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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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 May 6, 2024, the registrant had 151,447,763 shares of common stock, $0.001 par value per share, outstanding.

Seres Therapeutics, Inc.

INDEX

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, our intent or ability to transfer the listing of our common stock to The Nasdaq Capital Market, regain compliance with any applicable Nasdaq listing requirements, implement a reverse stock split, 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:

- 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.
- We have received a notice of delisting or failure to satisfy a continued listing rule from The Nasdaq Stock Market LLC.
- Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.
- 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 microbiome therapeutics 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)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 111,184	$ 127,965
Collaboration receivable - related party	7,418	8,674
Inventories	41,973	29,647
Prepaid expenses and other current assets	4,606	9,124
Total current assets	165,181	175,410
Property and equipment, net	19,115	22,457
Operating lease assets	105,669	109,793
Restricted cash	8,430	8,185
Restricted investments	1,401	1,401
Other non-current assets (1)	41,466	41,354
Total assets	$ 341,262	$ 358,600
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 5,219	$ 3,641
Accrued expenses and other current liabilities (2)	76,317	80,611
Operating lease liabilities	8,833	6,677
Deferred income - related party	8,109	7,730
Total current liabilities	98,478	98,659
Long term portion of note payable, net of discount	102,009	101,544
Operating lease liabilities, net of current portion	103,341	105,715
Deferred revenue - related party	95,364	95,364
Warrant liabilities	130	546
Other long-term liabilities	1,678	1,628
Total liabilities	401,000	403,456
Commitments and contingencies (Note 15)		
Stockholders' deficit:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2024 and December 31, 2023; no shares issued and outstanding at March 31, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value; 240,000,000 shares authorized at March 31, 2024 and December 31, 2023, respectively; 151,442,034 and 135,041,467 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	151	135
Additional paid-in capital	958,479	933,244
Accumulated other comprehensive loss	—	—
Accumulated deficit	(1,018,368)	(978,235)
Total stockholders' deficit	(59,738)	(44,856)
Total liabilities and stockholders' deficit	$ 341,262	$ 358,600

[1] Includes $38,877 as of March 31, 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 $36,211 and $28,053 at March 31, 2024 and December 31, 2023, respectively (see Note 17)

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
(unaudited, in thousands, except share and per share data)

	Three Months Ended March 31,	
	2024	2023
Revenue:		
Collaboration revenue - related party	$ —	$ (522)
Total revenue	—	(522)
Operating expenses:		
Research and development expenses	21,702	43,969
General and administrative expenses	15,466	22,470
Collaboration (profit) loss sharing - related party	2,418	3,607
Total operating expenses	39,586	70,046
Loss from operations	(39,586)	(70,568)
Other income (expense):		
Interest income	1,648	1,032
Interest expense	(4,663)	(1,948)
Other income	2,468	310
Total other expense, net	(547)	(606)
Net loss	$ (40,133)	$ (71,174)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.27)	$ (0.57)
Weighted average common shares outstanding, basic and diluted	146,101,581	125,862,975
Other comprehensive income (loss):		
Unrealized gain (loss) on investments, net of tax of $0	—	12
Currency translation adjustment	—	2
Total other comprehensive income (loss)	—	14
Comprehensive loss	$ (40,133)	$ (71,160)

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 Loss (Income)		Total
	Shares	Par Value	Paid-in Capital		Accumulated Deficit	Stockholders' (Deficit) Equity
Balance at December 31, 2022	125,222,273	$ 125	$ 875,181	$ (12)	$ (864,511)	$ 10,783
Issuance of common stock upon exercise of stock options	56,523	—	188	—	—	188
Issuance of common stock upon vesting of RSUs, net of tax withholdings	259,023	—	—	—	—	—
Issuance of common stock under ESPP	267,615	1	1,228	—	—	1,229
Issuance of common stock from at the market equity offering, net of issuance costs of $225	787,170	1	4,238	—	—	4,239
Stock-based compensation expense	—	—	6,850	—	—	6,850
Other comprehensive income	—	—	—	14	—	14
Net loss	—	—	—	—	(71,174)	(71,174)
Balance at March 31, 2023	126,592,604	$ 127	$ 887,685	$ 2	$ (935,685)	$ (47,871)

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

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

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

	Three Months Ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (40,133)	$ (71,174)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation expense	6,489	6,850
Depreciation and amortization expense	1,559	1,400
Non-cash operating lease cost	2,393	2,070
Net (accretion) amortization of (discounts) premiums on investments	—	(187)
Amortization of debt issuance costs	465	187
Loss on disposal of fixed assets	293	—
Impairment of long-lived assets	3,267	—
Change in fair value of warrant liabilities	(416)	—
Collaboration (profit) loss sharing - related party (3)	—	3,607
Changes in operating assets and liabilities:		
Prepaid expenses and other current and other non-current assets	4,406	3,044
Collaboration receivable - related party	1,256	—
Inventories	(12,326)	—
Deferred income - related party	379	—
Deferred revenue - related party	—	522
Accounts payable	1,594	(3,806)
Operating lease liabilities	(218)	(67)
Accrued expenses and other current and long-term liabilities (4)	(4,244)	(19,030)
Net cash used in operating activities	(35,236)	(76,584)
Cash flows from investing activities:		
Purchases of property and equipment	(62)	(4,068)
Purchases of investments	—	(4,426)
Sales and maturities of investments	—	11,233
Net cash (used in) provided by investing activities	(62)	2,739
Cash flows from financing activities:		
Proceeds from at the market equity offering, net of issuance costs	18,409	4,239
Proceeds from exercise of stock options	—	188
Issuance of common stock under ESPP	353	1,229
Net cash provided by financing activities	18,762	5,656
Net (decrease) in cash, cash equivalents, and restricted cash	(16,536)	(68,189)
Cash, cash equivalents and restricted cash at beginning of period	136,150	171,215
Cash, cash equivalents and restricted cash at end of period	$ 119,614	$ 103,026
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,580	$ 1,737
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment purchases included in accounts payable and accrued expenses	$ —	$ 928

[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 $8,158 and $(9,812) at March 31, 2024 and 2023, respectively (see Note 17)

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

1. Nature of the Business and Basis of Presentation

Seres Therapeutics, Inc. (the "Company") was incorporated under the laws of the State of Delaware in October 2010 under the name Newco LS21, Inc. In October 2011, the Company changed its name to Seres Health, Inc., and in May 2015, the Company changed its name to Seres Therapeutics, Inc. The Company is a 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 microbiome therapeutic 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 late in the third quarter of 2024.

The Company has built and deploys a reverse translational platform and knowledge base for the discovery and development of microbiome therapeutics, 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 microbiome therapeutics; 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 microbiome therapeutics.

On October 29, 2023, the Company's board of directors approved 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"). 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. For additional information on the Restructuring Plan, see Note 12, *Restructuring*.

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 March 31, 2024, the Company had an accumulated deficit of $1,018,368 and cash and cash equivalents of $111,184.

The Company's primary focus in recent months has been and will continue to be supporting commercialization, including the manufacture of VOWST, and the completion of the SER-155 Phase 1b study, 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 $40,133 and had net operating cash outflows of $35,236 for the three months ended March 31, 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 supply product and support commercialization of VOWST, continue to progress the SER-155 Phase 1b study, and meet its operational obligations as they come due. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

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

Unaudited Interim Financial Information

The accompanying unaudited condensed consolidated financial statements as of March 31, 2024 and for the three months ended March 31, 2024 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 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 months ended March 31, 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 three months ended March 31, 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 $8,430 as of March 31, 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):

	March 31, 2024	December 31, 2023
Cash and cash equivalents	$ 111,184	$ 127,965
Restricted cash, non-current	8,430	8,185
Total cash, cash equivalents and restricted cash	$ 119,614	$ 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 information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280, on an interim and annual basis. 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 that the adoption of ASU 2023-07 may have on its consolidated financial statements.

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 additional information for reconciling items that exceed a quantitative threshold. ASU 2023-09 also requires all entities to disclose income taxes paid disaggregated by federal, state and foreign taxes, and further disaggregated for specific jurisdictions that exceed 5% of total income taxes paid, among other expanded disclosures. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-09 may have on its consolidated financial statements.

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 March 31, 2024 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 82	$ —	$ —	$ 82
Total assets	$ 82	$ —	$ —	$ 82
Warrant liabilities	$ —	$ —	$ 130	$ 130
Total liabilities	$ —	$ —	$ 130	$ 130

	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 both March 31, 2024 and December 31, 2023, the Company held a restricted investment of $1,401, 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 March 31, 2024 and December 31, 2023, the Level 3 inputs to the warrant liabilities are as follows:

	March 31, 2024	December 31, 2023
Volatility	100.2%	101.0%
Term (in years)	1.3	1.3

A reconciliation of the beginning and ending balances for the three months ended March 31, 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	(416)
Balance as of March 31, 2024	130

There were no assets or liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the three months ended March 31, 2023. There were no transfers between Level 1, Level 2, or Level 3 during the three months ended March 31, 2024 and 2023.

4. Investments

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

	March 31, 2024	December 31, 2023
Raw materials	$ 4,224	$ 4,426
Work in process	37,265	25,221
Finished goods	484	—
Total	$ 41,973	$ 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 and $15,613 for the three months ended March 31, 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 months ended March 31, 2024.

6. Property and Equipment, Net

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

	March 31, 2024	December 31, 2023
Laboratory equipment	$ 29,003	$ 29,081
Computer equipment	4,142	4,142
Furniture and office equipment	5,188	5,430
Leasehold improvements	32,039	33,549
Construction in progress	1,139	1,393
	71,511	73,595
Less: Accumulated depreciation and amortization	(52,396)	(51,138)
	$ 19,115	$ 22,457

Depreciation and amortization expense was $1,559 and 1,400 for the three months ended March 31, 2024 and 2023, respectively. During the three months ended March 31, 2024 and 2023, the Company disposed of certain assets with a cost basis of $594 and $9, respectively. In addition, the Company recorded an impairment loss of $1,536 related to leasehold improvements at one of the Company's locations for which impairment indicators were determined to exist as of March 31, 2024. See Note 8, *Leases*, for further details.

7. Accrued Expenses and Other Current Liabilities

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

	March 31, 2024	December 31, 2023
Clinical and development costs	$ 1,405	$ 1,404
Manufacturing and quality costs	30,574	31,917
Payroll and payroll-related costs	6,137	16,465
Collaboration payable - related party (Note 17)	36,211	28,053
Facility and other	1,990	2,772
	$ 76,317	$ 80,611

As of March 31, 2024, the Company accrued a total of $28,046 payable to Bacthera for the substantial completion of the Company's dedicated production suite for long-term supply of VOWST. This amount is included in the Manufacturing and quality costs category above.

