, (iii) the Tranche C Loan, that we may borrow subject to certain conditions, and (iv) the Tranche D Loan, available in Oaktree's sole discretion (collectively with the Tranche A Loan, the Tranche B Loan, the Tranche C Loan, and the Tranche D Loan, the “Oaktree Term Loan”). We may draw the Tranche B Loan until September 30, 2024, if VOWST net sales for the trailing six consecutive months are at least $35.0 million and at least 4.5% greater in the calendar quarter prior to the Applicable Funding Date (as defined in the Oaktree Credit Agreement) over the calendar quarter immediately preceding it. We may draw the Tranche C Loan until September 30, 2025, if VOWST net sales for the trailing 12 consecutive months are at least $120.0 million and at least 4.5% greater in each of the two calendar quarters prior to the Applicable Funding Date relative, in each case, to the calendar quarter immediately preceding it. However, given the anticipated Transaction (as defined herein) and expected repayment of the Oaktree Loan, the probability of drawing the Tranche B and C Loans is deemed to be remote. The Oaktree Term Loan has a maturity date of April 27, 2029 (the “Oaktree Maturity Date”).

Our obligations under the Oaktree Credit Agreement and the other Loan Documents (as defined in the Oaktree Credit Agreement) will be guaranteed by any of our domestic subsidiaries that become Guarantors (as defined in the Oaktree Credit Agreement), subject to certain exceptions. Our and our Guarantors' (collectively, the "Loan Parties") respective obligations under the Oaktree Credit Agreement and the other Loan Documents are secured by first priority security interests in substantially all assets of the Loan Parties, including intellectual property, subject to certain customary thresholds and exceptions. As of June 30, 2024, there were no Guarantors.

The Oaktree Credit Agreement contains customary representations, warranties and affirmative and negative covenants, including a financial covenant requiring us to maintain certain levels of cash and cash equivalents in accounts subject to a control agreement in favor of the Agent of at least $30.0 million at all times commencing from 30 days after the Oaktree Closing Date and decreasing to $25.0 million of cash and cash equivalents in such controlled accounts after we borrow any Tranche B Loan.
As of June 30, 2024, we were in compliance with all financial covenants pursuant to the Oaktree Credit Agreement.

In addition, the Oaktree Credit Agreement contains certain events of default that entitle the Agent to cause our indebtedness under the Oaktree Credit Agreement to become immediately due and payable, and to exercise remedies against the Loan Parties and the collateral securing the Oaktree Term Loan, including cash. Under the Oaktree Credit Agreement, an event of default will occur if, among other things, we fail to make payments under the Oaktree Credit Agreement (subject to specified cure periods with respect to certain payments), we or our subsidiaries breach any of the covenants under the Oaktree Credit Agreement (subject to specified cure periods with respect to certain breaches), a material adverse change occurs, we, our subsidiaries or our or their respective assets become subject to certain legal proceedings, such as bankruptcy proceedings, we and/or our subsidiaries are unable to pay our or their debts as they become due or default on contracts with third parties which would permit the holder of indebtedness in excess of a certain threshold to accelerate the maturity of such indebtedness or that could cause a material adverse change. Upon the occurrence and for the duration of an event of default, an additional default interest rate equal to 2.0% per annum may apply to all obligations owed under the Oaktree Credit Agreement.

Any declaration by the Oaktree Lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

On May 1, 2024, we received a Notice of Default and Reservation of Rights (the "Notice") from the Agent under the Oaktree Credit Agreement.

The Notice specified that in the Agent's view, one or more events of default have occurred under the Oaktree Credit Agreement due to (a) our non-payment of a milestone payment to Bacthera under the Bacthera Agreement which the Agent characterized as "Indebtedness" that would not be permitted under the Oaktree Credit Agreement and (b) our failure to deliver written notice to the Agent regarding such non-payment.

Under the Bacthera Agreement, approximately $28.1 million would be due to Bacthera upon their substantial completion of our dedicated production suite. However, we have identified certain incomplete elements of the project required to satisfy the "Substantial Completion" criteria as set forth in the Bacthera Agreement. We believe that it is probable that these elements can be completed in 2024 and discussions with Bacthera are continuing to align on the steps necessary to complete those steps and the related timing of any milestone payment.

We have responded by letter to the Notice, advising the Agent that no default or event of default under the Oaktree Credit Agreement has occurred or is continuing, because the payment under the Bacthera Agreement is not due, and, as a result, no notice of non-payment was required. Moreover, even if the payment were due, we do not believe such payment would constitute Indebtedness (as defined in the Oaktree Credit Agreement).

Based on the above, we believe that we are not in default under the Oaktree Credit Agreement, and that the Agent does not have the right to accelerate the indebtedness or otherwise pursue remedies thereunder. If the Agent were to pursue any such actions, we intend to vigorously defend ourselves against them and to pursue any counterclaims available to us.

See also *Risk Factors—Risks Related to our Dependence on Third Parties and Manufacturing—We rely on third parties for certain aspects of the manufacture of our product and 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 and product candidates or that such quantities may not be available at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts*.

We may be unable to realize the expected benefits from our restructuring plan and our business might be adversely affected.

In November 2023, we announced, based on a challenging macro environment and financial backdrop, a restructuring plan to focus our business operations 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. Under the restructuring plan, we reduced our workforce by approximately 41% and significantly scaled back all non-partnered research and development activities other than the completion of the SER-155 Phase 1b study. The restructuring plan has been substantially implemented.

These types of restructuring and cost reduction activities are complex and may result in unintended consequences and costs, such as unforeseen delays in the implementation of our strategic initiatives, business and operational disruptions, decreased employee morale and retention, loss of institutional knowledge and expertise, and potential impacts on financial reporting. The significant reduction in our workforce under the restructuring plan could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. In addition, the decision to significantly scale back all non-partnered research and development activities other than the completion of the SER-155 Phase 1b study may negatively impact our growth, competitive positioning, business and results of operations. If we do not successfully manage the impact of the restructuring plan or any other similar activities that we may undertake in the future, we may not achieve the expected costs savings and other expected benefits in the expected timeframe or at all, and our business, financial condition, and results of operations may be materially adversely affected.

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 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. Our restructuring plan may make it more difficult for us to hire qualified personnel. 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 with respect to VOWST and 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. We currently plan to rely on collaborators, including Nestlé, to commercialize certain approved products outside of North America. Also, for certain manufacturing services for VOWST, we rely on GenIbet in Portugal, and Bacthera, which is constructing a dedicated full-scale production suite for us in Switzerland. 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 products 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 products 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 August 5, 2024, we entered into the Purchase Agreement with Nestlé pursuant to which we have agreed to sell our VOWST microbiome therapeutic business, including 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

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, the Oaktree Credit Agreement currently prohibits us from paying dividends on our equity securities, and any future debt agreements may likewise 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 obtain stockholder approval and realize the benefits of the Transaction with Nestlé;
- our ability to execute and realize the benefits of strategic plans, such as the restructuring plan we announced in November 2023;
- our requirement for additional funding by the fourth quarter of 2025 (or, if the Transaction is not consummated, the fourth quarter of 2024);
- 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 our 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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

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

None.

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

None.

c) *Insider trading arrangements and policies.*

During the three months ended June 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				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
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	Form of Securities Purchase Agreement, by and between Seres Therapeutics, Inc. and Société des Produits Nestlé S.A.	8-K	001-37465	10.1	8/6/24	
10.2†	Form of Transition Services Agreement, by and between Seres Therapeutics, Inc. and Société des Produits Nestlé S.A.	8-K	001-37465	10.2	8/6/24	
10.3	Form of Cross-License Agreement, by and between Seres Therapeutics, Inc. and Société des Produits Nestlé S.A.	8-K	001-37465	10.3	8/6/24	
10.4	Form of Employee Support Agreement, by and between Seres Therapeutics, Inc. and Société des Produits Nestlé S.A.	8-K	001-37465	10.4	8/6/24	
10.5†	Assignment and Termination of Manufacturing Agreement, dated August 5, 2024, by and between Seres and Bacthera AG					*
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: August 13, 2024	By:	/s/ Marella Thorell
		Marella Thorell
		Executive Vice President and Chief Financial Officer
		(Principal Financial and Accounting Officer)

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

ASSIGNMENT AND TERMINATION OF MANUFACTURING AGREEMENT

This **ASSIGNMENT AND TERMINATION OF MANUFACTURING AGREEMENT** (the "**Manufacturing Agreement Termination Agreement**") is dated as of August 5, 2024, and is made by and among 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**"), Nestlé Enterprises S.A., a *société anonyme* organized under the laws of Switzerland, having an office located at Avenue Nestlé 55, 1800 Vevey, Switzerland ("**NESA**") and BacThera AG, a joint venture between Chr. Hansen A/S and Capsugel Belgium NV, a Lonza Group Affiliate, organized under the laws of Switzerland, having an office located at Hochbergerstrasse 60A, 4057 Basel, Switzerland ("**Bacthera**"). Seres, NESA and Bacthera are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**". Capitalized terms used herein without definition are used as defined in the Manufacturing Agreement (as defined below).