Additionally, included within payroll and payroll-related costs as of March 31, 2024 and December 31, 2023 is $564 and $5,080, respectively, of accrued severance related to the 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.

As of 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. For the three months ended March 31, 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):

	March 31, 2024	December 31, 2023
Assets:		
Operating lease assets	$ 105,669	$ 109,793
Liabilities:		
Operating lease liabilities	$ 8,833	$ 6,677
Operating lease liabilities, net of current portion	103,341	105,715
Total operating lease liabilities	$ 112,174	$ 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 March 31,	
	2024	2023
Operating lease costs	$ 5,771	$ 5,410
Short-term lease costs	374	368
Variable lease costs	1,967	1,763
Sublease income	(376)	—
Total lease costs	$ 7,736	$ 7,541

During the three months ended March 31, 2024 and 2023, the Company made cash payments for operating leases of $3,596 and $3,413 respectively.

As of March 31, 2024, future payments of operating lease liabilities are as follows (in thousands):

	As of March 31, 2024
2024 (remaining 9 months)	$ 16,273
2025	$ 22,062
2026	$ 22,674
2027	$ 23,347
2028	$ 23,580
2029 and thereafter	$ 65,819
Total future minimum lease payments	$ 173,755
Less: interest	(61,581)
Present value of operating lease liabilities	$ 112,174

As of March 31, 2024, the weighted average remaining lease term was 7.70 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 13%. As of March 31, 2023, the weighted average remaining lease term was 8.68 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 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 March 31, 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 March 31, 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*. The fair value of the Tranche B Warrant and Tranche C Warrant derivative liabilities was $66, $64, $276, and $270 as of March 31, 2024 and 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 March 31, 2024 was 15.9%. As of March 31, 2024 and December 31, 2023, the carrying value of the Term Loan was $102,009 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 9 months)	$ —
2025	—
2026	24,750
2027	33,000
2028	33,000
Thereafter	19,250
Total	$ 110,000

During the three months ended March 31, 2024, the Company recognized $4,046 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 months ended March 31, 2023, the Company recognized $1,948 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 March 31, 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.

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 months ended March 31, 2024 and 2023, the Company sold 15,366,630 and 787,170 shares of common stock under the Sales Agreement, at an average price of approximately $1.23 and $5.67 per share, raising aggregate net proceeds of approximately $18,409 and $4,238, 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	6,743,362	$ 1.07		
Exercised	—	$ —		
Forfeited	(2,428,857)	$ 8.93		
Outstanding as of March 31, 2024	19,158,617	$ 6.72	7.59	$ —
Vested or expected to vest as of March 31, 2024	19,158,617	$ 6.72	7.59	$ —
Options exercisable as of March 31, 2024	9,026,731	$ 10.16	5.68	$ —

The weighted average grant date fair value of stock options granted during the three months ended March 31, 2024 and 2023 was $0.95 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 $45 and $0 of compensation expense during the three months ended March 31, 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 will be recognized ratably through April 2024, for all such options for which ongoing performance targets are achieved and service requirements are 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 months ended March 31, 2024, the Company recognized $142 of compensation expense related to these awards.

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	1,282,941	$ 1.09
Vested	(329,981)	$ 6.24
Forfeited	(178,039)	$ 3.35
Unvested restricted stock units as of March 31, 2024	4,152,725	$ 3.16

During the three months ended March 31, 2024 and 2023, the Company granted 1,282,941and 1,692,095 RSUs, respectively. During the three months ended March 31, 2024 and 2023, the Company granted 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 months ended March 31, 2024, the Company recognized $185 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 $260 and $0 in compensation expense during the three months ended March 31, 2024 and 2023, respectively, with respect to these PSUs. The remaining $725 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 March 31,	
	2024	2023
Research and development expenses	$ 3,610	$ 3,731
General and administrative expenses	2,879	3,119
	$ 6,489	$ 6,850

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 March 31,	
	2024	2023
Numerator:		
Net loss attributable to common stockholders	$ (40,133)	$ (71,174)
Denominator:		
Weighted-average shares outstanding, basic and diluted	146,101,581	125,862,975
Net loss per share attributable to common stockholders, basic and diluted	$ (0.27)	$ (0.57)

Anti-dilutive potential common stock equivalents excluded from the calculation of net loss per share:		
Stock options to purchase common stock	19,158,617	16,826,144
Unvested restricted stock units	4,152,725	4,215,834
Shares issuable under employee stock purchase plan	75,488	68,594
Warrants to purchase common stock	1,177,433	—

The Company's potential dilutive securities, which include stock options, unvested restricted common stock and shares issuable under the 2015 Employee Stock Purchase Plan, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share and therefore be anti-dilutive. 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. Additionally, for the three months ended March 31, 2024, 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 the 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 three months ended March 31, 2024 (in thousands):

	As of March 31, 2024
Restructuring expenses	$ 5,606
Less: stock-based compensation	(261)
Cash payments made through March 31, 2024	(4,781)
Remaining liability included in accrued expenses and other current liabilities	$ 564

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 Société des Produits Nestlé S.A., 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 months ended March 31, 2024 and 2023, the Company recognized $0 and $1,122 of collaboration revenue - related party, respectively, related to the services performance obligation under the 2021 License Agreement.

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.

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.

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 Société des Produits Nestlé S.A. (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 March 31, 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 months ended March 31, 2024 and 2023, using the cost-to-cost method, which best depicts the transfer of control to the customer, the Company recognized $0 and ($1,644), of collaboration revenue – related party, respectively.

As of March 31, 2024 and December 31, 2023, there was $95,364 and $95,364, respectively, of deferred revenue related to the unsatisfied portion of the performance obligation under the Nestlé agreements. As of March 31, 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 three months ended March 31, 2024 and 2023 (in thousands):

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

	Balance as of December 31, 2022	Additions	Deductions	Balance as of March 31, 2023
Three Months Ended March 31, 2023				
Contract liabilities:				
Deferred revenue - related party	$ 96,689	1,644	(1,122)	$ 97,211

During the three months ended March 31, 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 March 31,	
	2024	2023
Revenue recognized in the period from:		
Amounts included in the contract liability at the beginning of the period	$ —	$ (522)

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 March 31, 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 Seres.

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 months ended March 31, 2024 and 2023, the Company recognized $0, and $801 respectively, in research and development expenses and $0 and $2,703 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 months ended March 31, 2024 and 2023 are as follows:

	Three Months Ended March 31,	
	2024	2023
Share of VOWST net loss	$ 7,128	$ —
Profit on transfer of VOWST inventory to Nestlé	(4,710)	—
Collaboration (profit)/loss related to pre-launch activities	—	3,607
Total collaboration (profit) loss sharing - related party	$ 2,418	$ 3,607

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 March 31, 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 March 31, 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 months ended March 31, 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 March 31, 2024 and December 31, 2023, and has not recorded any income taxes for the three months ended March 31, 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 Société des Produits Nestlé S.A., their affiliates, and their subsidiaries, "Nestlé"). NHSc Rx License GmbH is an affiliate of one of the Company's significant stockholders, Société des Produits Nestlé S.A. During the three months ended March 31, 2024 and 2023, the Company recognized $0 and $1,122, respectively, of related party revenue associated with the 2021 License Agreement. As of both March 31, 2024 and December 31, 2023, there was $0 of deferred revenue related to the 2021 License Agreement. As of March 31, 2024 and December 31, 2023, there was $36,211 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 March 31, 2024 and December 31, 2023 there was $8,109 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 months ended March 31, 2024 and 2023, the Company paid Nestlé $0 and $13,419, respectively, for Nestlé's share of the collaboration losses pursuant to the 2021 License Agreement. During the three months ended March 31, 2024 and 2023, the Company received $8,674 and $0, respectively in payments from Nestlé for the transfer of VOWST to Nestlé. As of March 31, 2024 and December 31, 2023, there is $7,418 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 Société des Produits Nestlé S.A. 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. Société des Produits Nestlé S.A. is one of the Company's significant stockholders. During the three months ended March 31, 2024 and 2023, the Company recognized $0 and ($1,644), respectively, of related party revenue associated with the 2016 License Agreement. As of March 31, 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 months ended March 31, 2024 and 2023 pursuant to the 2016 License Agreement. There is no amount due from Nestlé pursuant to the 2016 License Agreement as of March 31, 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 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. 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 microbiome therapeutic candidates are consortia of bacteria designed to optimize specific, targeted pharmacological properties, and are formulated for oral delivery. We maintain a differentiated microbiome therapeutics drug discovery and development platform that includes good manufacturing practices, or GMP, manufacturing capabilities for this novel drug modality.

Our highest priority is the commercialization of VOWST in the United States, the first orally administered microbiome therapeutic approved by the FDA. We launched VOWST in the United States with our collaborator, Nestlé Health Science, or Nestlé, in June 2023.

We are also designing microbiome therapeutics optimized to prevent the colonization and overgrowth of pathogens in the gastrointestinal tract and modulate host function to increase epithelium integrity and induce immune tolerance. We believe clinical and nonclinical data across our programs support the development of microbiome therapeutics 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, which we refer to as Infection Protection. We believe the Infection Protection approach may be replicable across different bacterial pathogens to develop microbiome therapeutics 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 late in the third quarter of 2024.

We believe our pending clinical and drug pharmacology results, if positive, will validate the promise of microbiome therapeutics 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 microbiome therapeutics in immunocompromised patients and additionally into mechanisms by which microbiome therapeutics can modulate host immune pathways. We intend to evaluate SER-155 and other microbiome therapeutic 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 microbiome therapeutics 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 microbiome therapeutic 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 microbiome therapeutics, 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 microbiome therapeutics; 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 microbiome therapeutics.

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 still in preclinical development or early-stage discovery. 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 $40.1 million for the three months ended March 31, 2024. As of March 31, 2024, we had an accumulated deficit of $1,018.4 million.