WHEREAS, Seres and Bacthera are parties to that certain Long Term Manufacturing Agreement, dated November 8, 2021, as amended by certain Amendment to Long Term Manufacturing Agreement, dated December 14, 2022 (the "**Manufacturing Agreement**"), pursuant to which Bacthera agreed to Manufacture and supply to Seres SER-109 (the "**Product**") from Bacthera's Microbiome Center of Excellence in Visp, Switzerland (the "**Facility**");

WHEREAS, Seres and Société des Produits Nestlé S.A., an Affiliate of NESA ("**SPN**"), concurrently with the execution hereof are entering into that certain Asset Purchase Agreement dated August 5, 2024 (the "**APA**"), pursuant to which SPN has agreed to purchase and acquire, or to cause its Affiliates to purchase and acquire, from Seres, subject to the satisfaction of the conditions contained therein, certain assets related to the exploitation of the Product worldwide;

WHEREAS, concurrently with the closing of the transactions contemplated in the APA (the "**Closing**"), Seres and NESA desire that the Manufacturing Agreement be assigned to NESA and, immediately thereafter, that the Manufacturing Agreement be terminated by mutual agreement, upon the terms and subject to the conditions set forth herein.

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. Assignment; Termination and Effect of Termination.

   a) Concurrently with the Closing, the Manufacturing Agreement will be assigned to NESA, and NESA shall be deemed to have assumed the obligations of Seres thereunder, subject to the terms and conditions hereof, without the need for any further act or deed (the "**Assignment**"). Following such Assignment, Seres shall remain jointly and severally liable with NESA for all obligations owed to Bacthera under the Manufacturing Agreement until Bacthera receives the Closing Payment (defined below). Bacthera hereby consents to such assignment and assumption, to the extent such consent is required under the Manufacturing Agreement and subject to the terms hereof. Notwithstanding any provision in the Manufacturing Agreement to the contrary, immediately following Bacthera's receipt of the Closing Payment, the Manufacturing Agreement shall be deemed to be terminated by mutual agreement pursuant to Section 18 thereof(the date of such termination being referred to herein as the "**Manufacturing Agreement Termination Effective Date**").

b) Concurrently with the Closing, NESA shall pay, or cause its Affiliate to pay, to Bacthera an amount equal to [***] ([***]) by direct wire transfer of Swiss Francs in immediately available funds to such bank account as Bacthera may designate by written notice to NESA (such payment, the "**Closing Payment**"). The Parties agree that the Closing Payment shall constitute full and final settlement of all outstanding liabilities (including any unpaid invoices) owed to Bacthera pursuant to the Manufacturing Agreement. The Parties further agree that, notwithstanding the Closing Payment, Bacthera shall retain ownership of all Equipment located at the Facility (each as defined in the Manufacturing Agreement).

c) Subject to the terms of this Manufacturing Agreement Termination Agreement, notwithstanding any provision in the Manufacturing Agreement to the contrary, the following sections (and no other parts, other than to the extent incorporated in the following sections) of the Manufacturing Agreement shall continue in full force and effect after the Manufacturing Agreement Termination Effective Date in accordance with the terms thereof and the same shall be enforceable by Bacthera and NESA (in its capacity as the assignee of the Manufacturing Agreement): Sections 10 (*Intellectual Property*), 13.3 (*Payment Terms*) – 13.7 (*Audits*), 14 (*Confidentiality*), 16.1(c) (*Indemnification*), except that any indemnification under clause (a) of Section 16.1 shall only apply to any breach arising after the Manufacturing Agreement Termination Effective Date, 17 (*Dispute Resolution*), 18.4(i) (*Consequences of Termination or Expiration*), 18.4(j) (*Consequences of Termination or Expiration*) , 20.3 (*Third-Party Beneficiaries*), 20.8 (*Governing Law*), 20.9 (*Notices and Deliveries*) (as amended pursuant to Section 2 hereof), 20.13 (*Severability*) and 20.14 (*Counterparts*).

d) Following the Manufacturing Agreement Termination Effective Date, upon NESA's reasonable written request, subject to the availability, knowledge, and expertise of the remaining staff at the Facility, Bacthera agrees to use commercially reasonable efforts to support the transfer of the Manufacturing Process to NESA or its Affiliate or third party manufacturer, which support may include one or more site visit to the Facility, subject to Bacthera's applicable security and other applicable requirements. In furtherance of the foregoing, Bacthera and NESA agree to confer in good faith regarding the specific details of such support and any costs associated therewith.