While we plan to focus our investment on supporting commercialization of VOWST and on our SER-155 Phase 1b study in the near-term, our expenses may increase in connection with 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.*"

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 March 31, 2024, we had cash and cash equivalents totaling $111.2 million. Based on our currently available cash resources and our planned level of operations and cash flows for the 12-month period subsequent to the date of issuance of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, under various scenarios, we have sufficient cash to support our operations into the fourth quarter of 2024 and we will require additional funding at that time. 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 future equity issuances cannot be considered probable, as these events are outside our control. Accordingly, management has concluded that substantial doubt exists about the Company's 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, in June 2023. Under the terms of the 2021 License Agreement, Nestlé is assuming 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 March 31, 2024, Nestlé reported 642 VOWST units sold and $10.1 million in net sales, reflecting an estimated gross-to-net reduction of 15%, primarily due to returns reserve, prompt payment discounts, statutory discounts and rebates, and commercial rebates. The total collaboration loss for the three months ended March 31, 2024 was $14.3 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 three months ended March 31, 2024, our share of the VOWST net loss was $7.1 million.

As part of the commercialization of VOWST, we are closely monitoring the launch and focusing on a number of quantitative metrics. VOWST became commercially available in early June. Broad demand for VOWST has been observed across both recurrent patients and healthcare providers since June 2023 (metrics noted below are based on data provided by Nestlé through March 31, 2024):

- In the first quarter of 2024, approximately 1,411 completed prescription enrollment forms were received for VOWST; of those, 1,083 resulted in new patient starts by March 31, 2024;
- From launch through March 31, 2024, there were 4,239 completed prescription enrollment forms received for VOWST; of those 3,096 resulted in new patient starts by March 31, 2024
- Prescription enrollment forms were submitted by approximately 1,939 unique healthcare providers since launch, including 609 in the first quarter, with approximately 65% of enrollments from gastroenterology and the remainder from other specialties; approximately 604 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.

We continue to support Nestlé in scaling their HCP education efforts, creating a positive customer experience with faster and higher conversion of enrollments to new patient starts, and continuing to establish payer coverage. Since the FDA approval of VOWST, Nestlé commercial customer facing field teams have been promoting VOWST and generating healthcare provider demand. Nestlé's 170 field sales representatives promoting VOWST are divided into two teams, comprised of 150 gastroenterology representatives and 20 hospital/infectious disease representatives. Nestlé has recently 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.

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'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 March 31, 2024, coverage policies were issued for VOWST across approximately 83% of commercial and 55% of Medicare Part D covered lives, according to data provided by Nestlé. 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 56% of the 1,083 first 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 first quarter of 2024, we saw approximately 44% of new patient starts dispensed via our free drug programs, mostly for Medicare patients. We expect utilization of these programs to drop 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 Protection and SER-155

We believe that the scientific and clinical data from our SER-109 program validate our novel approach of using microbiome therapeutics 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 microbiome therapeutics 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 microbiome therapeutics to prevent the colonization and overgrowth of pathogens that can establish in the gut and ultimately to reduce infections. We believe this Infection Protection approach may be replicable in protecting a range of medically compromised patients 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.

We are evaluating SER-155, an oral microbiome therapeutics 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 microbiome therapeutics 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 late in the third quarter of 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.

Nasdaq Notice

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 has 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 have been 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.

If we do not regain compliance with the Bid Price Requirement by October 16, 2024, we may be eligible for an additional 180 calendar day compliance period. To qualify, we must submit an application to transfer the listing of the common stock to The Nasdaq Capital Market, which requires us to meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, other than the Bid Price Requirement. We would also need to pay an application fee to Nasdaq and to provide written notice of our intention to cure the deficiency during the additional compliance period. As part of its review process, Nasdaq will make a determination of whether it believes we will be able to cure this deficiency.

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

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

Intellectual Property

Patent Portfolio

We have an extensive patent portfolio directed to rationally designed ecologies of spores and microbes. The portfolio includes both company-owned patents and applications, and those that we have rights to as licensee. 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 30 issued U.S. patents.

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 microbiome therapeutics 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 we expect the Restructuring Plan (as defined in Note 1 to our condensed consolidated financial statements included elsewhere in this Quarterly Report) to significantly reduce research and development activities other than the completion of the SER-155 Phase 1b study. Research and development expenses may increase in the future as we initiate technology transfer activities with Bacthera and prepare for qualification of the Bacthera manufacturing facility, and if and as we resume development of any clinical or preclinical programs.

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 is expected to result in a reduction of personnel expenses due the workforce reduction and a reduction in external expenses including the elimination of non-essential expenses and consolidation of office space. General and administrative expenses may increase as we undertake efforts from time to time to raise additional capital. We may also 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 Securities and Exchange Commission, 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 months ended March 31, 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 months ended March 31, 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 March 31, 2024 and 2023

The following table summarizes our results of operations for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,		
	2024	2023	Change
Revenue:			
Collaboration revenue - related party	$ —	$ (522)	$ 522
Total revenue	—	(522)	522
Operating expenses:			
Research and development	21,702	43,969	(22,267)
General and administrative	15,466	22,470	(7,004)
Collaboration (profit) loss sharing - related party	2,418	3,607	(1,189)
Total operating expenses	39,586	70,046	(30,460)
Income (loss) from operations	(39,586)	(70,568)	30,982
Other income (expense):			
Interest income	1,648	1,032	616
Interest expense	(4,663)	(1,948)	(2,715)
Other income (expense)	2,468	310	2,158
Total other expense, net	(547)	(606)	59
Net loss	$ (40,133)	$ (71,174)	$ 31,041

Revenue

Total revenue was $0.0 million and $(0.5) million for the three months ended March 31, 2024 and 2023, respectively. The change in revenue as compared to the prior period was primarily due to an increase in the estimate of total costs expected to be incurred to fulfill our obligations under the 2016 License Agreement with Nestlé, which resulted in a reversal of revenue for the three months ended March 31, 2023 based on our cost-to-cost methodology. In the current period, we did not recognize any revenue under the 2016 License Agreement, as we have significantly scaled back our research and development activities as part of the Restructuring Plan. 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 March 31,		
	2024	2023	Change
Microbiome therapeutics platform and research and development operations	$ 9,516	$ 13,117	$ (3,601)
VOWST	576	9,041	(8,465)
SER-155	2,400	1,345	1,055
Early stage programs	85	303	(218)
Total direct research and development expenses	12,577	23,806	(11,229)
Personnel-related (including stock-based compensation)	9,125	20,163	(11,038)
Total research and development expenses	$ 21,702	$ 43,969	$ (22,267)

Research and development expenses were $21.7 million for the three months ended March 31, 2024 and $44.0 million for the three months ended March 31, 2023. The decrease of $22.3 million was primarily due to the following:

- a decrease in personnel-related costs of $11.0 million primarily due to a decrease of $5.6 million resulting from the capitalization of labor costs into inventory following FDA approval of VOWST and a decrease of $7.3 million in salaries, bonus, employee benefits expenses, and stock-based compensation expense as a result of the Restructuring Plan implemented in 2023, partially offset by an increase of $1.9 million in payroll taxes related to tax credits we received during the three months ended March 31, 2023;
- a decrease of $8.5 million in expenses related to our VOWST program due to a decrease in facilities, lab supplies and consumables of $3.1 million and a decrease in contract manufacturing costs of $3.3 million, as we have capitalized manufacturing and overhead costs into inventory in conjunction with the commercialization of VOWST, a $1.5 million decrease in consulting expenses, and a $0.5 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 $3.6 million in expenses related to our microbiome therapeutics platform and research and development operations, primarily due to a decrease of $2.8 million related to the capitalization of costs that relate to VOWST manufacturing into inventory, a decrease in employee-related costs of $1.3 million primarily due to a reduction in the use of contractors following the implementation of the Restructuring Plan, a decrease in facilities-related costs of $0.9 million, a decrease in consulting expenses of $0.5 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;
- a decrease of $0.2 million in expenses related to our early stage programs due to the Restructuring Plan;

partially offset by:

- an increase of $1.1 million in expenses related to our SER-155 program due to an increase in clinical trial costs.

General and Administrative Expenses

	Three Months Ended March 31,		
	2024	2023	Change
Personnel related (including stock-based compensation)	$ 6,764	$ 8,690	$ (1,926)
Professional fees	2,917	7,890	(4,973)
Facility-related and other	5,785	5,890	(105)
Total general and administrative expenses	$ 15,466	$ 22,470	$ (7,004)

General and administrative expenses were $15.5 million for three months ended March 31, 2024 compared to $22.5 million for the three months ended March 31, 2023. The decrease of $7.0 million was primarily due to the following:

- a decrease in personnel related costs of $1.9 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 $5.0 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, laboratory and office rent expenses, license costs and office supplies.

Collaboration (Profit) Loss Sharing - related party

Collaboration (profit) loss sharing – related party resulted in $2.4 million of expense to us for the three months ended March 31, 2024, compared to $3.6 million of expense for the three months ended March 31, 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 three months ended March 31, 2024, our share of the VOWST net loss was $7.1 million. 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 March 31, 2024 these amounts were $4.7 million in net profit. For the three months ended March 31, 2023, collaboration (profit) loss sharing – related party was $3.6 million of net loss, which consisted of our share of pre-launch expenses.

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

	Three Months Ended March 31,	
	2024	2023
Share of VOWST net loss	$ 7,128	$ —
Profit on transfer of VOWST inventory to Nestlé	(4,710)	—
Collaboration (profit)/loss related to pre-launch activities	—	3,607
Total collaboration (profit) loss sharing - related party	$ 2,418	$ 3,607

Other Expense, Net

Other expense, net for the three months ended March 31, 2024 and 2023 was $0.5 million and $0.6 million, respectively. The decrease in other expense, net was primarily due to an increase in interest income of $0.6 million and an increase in other income of $2.0 million due to foreign currency gains and $0.4 million due to the change in the fair value of the Additional Warrants. 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 an increase in interest expense of $2.7 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 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 March 31, 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 March 31, 2024, we had cash and cash equivalents totaling $111.2 million and an accumulated deficit of $1,018.4 million. For the three months ended March 31, 2024, we incurred a net loss of $40.1 million, and used cash in operations of $35.2 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 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. Based on our currently available cash resources, we will require additional funding by the fourth quarter of 2024. 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 the 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. We expect to achieve annual cash savings of approximately $75.0 million to $85.0 million in 2024, of which approximately $35.0 million is expected to result from the reduction in workforce, and which excludes any one-time charges primarily associated with the workforce reduction.

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 Société des Produits Nestlé S.A., 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 $296 million using the USD/CHF exchange rate in effect as of March 31, 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.

Indebtedness

Loan and Security Agreement with Hercules

In October 2019, we entered into a loan and security agreement, or the Hercules Loan Agreement, with Hercules Capital, Inc., or Hercules, pursuant to which a term loan in an aggregate principal amount of up to $50.0 million, or the Original Credit Facility, was available to us in three tranches, subject to certain terms and conditions. We received the first tranche of $25.0 million upon signing the agreement on October 29, 2019, but did not borrow either of the second two tranches, which were available at different times upon Hercules' approval until June 30, 2021.

On April 16, 2020, we entered into an amendment to the Hercules Loan Agreement, or the First Amendment, permitting us to enter into a promissory note under the Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Stability Act. On April 17, 2020 we issued a Promissory Note to Bank of America, NA, or the Loan, pursuant to which we received loan proceeds of $2.9 million, however, based on updated guidance related to this program, we decided to repay the full amount of the Loan, and repaid the Loan on May 4, 2020.

Effective as of February 24, 2022, we entered into a Second Amendment to the Original Credit Facility (as amended by the First Amendment), or the Hercules Credit Facility, pursuant to which term loans in an aggregate principal amount of up to $100.0 million became available to us in five tranches including the first tranche under the Original Credit Facility, subject to certain terms and conditions.

The Hercules Credit Facility was secured by substantially all of our assets, other than our intellectual property. We agreed to not pledge or secure our intellectual property to others.

The Hercules Credit Facility was repaid on the Oaktree Closing Date (as defined below). For a further description of the Hercules Credit Facility, see Note 9, *Notes Payable*, to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

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 March 31, 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 March 31, 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.

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 $28.0 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.

Cash Flows

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

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
Cash used in operating activities	$ (35,236)	$ (76,584)
Cash (used in) provided by investing activities	(62)	2,739
Cash provided by financing activities	18,762	5,656
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (16,536)	$ (68,189)

Operating Activities

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

During the three months ended March 31, 2023, operating activities used $76.6 million of cash, primarily due to a net loss of $71.2 million and changes in our operating assets and liabilities of $19.3 million, partially offset by non-cash charges of $13.9 million. Non-cash charges consisted of stock-based compensation expense of $6.9 million, $2.1 million related to the amortization of right-of-use assets, $1.4 million of depreciation and amortization, and loss sharing under the 2021 License Agreement with Nestlé of $3.6 million. Changes in our operating assets and liabilities during the three months ended March 31, 2023 consisted of a decrease in accrued expenses and other current and long-term liabilities of $19.0 million, primarily due to a payment of $13.4 million to Nestlé for their share of collaboration expenses under the 2021 License Agreement, a decrease in accounts payable of $3.8 million, and a decrease in operating lease liabilities of $0.1 million, partially offset by an increase in deferred revenue of $0.5 million and a decrease in prepaid expenses and other current and other non-current assets of $3.0 million.

Investing Activities

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

During the three months ended March 31, 2023, net cash provided by investing activities was $2.7 million, consisting of sales and maturities of investments of $11.2 million, partially offset by purchases of investments of $4.4 million and purchases of property and equipment of $4.1 million.

Financing Activities

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

During the three months ended March 31, 2023, net cash provided by financing activities was $5.7 million, consisting of $4.2 million from the issuance of common stock under our at the market equity program, net of issuance costs. We also received $0.2 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 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;
- 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 microbiome therapeutic 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 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 shareholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our shareholders' 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 shareholders' 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 future equity issuances cannot be considered probable, as these events are outside of our control. Based on our currently available cash resources and our planned level of operations and cash flow analysis for the 12-month period subsequent to the date of issuance of our condensed consolidated financial statements, under various scenarios, we have sufficient cash to support our operations into the fourth quarter of 2024, and we will require additional funding at that time. Accordingly, management has concluded that these circumstances raise substantial doubt about our ability to continue as a going concern.

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.

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 March 31, 2024, total $284.0 million. Under the Bacthera Agreement, $28.0 million was 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. The remaining construction milestones are approximately $11.8 million and $27.3 million, which will be due and payable upon provisional acceptance and final acceptance, respectively, and are expected to be due within the next 12 months. We have entered into negotiations with Bacthera to realign the timing of milestone payments. The Bacthera Agreement also includes $10.6 million in operating fees expected to be paid in the next 12 months, with the remaining $206.3 million in operating fees paid over the remaining 9 years of the contract, beginning in 2025. 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*.

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 March 31, 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 March 31, 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 March 31, 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 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 $40.1 million for the three months ended March 31, 2024. As of March 31, 2024, we had an accumulated deficit of $1,018.4 million. As noted elsewhere in this Quarterly Report on Form 10-Q, we have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. To date, we have financed our operations through the public offerings of our common stock, private placements of our common stock and preferred stock, payments under our 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 microbiome therapeutic 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 in the near-term, 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;
- 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 microbiome therapeutic 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 and our planned level of operations and cash flows for the 12-month period subsequent to the date of issuance of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, under various scenarios, we have sufficient cash to support our operations into the fourth quarter of 2024, and we will require additional funding at that time. Because the ability to obtain sufficient 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 months ended March 31, 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 audited 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, 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 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 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 microbiome therapeutics platform to build a pipeline of product candidates and develop additional marketable drugs.

We are using our reverse translational microbiome therapeutics platform to develop microbiome therapeutic 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 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 microbiome therapeutic 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 microbiome therapeutic 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 microbiome therapeutic 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 microbiome therapeutic 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. 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. 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 microbiome therapeutics, 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 microbiome therapeutic 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, 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 30 issued U.S. patents, we cannot provide any assurances that any of our pending patent applications will mature into issued patents and, if they do, that such patents or our current patents will include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. For example, we are pursuing claims to therapeutic, binary compositions of certain bacterial populations. Any claims that may issue may provide coverage for such binary compositions and/or their use. However, there can be no assurance that an alternative composition that may fall outside the scope of such claims will not be equally effective. Further, 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.

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. 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 March 31, 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 March 31, 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 $28.0 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 or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. We have not made any acquisitions to date, and our ability to do so successfully is unproven. 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;
- additional exposure to cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- diversion of management time and focus from operating our business to acquisition integration 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 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 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 the effect that any such transactions might have on our operating results.

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

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

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials such as human stool. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury, including from the novel coronavirus SARS-CoV-2, which causes the COVID-19 disease, from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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

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

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

As of December 31, 2023, we had net operating loss carryforwards, or NOLs, of $527.1 million for federal income tax purposes and $504.2 million for state income tax purposes, which may be available to offset our future taxable income, if any. Our federal NOLs subject to expiration begin to expire in various amounts in 2035. Our federal NOLs generated in taxable years beginning after December 31, 2017 are not subject to expiration, but may generally only be used to offset 80% of taxable income in years beginning after December 31, 2020. Our state NOLs also begin to expire in various amounts in 2035. As of December 31, 2023, we also had federal and state research and development and other tax credit carryforwards of approximately $45.1 million and $7.7 million, respectively, net of uncertain tax position reserves, available to reduce future income tax liabilities, if any. Our federal and state tax credit carryforwards begin to expire in various amounts in 2031 and 2028, respectively. The federal research and development tax credit carryforwards include an orphan drug credit carryforward of $25.9 million. These NOLs and tax credit carryforwards could expire unused, to the extent subject to expiration, and be unavailable to offset future taxable income or income tax liabilities.

In addition, in general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an “ownership change” is subject to limitations on its ability to use its pre-change NOLs and tax credit carryforwards to offset future taxable income and income taxes. For these purposes, an ownership change generally occurs where the aggregate change in stock ownership of one or more stockholders or groups of stockholders owning at least 5% of a corporation’s stock exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We have experienced ownership changes in the past, per a Section 382 study performed through December 31, 2020. We believe that none of our existing tax assets will expire unused as a result of the calculated limitations resulting from such ownership changes. However, we may have experienced additional ownership changes since December 31, 2020, and we may experience ownership changes in the future as a result of future transactions in our stock, some of which may be outside our control. If we have undergone additional ownership changes, or if we undergo ownership changes in the future, our ability to use our NOLs and tax credit carryforwards could be further limited. For these reasons, we may not be able to use a material portion of our NOLs or tax credit carryforwards, even if we attain profitability. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future tax benefits of such assets.

Risks Related to Our Common Stock

We have received a notice of delisting or failure to satisfy a continued listing rule from Nasdaq.

Nasdaq maintains several requirements for continued listing of our common stock, one of which is the maintenance of a minimum closing bid price of $1.00. On April 19, 2024, we received written notice from Nasdaq notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the $1.00 Bid Price Requirement for continued inclusion on The Nasdaq Global Select Market. The notice had no immediate effect on the listing of our common stock, which continues to trade on The Nasdaq Global Select Market under the symbol "MCRB". Pursuant to the Nasdaq listing rules, we were provided a period of 180 calendar days, or until October 16, 2024 to regain compliance with the Bid Price Requirement. If we do not regain compliance with this requirement by October 16, 2024, we may be eligible for an additional 180-calendar day compliance period by transferring the listing of our common stock to The Nasdaq Capital Market and satisfying certain requirements. To qualify for the additional grace period, we would be required to submit a transfer application for transfer between Nasdaq market tiers and pay an application fee. In addition, we would be required to meet the continued listing requirement for the market value of our publicly held shares and all other applicable initial listing standards for The Nasdaq Capital Market, with the exception of the Bid Price Requirement, and would need to provide written notice of our intention to cure the deficiency during the second grace period. If we fail to regain compliance during the compliance period (including a second compliance period provided by a transfer to The Nasdaq Capital Market, if applicable), then we expect that Nasdaq will notify us of its determination to delist our common stock, at which point we may appeal Nasdaq’s delisting determination to a Nasdaq hearing panel or pursue other available options to regain compliance

We intend to actively monitor the closing bid price of our common stock and will consider all available options to regain compliance with the Bid Price Requirement, which may include transferring the listing to The Nasdaq Capital Market and/or seeking stockholder approval to effect a reverse stock split. However, there can be no assurance that any such reverse stock split, if approved by the stockholders and implemented, would increase the market price of our common stock in proportion to the reverse split ratio or result in a sustained increase in the market price of our common stock. In addition, it is possible that the reduced number of issued

shares of common stock resulting from such a reverse stock split could adversely affect the liquidity of our common stock. There can also be no assurance that we will regain compliance with the Bid Price Requirement during the 180-day compliance period, secure a second 180-day period to regain compliance, maintain compliance with the other Nasdaq listing requirements, or be successful in appealing any delisting determination.

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

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

Our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock and their respective affiliates, in the aggregate, hold shares representing approximately 43% of our outstanding voting stock as of December 31, 2023. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

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

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

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

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

We are a "smaller reporting company" as defined under the rules promulgated under the Exchange Act. We will remain a smaller reporting company until the fiscal year following the determination that both (i) the value of our voting and non-voting common shares held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter and (ii) our annual revenues are more than $100 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 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:

- potential delisting of our common stock as described elsewhere herein;
- 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 2024;
- 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.