e) Following the Assignment, and notwithstanding the Manufacturing Agreement Termination Effective Date, to the extent Seres continues to possess or have access to any New Bacthera Intellectual Property or any Confidential Information of Bacthera (each as defined in the Manufacturing Agreement), Seres shall continue to comply with the requirements of Section 10 (*Intellectual Property*) and Section 14 (*Confidentiality*) of the Manufacturing Agreement.

f) From and after the date hereof, until the Manufacturing Agreement Termination Effective Date, the respective affirmative obligations of Seres and Bacthera under the Manufacturing Agreement shall be suspended (the "**Suspension**") and neither Seres nor Bacthera shall be required to perform their respective obligations thereunder; provided, however, that if the Closing of the APA does not occur on or prior to December 31, 2024 or if the APA is terminated prior to the consummation of the Closing (written notice of which shall be promptly provided by NESA to Bacthera)(each a "**Termination Event**"), this Agreement will terminate and each of Seres and Bacthera will each use commercially reasonable efforts to otherwise comply with the terms of the Manufacturing Agreement. Subject to the foregoing, Seres and Bacthera agree that neither Party shall be liable to the other for any damages, losses or other liabilities that may be suffered or incurred by the other Party as a result of the Suspension. In the event of the occurrence of a Termination Event, except as provided in the immediately preceding sentence, all right, remedies and defenses of each of Seres and Bacthera shall be restored in full to the same extent as if this Agreement had never come into full force and effect.

2. Future Notices under the Manufacturing Agreement. Pursuant to Section 20.9 of the Manufacturing Agreement, from and after the Manufacturing Agreement Termination Effective Date, all notices or other correspondence related thereto from Bacthera shall be made to NESA as the assignee of Seres at the address or email address below:

Nestlé Enterprises S.A.
Avenue Nestlé 55
1800 Vevey, Switzerland
Attention: Martin Hendrix and Claudio Kuoni
Email: [***]
[***]

With a copy (which shall not constitute notice) to:

Mayer Brown LLP
1221 Avenue of the Americas
New York, NY 10020
Attention: David A. Carpenter
Email: dacarpenter@mayerbrown.com

3. Release. Except for the obligations of the Parties expressly set forth in this Manufacturing Agreement Termination Agreement, with effect as of the Manufacturing Agreement Termination Effective Date, each Party will and hereby does, on behalf of itself and its officers, directors, managers, employees, agents, representatives, shareholders, members, predecessors, successors, and assigns (collectively, the "**Releasing Parties**"), forever release and discharge each 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 point in time against the Released Parties, or any of them, which relate to or arise out of the Manufacturing Agreement, including, without limitation, any liability for any breach of the Manufacturing Agreement occurring on or prior to the Manufacturing Agreement Termination Effective Date, provided that, solely as between Seres and NESA, nothing express or implied in this Manufacturing Agreement Termination Agreement shall in any way supersede, modify, replace, amend, change, rescind, waive, limit, exceed, expand, enlarge or in any way affect the provisions of the APA and, in the event of any conflict or inconsistency between this Manufacturing Agreement Termination Agreement and the APA, the terms and conditions of the APA shall govern and control.

4. Miscellaneous.

a) Governing Law. This Manufacturing Agreement Termination Agreement, and any dispute arising out of, relating to or in connection with this Manufacturing Agreement Termination Agreement, shall be governed by, and enforced in accordance with, the internal laws of the State of New York, without giving effect to any laws, rules or provisions of the State of New York that would cause the application of the laws, rules or provisions of any jurisdiction other than the State of New York. 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 state courts located in New York County in the State of New York (or, only if the state courts located in New York County in the State of New York decline to accept or do not have jurisdiction over a particular matter, any federal or other state court within the State of New York) (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 Manufacturing Agreement Termination Agreement; (ii) to commence any Action arising out of or relating to this Manufacturing 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 NESA, 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 Manufacturing 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 MANUFACTURING 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 MANUFACTURING 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 Manufacturing Agreement Termination Agreement. This Manufacturing 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 Manufacturing 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 Manufacturing Agreement Termination Agreement shall become binding when any number of counterparts, individually or taken together, shall bear the signatures of all Parties. This Manufacturing 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 Manufacturing Agreement Termination Agreement as of the Manufacturing Agreement Termination Effective Date.

SERES THERAPEUTICS, INC.

By:/s/ Eric D. Shaff

Name: Eric D. Shaff

Title: President and Chief Executive Officer

NESTLÉ ENTERPRISES S.A.

By: /s/ Claudio Kuoni

Name: Claudio Kuoni

Title: Vice President

BACTHERA, AG

By: /s/ Philippe Deecke

Name: Philippe Deecke

Title: Chief Financial Officer, Lonza Group AG

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: August 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: August 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 June 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.

August 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 June 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.

August 13, 2024

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