Further declines in our stock price could, among other things, make it more difficult to raise capital on terms acceptable to us, or at all, and make it difficult for our investors to sell their shares of common stock. On April 19, 2024, we received written notice from Nasdaq notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the $1.00 Bid Price Requirement for continued inclusion on The Nasdaq Global Select Market; therefore, we are at risk of our stock being delisted from The Nasdaq Global Select Market. There are actions we can take to prevent such a delisting, such as becoming eligible for an additional 180-calendar day compliance period by transferring the listing of our common stock to The Nasdaq Capital Market

and/or seeking stockholder approval to effect a reverse stock split, but there can be no assurance that we could successfully execute such actions and prevent a delisting or that our common stock would not continue to experience significant declines. In addition, companies that experience volatility in the market price of their securities often are the subject of securities class action litigation. See "*We have received a notice of delisting or failure to satisfy a continued listing rule from Nasdaq*."

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 March 31, 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	
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#	Employment Agreement, dated February 24, 2024, by and between the Registrant and Marella Thorell					*
10.2#	Non-Employee Director Compensation Program					*
10.3#	Separation Agreement and Release, dated March 15, 2024, by and between the Registrant and David Arkowitz					*
10.4#	Advisory Agreement, dated March 15, 2024, by and between the Registrant and David Arkowitz					*
10.5†	Supply Agreement, dated September 15, 2015, by and between the Registrant and GenIbet BioPharmaceuticals, SA, as amended					*
10.6	Form of Performance Option Agreement under the 2015 Incentive Award Plan					*
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.
# Indicates management contract or compensatory plan.
† 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.

SIGNATURES

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

SERES THERAPEUTICS, INC.

Date: May 8, 2024

By: /s/ Marella Thorell

Marella Thorell

Executive Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)

EMPLOYMENT AGREEMENT

This Employment Agreement (this "Agreement"), dated as of February 24, 2024, is made by and between Seres Therapeutics, Inc., a Delaware corporation (together with any successor thereto, the "Company"), and Marella Thorell ("Executive") (collectively referred to as the "Parties" or individually referred to as a "Party").

RECITALS

A. It is the desire of the Company to assure itself of the services of Executive by entering into this Agreement.

B. Executive and the Company mutually desire that Executive be employed by the Company on the terms herein provided, commencing on March 25, 2024 or another date mutually agreed by the Parties (the date Executive actually commences such employment, the "Effective Date").

C. This Agreement will become effective upon the Effective Date.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements set forth below, the Parties hereto agree as follows:

1. Employment.

(a) General. Effective as of the Effective Date, the Company shall employ Executive and Executive shall remain in the employ of the Company, for the period and in the positions set forth in this Section 1, and subject to the other terms and conditions herein provided.

(b) At-Will Employment. The Company and Executive acknowledge that Executive's employment is and shall continue to be at-will, as defined under applicable law, and that Executive's employment with the Company may be terminated by either Party at any time for any or no reason (subject to the notice requirements of Section 3(b)). This "at-will" nature of Executive's employment shall remain unchanged during Executive's tenure as an employee and may not be changed, except in an express writing signed by Executive and a duly authorized officer of the Company. If Executive's employment terminates for any reason, Executive shall not be entitled to any payments, benefits, damages, award or compensation other than as provided in this Agreement or otherwise agreed to in writing by the Company or as provided by applicable law. The term of this Agreement (the "Term") shall commence on the Effective Date and end on the date this Agreement is terminated under Section 3.

(c) Positions and Duties. During the Term, Executive shall serve as Executive Vice President and Chief Financial Officer of the Company, initially reporting directly to the Chief Executive Officer of the Company (the "CEO") with such responsibilities, duties and authority normally associated with such positions and as may from time to time be assigned to Executive, or altered, by the CEO. Executive shall devote substantially all of Executive's working time and

efforts to the business and affairs of the Company (which shall include service to its affiliates, if applicable) and shall not engage in outside business activities (including serving on outside boards or committees) without the consent of the CEO, provided that Executive shall be permitted to (i) manage Executive's personal, financial and legal affairs, (ii) participate in trade associations, (iii) serve on the board of directors of not-for-profit or tax-exempt charitable organizations, and (iv) continue to serve on the board of directors of ESSA Pharma, Inc. and serve on the board of directors of another public company (with the prior consent of the CEO) or not-for-profit or tax-exempt charitable organizations, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with Executive's performance of Executive's duties and responsibilities hereunder. Executive agrees to observe and comply with the rules and policies of the Company as adopted by the Company from time to time, in each case as amended from time to time, as set forth in writing, and as delivered or made available to Executive (each, a "Policy").

2. Compensation and Related Matters.

(a) Annual Base Salary. During the Term, Executive shall receive a base salary at a rate of $480,000 per annum, which shall be paid in accordance with the customary payroll practices of the Company and shall be pro-rated for partial years of employment. Such annual base salary shall be reviewed (and may be adjusted) from time to time by the Board of Directors of the Company or an authorized committee of the Board (in either case, the "Board," and such annual base salary, as it may be adjusted from time to time, the "Annual Base Salary").

(b) Bonus. During the Term, Executive will be eligible to participate in an annual incentive program established by the Board. Executive's annual incentive compensation under such incentive program (the "Annual Bonus") shall be targeted at 40% of Executive's Annual Base Salary (such target, as may be adjusted by the Board from time to time, the "Target Bonus"). The Annual Bonus payable under the incentive program shall be based on the achievement of performance goals to be determined by the Board and may be pro-rated for any partial year of employment. The payment of any Annual Bonus pursuant to the incentive program shall be subject to Executive's continued employment with the Company through the date of payment, except as otherwise provided in Section 4(b).

(c) Benefits. During the Term, Executive shall be eligible to participate in employee benefit plans, programs and arrangements of the Company (including medical, dental and 401(k) plans), subject to the terms and eligibility requirements thereof and as such plans, programs and arrangements may be amended or in effect from time to time. In no event shall Executive be eligible to participate in any severance plan or program of the Company, except as set forth in Section 4 of this Agreement.

(d) Vacation. During the Term, Executive shall be entitled to paid personal leave in accordance with the Company's Policies. Any vacation shall be taken at the reasonable and mutual convenience of the Company and Executive.

(e) Business Expenses. During the Term, the Company shall reimburse Executive for all reasonable travel and other business expenses incurred by Executive in the performance of

Executive's duties to the Company in accordance with the Company's expense reimbursement Policy.

(f) Key Person Insurance. At any time during the Term, the Company shall have the right to insure the life of Executive for the Company's sole benefit. The Company shall have the right to determine the amount of insurance and the type of policy. Executive shall reasonably cooperate with the Company in obtaining such insurance by submitting to physical examinations, by supplying all information reasonably required by any insurance carrier, and by executing all necessary documents reasonably required by any insurance carrier, provided that any information provided to an insurance company or broker shall not be provided to the Company without the prior written authorization of Executive. Executive shall incur no financial obligation by executing any required document, and shall have no interest in any such policy.

(g) Equity. Subject to approval by the Board, the Company will grant Executive an option (the "Option") under the Company's 2022 Employment Inducement Award Plan (the "Plan") to purchase 700,000 shares of the Company's common stock (subject to adjustment for corporate events as set forth in the Plan) at an exercise price per share equal to the per share fair market value of the Company's common stock on the date of grant, as determined in accordance with the Plan. The Option will vest as to 25% of the shares subject to the Option on the first anniversary of the Effective Date and as to an additional 6.25% of such shares upon Executive's completing each three months of continuous service to the Company thereafter. In all respects, the Option will be governed by and subject to the terms of the Plan and a separate stock option agreement to be entered into between Executive and the Company.

(h) Sign-On Bonus. Executive will be paid a one-time sign-on bonus of $80,000 (the "Sign-On Bonus"), which shall be paid in a single lump sum on the first payroll date after the Effective Date. If Executive's employment with the Company terminates due to Executive's resignation from the Company without Good Reason or the Company's termination of Executive for Cause, which, in either case, occurs prior to the first anniversary of the Effective Date, then (x) Executive shall be required to repay the full gross amount of the Sign-On Bonus to the Company within 90 days following such termination of employment and (y) the Company may, but shall not be required to, offset any amounts required to be repaid under the foregoing clause (x) against any amounts otherwise owed to Executive by the Company to the extent that such offset will not cause a violation of, or result in any additional tax or penalty under, Section 409A (as defined below).

3. Termination.

Executive's employment hereunder and the Term may be terminated by the Company or Executive, as applicable, without any breach of this Agreement under the following circumstances and the Term will end on the Date of Termination:

(a) Circumstances.

(i) *Death*. Executive's employment hereunder shall terminate upon Executive's death.

(ii) *Disability*. If Executive has incurred a Disability, as defined below, the Company may terminate Executive's employment.

(iii) *Termination for Cause*. The Company may terminate Executive's employment for Cause, as defined below.

(iv) *Termination without Cause*. The Company may terminate Executive's employment without Cause.

(v) *Resignation from the Company for Good Reason.* Executive may resign Executive's employment with the Company for Good Reason, as defined below.

(vi) *Resignation from the Company Without Good Reason*. Executive may resign Executive's employment with the Company for any reason other than Good Reason or for no reason.

(b) Notice of Termination. Any termination of Executive's employment by the Company or by Executive under this Section 3 (other than termination pursuant to paragraph (a)(i)) shall be communicated by a written notice to the other Party hereto (i) indicating the specific termination provision in this Agreement relied upon, (ii) setting forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, if applicable, and (iii) specifying a Date of Termination which, if submitted by Executive, shall be at least forty-five (45) days following the date of such notice (a "Notice of Termination"); *provided, however*, that in the event that Executive delivers a Notice of Termination to the Company, the Company may, in its sole discretion, change the Date of Termination to any date that occurs following the date of the Company's receipt of such Notice of Termination and is prior to the date specified in such Notice of Termination but the termination will still be considered a resignation by Executive. A Notice of Termination submitted by the Company may provide for a Date of Termination on the date Executive receives the Notice of Termination, or any date thereafter elected by the Company in its sole discretion. The failure by the Company to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Cause shall not waive any right of the Company hereunder or preclude the Company from asserting such fact or circumstance in enforcing the Company's rights hereunder.

(c) Company Obligations upon Termination. Upon termination of Executive's employment pursuant to any of the circumstances listed in this Section 3, Executive (or Executive's estate) shall be entitled to receive the sum of: (i) the portion of Executive's Annual Base Salary earned through the Date of Termination, but not yet paid to Executive; (ii) any expense reimbursements owed to Executive pursuant to Section 2(e); and (iii) any amount accrued and arising from Executive's participation in, or benefits accrued under any employee benefit plans, programs or arrangements, which amounts shall be payable in accordance with the terms and conditions of such employee benefit plans, programs or arrangements (collectively, the "Company Arrangements"). Except as otherwise expressly required by law (e.g., COBRA) or as specifically provided herein, all of Executive's rights to salary, severance, benefits, bonuses and other compensatory amounts hereunder (if any) shall cease upon the termination of Executive's employment hereunder. In the event that Executive's employment is terminated by the Company

for any reason, Executive's sole and exclusive remedy shall be to receive the payments and benefits described in this Section 3(c) or Section 4, as applicable.

(d) Deemed Resignation. Upon termination of Executive's employment for any reason, Executive shall be deemed to have resigned from all offices and directorships, if any, then held with the Company or any of its subsidiaries.

4. Severance Payments.

(a) Termination for Cause, or Termination Upon Death, Disability or Resignation from the Company Without Good Reason. If Executive's employment shall terminate as a result of Executive's death pursuant to Section 3(a)(i) or Disability pursuant to Section 3(a)(ii), pursuant to Section 3(a)(iii) for Cause, or pursuant to Section 3(a)(vi) for Executive's resignation from the Company without Good Reason, then Executive shall not be entitled to any severance payments or benefits, except as provided in Section 3(c).

(b) Termination without Cause, or Resignation from the Company for Good Reason. If Executive's employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive's resignation for Good Reason, then, except as otherwise provided by Section 4(c) and subject to Executive signing on or before the 21st day following Executive's Separation from Service (as defined below), and not revoking, a release of claims substantially in the form attached as Exhibit A to this Agreement (the "Release"), and Executive's continued compliance with Section 5, Executive shall receive, in addition to payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to the product of (x) 1.0 times (y) the Annual Base Salary, payable in the form of salary continuation in regular installments over the 12-month period following the date of Executive's Separation from Service (the "Severance Period") in accordance with the Company's normal payroll practices;

(ii) to the extent unpaid as of the Date of Termination, an amount of cash equal to any Annual Bonus earned by Executive for the Company's fiscal year prior to the fiscal year in which the Date of Termination occurs, as determined by the Board in its discretion based upon actual performance achieved, which Annual Bonus, if any, shall be paid to Executive in the fiscal year in which the Date of Termination occurs when bonuses for such prior fiscal year are paid in the ordinary course to actively employed senior executives of the Company; and

(iii) if Executive timely elects to receive continued medical, dental or vision coverage under one or more of the Company's group healthcare plans pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), then the Company shall directly pay, or reimburse Executive for, the COBRA premiums for Executive and Executive's covered dependents under such plans during the period commencing on Executive's Separation from Service and ending upon the earliest of (X) the last day of the Severance Period, (Y) the date that Executive and/or Executive's covered dependents become no longer eligible for COBRA or (Z) the date Executive becomes

eligible to receive healthcare coverage from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility). Notwithstanding the foregoing, if the Company determines in its sole discretion that it cannot provide the foregoing benefit without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act) or incurring an excise tax, the Company shall in lieu thereof provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive's and Executive's covered dependents' group health coverage in effect on the Date of Termination (which amount shall be based on the premium for the first month of COBRA coverage), which payments shall be made regardless of whether Executive elects COBRA continuation coverage and shall commence in the month following the month in which the Date of Termination occurs and shall end on the earlier of (X) the last day of the Severance Period, (Y) the date that Executive and/or Executive's covered dependents become no longer eligible for COBRA or (Z) the date Executive becomes eligible to receive healthcare coverage from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility).

(c) Change in Control. In lieu of the payments and benefits set forth in Section 4(b), in the event Executive's employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive's resignation for Good Reason, in either case, within 60 days prior to or 12 months following the date of a Change in Control, subject to Executive signing on or before the 21st day following Executive's Separation from Service, and not revoking, the Release, and Executive's continued compliance with Section 5, Executive shall receive the following:

(i) without duplication, the payments and benefits described in Section 4(b);

(ii) an amount in cash equal to the product of (x) 1.0 times (y) the Target Bonus, payable in a lump sum within thirty (30) days following the later of Executive's Separation from Service and the date of a Change in Control; and

(iii) all unvested equity or equity-based awards held by Executive under any Company equity compensation plans that vest solely based on the passage of time shall immediately become 100% vested (and if the Date of Termination precedes the Change in Control, all such unvested awards shall remain outstanding and eligible to vest in accordance with this Section 4(c)(iii) if a Change Control occurs within 60 days after the Date of Termination, provided that in no event will any such award remain outstanding beyond the final expiration date of the award set forth in the documents governing such award), with any other equity or equity-based awards (including awards that vest in whole or in part based on the attainment of performance-vesting conditions) being governed by the terms of the applicable award agreement.

(d) Survival. Notwithstanding anything to the contrary in this Agreement, the provisions of Sections 5 through 9 will survive the termination of Executive's employment and the termination of the Term.

5. Restrictive Covenants. As a condition to the effectiveness of this Agreement, Executive will execute and deliver to the Company no later than the Effective Date the Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement attached as Exhibit B (the "Proprietary Information Agreement"). Executive agrees to abide by the terms of the Proprietary Information Agreement, which are hereby incorporated by reference into this Agreement. Executive acknowledges that the provisions of the Proprietary Information Agreement will survive the termination of Executive's employment and the termination of the Term for the periods set forth in the Proprietary Information Agreement.

6. Assignment and Successors.

The Company may assign its rights and obligations under this Agreement to any of its affiliates or to any successor to all or substantially all of the business or the assets of the Company (by merger or otherwise), and may assign or encumber this Agreement and its rights hereunder as security for indebtedness of the Company and its affiliates. This Agreement shall be binding upon and inure to the benefit of the Company, Executive and their respective successors, assigns, personal and legal representatives, executors, administrators, heirs, distributees, devisees, and legatees, as applicable. None of Executive's rights or obligations may be assigned or transferred by Executive, other than Executive's rights to payments hereunder, which may be transferred only by will or operation of law. Notwithstanding the foregoing, Executive shall be entitled, to the extent permitted under applicable law and applicable Company Arrangements, to select and change a beneficiary or beneficiaries to receive compensation hereunder following Executive's death by giving written notice thereof to the Company.

7. Certain Definitions.

(a) Cause. The Company shall have "Cause" to terminate Executive's employment hereunder upon:

(i) Executive's refusal to (A) substantially perform Executive's duties with the Company (other than any such failure resulting from Executive's Disability) or (B) comply with, in any material respect, any of the Company's Policies;

(ii) the Board's determination that Executive refused in any material respect to carry out or comply with any lawful and reasonable directive of the Board;

(iii) Executive's material breach of a material provision of this Agreement;

(iv) Executive's conviction, plea of no contest, plea of *nolo contendere*, or imposition of unadjudicated probation for any felony or crime involving moral turpitude;

(v) Executive's unlawful use (including being under the influence) or possession of illegal drugs on the Company's (or any of its affiliate's) premises or while performing Executive's duties and responsibilities under this Agreement; or

(vi) Executive's commission of an act of fraud, embezzlement,

misappropriation, willful misconduct, or breach of fiduciary duty against the Company or any of its affiliates;

provided, however, that Executive's termination will not be considered for Cause unless and until (a) the Company has provided Executive, within 60 days of the Company's knowledge of the occurrence of the facts and circumstances underlying the Cause event, written notice stating with reasonable specificity the applicable facts and circumstances underlying such finding of Cause and (b) in the case of alleged Cause under clause (i), (ii) or (iii) of the foregoing definition and to the extent the applicable condition or event is reasonably capable of being cured, Executive shall have failed to cure such condition or event within 30 days after the receipt of such notice.

(b) Change in Control. "Change in Control" shall have the meaning set forth in the version of the Seres Therapeutics, Inc. 2022 Employment Inducement Award Plan in effect on the Effective Date.

(c) Code. "Code" shall mean the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder.

(d) Date of Termination. "Date of Termination" shall mean (i) if Executive's employment is terminated by Executive's death, the date of Executive's death; or (ii) if Executive's employment is terminated pursuant to Section 3(a)(ii) – (vi) either the date indicated in the Notice of Termination or the date specified by the Company pursuant to Section 3(b), whichever is earlier.

(e) Disability. "Disability" shall mean, at any time the Company or any of its affiliates sponsors a long-term disability plan for the Company's employees, "disability" as defined in such long-term disability plan for the purpose of determining a participant's eligibility for benefits, *provided, however*, if the long-term disability plan contains multiple definitions of disability, "Disability" shall refer to that definition of disability which, if Executive qualified for such disability benefits, would provide coverage for the longest period of time. The determination of whether Executive has a Disability shall be made by the person or persons required to make disability determinations under the long-term disability plan. At any time the Company does not sponsor a long-term disability plan for its employees, "Disability" shall mean Executive's inability to perform, with or without reasonable accommodation, the essential functions of Executive's positions hereunder for a total of three months during any six-month period as a result of incapacity due to mental or physical illness as determined by a physician selected by the Company or its insurers and acceptable to Executive or Executive's legal representative, with such agreement as to acceptability not to be unreasonably withheld or delayed. Any refusal by Executive to submit to a medical examination for the purpose of determining Disability shall be deemed to constitute conclusive evidence of Executive's Disability.

(f) Good Reason. For the sole purpose of determining Executive's right to severance payments and benefits as described above, Executive's resignation will be for "Good Reason" if Executive resigns within ninety days after any of the following events, unless Executive consents to the applicable event: (i) a material decrease in Executive's Annual Base Salary, (ii) a material decrease in Executive's authority or areas of responsibility as are commensurate with Executive's title or positions, including Executive ceasing to report directly to the chief executive officer of

the Company's ultimate parent company following a Change in Control (or of the Company if there is no such parent entity), (iii) the Company's material breach of a material provision of this Agreement or another written agreement with Executive or (iv) the relocation of Executive's primary office to a location more than 50 miles from the Boston metropolitan area. Notwithstanding the foregoing, no Good Reason will have occurred unless and until Executive has: (a) provided the Company, within 60 days of Executive's knowledge of the occurrence of the facts and circumstances underlying the Good Reason event, written notice stating with reasonable specificity the applicable facts and circumstances underlying such finding of Good Reason; (b) provided the Company with an opportunity to cure the same within 30 days after the receipt of such notice; and (c) the Company shall have failed to cure such condition within such 30 day period.

8. Parachute Payments.

(a) Notwithstanding any other provisions of this Agreement or any Company equity plan or agreement, in the event that any payment or benefit by the Company or otherwise to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (all such payments and benefits, including the payments and benefits under Section 4(b) and Section 4(c) hereof, being hereinafter referred to as the "Total Payments"), would be subject (in whole or in part) to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Total Payments shall be reduced (in the order provided in Section 8(b)) to the minimum extent necessary to avoid the imposition of the Excise Tax on the Total Payments, but only if (i) the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state and local income and employment taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments), is greater than or equal to (ii) the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state and local income and employment taxes on such Total Payments and the amount of the Excise Tax to which Executive would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments).

(b) The Total Payments shall be reduced in the following order: (i) reduction on a pro-rata basis of any cash severance payments that are exempt from Section 409A of the Code ("Section 409A"), (ii) reduction on a pro-rata basis of any non-cash severance payments or benefits that are exempt from Section 409A, (iii) reduction on a pro-rata basis of any other payments or benefits that are exempt from Section 409A, and (iv) reduction of any payments or benefits otherwise payable to Executive on a pro-rata basis or such other manner that complies with Section 409A; provided, in case of clauses (ii), (iii) and (iv), that reduction of any payments attributable to the acceleration of vesting of Company equity awards shall be first applied to Company equity awards that would otherwise vest last in time.

(c) All determinations regarding the application of this Section 8 shall be made by an accounting firm or consulting group with experience in performing calculations regarding the applicability of Section 280G of the Code and the Excise Tax selected by the Company (the

"Independent Advisors"). For purposes of determinations, no portion of the Total Payments shall be taken into account which, in the opinion of the Independent Advisors, (i) does not constitute a "parachute payment" within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) or (ii) constitutes reasonable compensation for services actually rendered, within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the "base amount" (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation. The costs of obtaining such determination and all related fees and expenses (including related fees and expenses incurred in any later audit) shall be borne by the Company.

(d) In the event it is later determined that a greater reduction in the Total Payments should have been made to implement the objective and intent of this Section 8, the excess amount shall be returned promptly by Executive to the Company.

9. Miscellaneous Provisions.

(a) Governing Law. This Agreement shall be governed, construed, interpreted and enforced in accordance with its express terms, and otherwise in accordance with the substantive laws of the Commonwealth of Massachusetts without reference to the principles of conflicts of law of the Commonwealth of Massachusetts or any other jurisdiction that would result in the application of the laws of a jurisdiction other than the Commonwealth of Massachusetts, and where applicable, the laws of the United States.

(b) Validity. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.

(c) Notices. Any notice, request, claim, demand, document and other communication hereunder to any Party shall be effective upon receipt (or refusal of receipt) and shall be in writing and delivered personally or sent by facsimile or certified or registered mail, postage prepaid, as follows:

(i) If to the Company, the Chief Legal Officer at its headquarters,

(ii) If to Executive, at the last address that the Company has in its personnel records for Executive, or

(iii) at any other address as any Party shall have specified by notice in writing to the other Party.

(d) Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed to be an original, but all of which together will constitute one and the same Agreement. Signatures delivered by facsimile or PDF shall be deemed effective for all purposes.

(e) Entire Agreement. The terms of this Agreement, and the Proprietary Information Agreement incorporated herein by reference as set forth in Section 5, are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and supersede

all prior understandings and agreements, whether written or oral. The Parties further intend that this Agreement shall constitute the complete and exclusive statement of their terms and that no extrinsic evidence whatsoever may be introduced in any judicial, administrative, or other legal proceeding to vary the terms of this Agreement.

(f) Amendments; Waivers. This Agreement may not be modified, amended, or terminated except by an instrument in writing, signed by Executive and a duly authorized officer of Company. By an instrument in writing similarly executed, Executive or a duly authorized officer of the Company may waive compliance by the other Party with any specifically identified provision of this Agreement that such other Party was or is obligated to comply with or perform; *provided*, *however*, that such waiver shall not operate as a waiver of, or estoppel with respect to, any other or subsequent failure. No failure to exercise and no delay in exercising any right, remedy, or power hereunder will preclude any other or further exercise of any other right, remedy, or power provided herein or by law or in equity.

(g) No Inconsistent Actions. The Parties hereto shall not voluntarily undertake or fail to undertake any action or course of action inconsistent with the provisions or essential intent of this Agreement. Furthermore, it is the intent of the Parties hereto to act in a fair and reasonable manner with respect to the interpretation and application of the provisions of this Agreement.

(h) Construction. This Agreement shall be deemed drafted equally by both the Parties. Its language shall be construed as a whole and according to its fair meaning. Any presumption or principle that the language is to be construed against any Party shall not apply. The headings in this Agreement are only for convenience and are not intended to affect construction or interpretation. Any references to paragraphs, subparagraphs, sections or subsections are to those parts of this Agreement, unless the context clearly indicates to the contrary. Also, unless the context clearly indicates to the contrary, (i) the plural includes the singular and the singular includes the plural; (ii) "and" and "or" are each used both conjunctively and disjunctively; (iii) "any," "all," "each," or "every" means "any and all," and "each and every"; (iv) "includes" and "including" are each "without limitation"; (v) "herein," "hereof," "hereunder" and other similar compounds of the word "here" refer to the entire Agreement and not to any particular paragraph, subparagraph, section or subsection; and (vi) all pronouns and any variations thereof shall be deemed to refer to the masculine, feminine, neuter, singular or plural as the identity of the entities or persons referred to may require.

(i) Arbitration. Any controversy, claim or dispute arising out of or relating to this Agreement, shall be settled solely and exclusively by a binding arbitration process administered by JAMS/Endispute in Boston, Massachusetts. Such arbitration shall be conducted in accordance with the then-existing JAMS/Endispute Rules of Practice and Procedure, with the following exceptions if in conflict: (i) one arbitrator who is a retired judge shall be chosen by JAMS/Endispute; (ii) each Party to the arbitration will pay one-half of the expenses and fees of the arbitrator, together with other expenses of the arbitration incurred or approved by the arbitrator; and (iii) arbitration may proceed in the absence of any Party if written notice (pursuant to the JAMS/Endispute rules and regulations) of the proceedings has been given to such Party. Each Party shall bear its own attorney's fees and expenses; provided that the arbitrator may assess the

prevailing Party's fees and costs against the non-prevailing Party as part of the arbitrator's award. The Parties agree to abide by all decisions and awards rendered in such proceedings. Such decisions and awards rendered by the arbitrator shall be final and conclusive. All such controversies, claims or disputes shall be settled in this manner in lieu of any action at law or equity; *provided, however*, that nothing in this subsection shall be construed as precluding the bringing of an action for injunctive relief or specific performance as provided in this Agreement or Proprietary Information Agreement. This dispute resolution process and any arbitration hereunder shall be confidential and neither any Party nor the neutral arbitrator shall disclose the existence, contents or results of such process without the prior written consent of all Parties, except where necessary or compelled in a court to enforce this arbitration provision or an award from such arbitration or otherwise in a legal proceeding. If JAMS/Endispute no longer exists or is otherwise unavailable, the Parties agree that the American Arbitration Association ("AAA") shall administer the arbitration in accordance with its then-existing rules as modified by this subsection. In such event, all references herein to JAMS/Endispute shall mean AAA. Notwithstanding the foregoing, Executive and the Company each have the right to resolve any issue or dispute over intellectual property rights by court action instead of arbitration.

(j) Enforcement. If any provision of this Agreement is held to be illegal, invalid or unenforceable under present or future laws effective during the Term, such provision shall be fully severable; this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a portion of this Agreement; and the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance from this Agreement. Furthermore, in lieu of such illegal, invalid or unenforceable provision there shall be added automatically as part of this Agreement a provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and be legal, valid and enforceable.

(k) Withholding. The Company shall be entitled to withhold from any amounts payable under this Agreement any federal, state, local or foreign withholding or other taxes or charges which the Company is required to withhold. The Company shall be entitled to rely on the advice of counsel if any questions as to the amount or requirement of withholding shall arise.

(l) Section 409A.

(i) *General.* The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

(ii) *Separation from Service.* Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is designated under this Agreement as payable upon Executive's termination of employment shall be payable only upon Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section 4 shall not be paid, or, in the case

of installments, shall not commence payment, until the thirtieth (30th) day following Executive's Separation from Service (the "First Payment Date"). Any installment payments that would have been made to Executive during the thirty (30) day period immediately following Executive's Separation from Service but for the preceding sentence shall be paid to Executive on the First Payment Date and the remaining payments shall be made as provided in this Agreement.

(iii) *Specified Employee.* Notwithstanding anything in this Agreement to the contrary, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of Executive's Separation from Service with the Company or (ii) the date of Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to Executive (or Executive's estate or beneficiaries), and any remaining payments due to Executive under this Agreement shall be paid as otherwise provided herein.

(iv) *Expense Reimbursements.* To the extent that any reimbursements under this Agreement are subject to Section 409A, (i) any such reimbursements payable to Executive shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred, (ii) Executive shall submit Executive's reimbursement request promptly following the date the expense is incurred, (iii) the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, other than medical expenses referred to in Section 105(b) of the Code, and (iv) Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(v) *Installments.* Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

10. Executive Acknowledgement.

Executive acknowledges that Executive has read and understands this Agreement, is fully aware of its legal effect, has not acted in reliance upon any representations or promises made by

the Company other than those contained in writing herein, and has entered into this Agreement freely based on Executive's own judgment.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the date and year first above written.

SERES THERAPEUTICS, INC.

By: /s/ Eric D. Shaff
Name: Eric D. Shaff
Title: President, CEO

/s/ Marella Thorell
Marella Thorell

[Signature Page to Employment Agreement]

|US-DOCS\122808486.1||

EXHIBIT A

Separation Agreement and Release

This Separation Agreement and Release ("Agreement") is made by and between Marella Thorell ("Executive") and Seres Therapeutics, Inc. (the "Company") (collectively referred to as the "Parties" or individually referred to as a "Party"). Capitalized terms used but not defined in this Agreement shall have the meanings set forth in the Employment Agreement (as defined below).

WHEREAS, the Parties have previously entered into that certain Employment Agreement, dated as of _____, 2024 (the "Employment Agreement"); and

WHEREAS, in connection with Executive's termination of employment with the Company or a subsidiary or affiliate of the Company effective _____, 20__, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive's employment with or separation from the Company or its subsidiaries or affiliates but, for the avoidance of doubt, nothing herein will be deemed to release any rights or remedies in connection with Executive's ownership of vested equity securities of the Company or Executive's right to indemnification by the Company or any of its affiliates pursuant to contract or applicable law (collectively, the "Retained Claims").

NOW, THEREFORE, in consideration of the severance payments and benefits described in Section 4 of the Employment Agreement, which, pursuant to the Employment Agreement, are conditioned on Executive's execution and non-revocation of this Agreement, and in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

1. Severance Payments and Benefits; Salary and Benefits. The Company agrees to provide Executive with the severance payments and benefits described in Section 4(b) and/or Section 4(c) of the Employment Agreement, payable at the times set forth in, and subject to the terms and conditions of, the Employment Agreement. In addition, to the extent not already paid, and subject to the terms and conditions of the Employment Agreement, the Company shall pay or provide to Executive all other payments or benefits described in Section 3(c) of the Employment Agreement, subject to and in accordance with the terms thereof.

2. Release of Claims. Executive agrees that, other than with respect to the Retained Claims, the foregoing consideration represents settlement in full of all outstanding obligations owed to Executive by the Company, any of its direct or indirect subsidiaries and affiliates, and any of its or their respective current and former officers, directors, equity holders, managers, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, insurers, trustees, divisions, and subsidiaries and predecessor and successor corporations and assigns (collectively, the "Releasees"). Executive, on Executive's own behalf and on behalf of any of Executive's affiliated companies or entities and any of Executive's or their respective heirs, family members, executors, agents, and assigns, other than with respect to the Retained Claims, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation,

or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the date Executive signs this Agreement, including, without limitation:

(a) any and all claims relating to or arising from Executive's employment or service relationship with the Company or any of its direct or indirect subsidiaries or affiliates and the termination of that relationship;

(b) any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of any shares of stock or other equity interests of the Company or any of its affiliates, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state law, and securities fraud under any state or federal law;

(c) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

(d) any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Labor Standard Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; and the Sarbanes-Oxley Act of 2002;

(e) any and all claims for violation of the federal or any state constitution;

(f) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

(g) any claim for any loss, cost, damage, or expense arising out of any dispute over the non-withholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement;

(h) any and all claims arising out of the wage and hour and wage payments laws and regulations of the state or states in which Executive has provided service to the Company or any of its affiliates (including without limitation the Massachusetts Payment of Wages Law); and

(i) any and all claims for attorneys' fees and costs.

Executive agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not release claims that cannot be released as a matter of law, including, but not limited to, Executive's right to report possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation (including Executive's right to receive an award for information provided to any such government agencies), Executive's right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company (with the understanding that Executive's release of claims herein bars Executive from recovering monetary or other individual relief from the Company or any Releasee in connection with any charge, investigation or proceeding, or any related complaint or lawsuit, filed by Executive or by anyone else on Executive's behalf before the federal Equal Employment Opportunity Commission or a comparable state or local agency), claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims to continued participation in certain of the Company's group benefit plans pursuant to the terms and conditions of COBRA, claims to any benefit entitlements vested as the date of separation of Executive's employment, pursuant to written terms of any employee benefit plan of the Company or its affiliates and Executive's right under applicable law, and any Retained Claims. This release further does not release claims for breach of Section 3(c), Section 4(b) or Section 4(c) of the Employment Agreement.

3. Acknowledgment of Waiver of Claims under ADEA. Executive understands and acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive understands and agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Executive signs this Agreement. Executive understands and acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further understands and acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney prior to executing this Agreement; (b) Executive has 21 days within which to consider this Agreement, and the Parties expressly agree that such time period to review this Agreement shall not be extended upon any material or immaterial changes to this Agreement; (c) Executive has seven business days following Executive's execution of this Agreement to revoke this Agreement pursuant to written notice to the General Counsel of the Company; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the 21 day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement.

4. Post-Termination Obligations. Executive reaffirms Executive's continuing obligations under the Proprietary Information Agreement between Executive and the Company dated as of [_____], and, without limiting the foregoing, Executive remakes the non-competition covenants set forth in the Proprietary Information Agreement as if set forth herein. In addition, Executive agrees to refrain from Disparaging (as defined below) the Company and its affiliates, including their respective services, technologies, practices, directors and officers. The Company agrees to instruct its officers and directors to refrain from Disparaging Executive. Nothing in this Section shall preclude any Party from making truthful statements that are reasonably necessary to comply with applicable law, regulation or legal process, or to defend or enforce a Party's rights under this Agreement or the Employment Agreement. For purposes of this Agreement, "Disparaging" means making remarks, comments or statements, whether written or oral, that impugn the character, integrity, reputation or abilities of the individual or entity being disparaged.

5. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

6 No Oral Modification. This Agreement may only be amended in a writing signed by Executive and a duly authorized officer of the Company.

7. Governing Law; Dispute Resolution. This Agreement shall be subject to the provisions of Sections 9(a), 9(c) and 9(i) of the Employment Agreement.

8. Effective Date. Executive has seven business days after Executive signs this Agreement to revoke it and this Agreement will become effective upon the expiration of such seven business day period, so long as it has been signed by the Parties and has not been revoked by Executive before that date.

9. Trade Secrets; Whistleblower Protections. In accordance with 18 U.S.C. §1833, notwithstanding anything to the contrary in this Agreement, the Employment Agreement, the Proprietary Information Agreement or any other agreement between Executive and the Company or any of its subsidiaries in effect as of the date Executive receives this Agreement (together, the "Subject Documents"): (a) Executive will not be in breach of the Subject Documents, and shall not be held criminally or civilly liable under any federal or state trade secret law (i) for the disclosure of a trade secret that is made in confidence to a federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (ii) for the disclosure of a trade secret that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; and (b) if Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Executive may disclose the trade secret to Executive's attorney, and may use the trade secret information in the court proceeding, if Executive files any document containing the trade secret under seal, and does not disclose the trade secret, except pursuant to court order. Furthermore, the Parties agree that nothing in the Subject Documents prohibits Executive from reporting possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and

rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation or releases or restrains Executive's right to receive an award for information provided to any such government agencies.

10. Voluntary Execution of Agreement. Executive understands and agrees that Executive executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive acknowledges that: (a) Executive has read this Agreement; (b) Executive has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement; (c) Executive has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel; (d) Executive understands the terms and consequences of this Agreement and of the releases it contains; and (e) Executive is fully aware of the legal and binding effect of this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

Dated:

_____
Marella Thorell

SERES THERAPEUTICS, INC.

Dated:

By:_____
Name:
Title:

EXHIBIT B

Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement

In consideration and as a condition of my employment or continued employment (including my salary or wage, any bonus I may receive, and any equity granted to me) by Seres Therapeutics, Inc. (the "Company"), I hereby agree as follows:

11. Proprietary Information. I agree that all information, whether or not in writing, whether or not disclosed before or after I was first employed by the Company, concerning the Company's business, technology, business relationships or financial affairs that the Company has not released to the general public (collectively, "Proprietary Information"), and all tangible embodiments thereof, are and will be the exclusive property of the Company. By way of illustration, Proprietary Information may include information or material that has not been made generally available to the public, such as: (a) corporate information, including plans, strategies, methods, policies, resolutions, notes, email correspondence, negotiations or litigation; (b) marketing information, including strategies, methods, customer identities or other information about customers, prospect identities or other information about prospects, or market analyses or projections; (c) financial information, including cost and performance data, debt arrangements, equity structure, investors and holdings, purchasing and sales data and price lists; and (d) operational and technological information, including plans, specifications, manuals, forms, templates, software, designs, methods, procedures, formulas, discoveries, inventions, improvements, biological or chemical materials, concepts and ideas; and (e) personnel information, including personnel lists, reporting or organizational structure, resumes, personnel data, compensation structure, performance evaluations and termination arrangements or documents. Proprietary Information includes, without limitation, (1) information received in confidence by the Company from its customers or suppliers or other third parties, and (2) all biological or chemical materials and other tangible embodiments of the Proprietary Information. Nothing in this Agreement shall prohibit me from reporting possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 805 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation.

12. **Recognition of Company's Rights**. I will not, at any time, without the Company's prior written permission, either during or after my employment, disclose or transfer any Proprietary Information to anyone outside of the Company, or use or permit to be used any Proprietary Information for any purpose other than the performance of my duties as an employee of the Company. I will cooperate with the Company and use my best efforts to prevent the unauthorized disclosure of all Proprietary Information. I will deliver to the Company all copies and other tangible embodiments of Proprietary Information in my possession or control upon the earlier of a request by the Company or termination of my employment.

13. **Rights of Others**. I understand that the Company is now and may hereafter be subject to non-disclosure or confidentiality agreements with third persons which require the Company to protect or refrain from use of proprietary information. I agree to be bound by the terms of such agreements in the event I have access to such proprietary information.

14. **Commitment to Company; Avoidance of Conflict of Interest**. While an employee of the Company, I will devote my full-time efforts to the Company's business and I will not engage in any other business activity that conflicts with my duties to the Company. I will advise the president of the Company or his or her nominee at such time as any activity of either the Company or another business presents me with a conflict of interest or the appearance of a conflict of interest as an employee of the Company. I will take whatever action is requested of me by the Company to resolve any conflict or appearance of conflict which it finds to exist.

15. **Developments**. I hereby assign and transfer and, to the extent any such assignment cannot be made at present, will assign and transfer, to the Company and its successors and assigns, all my right, title and interest in and to all Developments (as defined below) that: (a) are created, developed, made, conceived or reduced to practice by me (alone or jointly with others) or under my direction (collectively, "conceived") during the period of my employment and six (6) months thereafter and that relate to the business of the Company or to products, methods or services being researched, developed, manufactured or sold by the Company; or (b) result from tasks assigned to me by the Company; or (c) result from the use of premises, Proprietary Information or personal property (whether tangible or intangible) owned, licensed or leased by the Company (collectively, "Company-Related Developments"), and all patent rights, trademarks, copyrights and other intellectual property rights in all countries and territories worldwide claiming, covering or otherwise arising from or pertaining to Company-Related Developments (collectively, "Intellectual Property Rights"). I further agree that "Company-Related Developments" include, without limitation, all Developments that (i) were conceived by me before my employment, (ii) relate to the business of the Company or to products, methods or services being researched, developed, manufactured or sold by the Company, and (iii) were not subject to an obligation to assign to another entity when conceived. I will make full and prompt disclosure to the

Company of all Company-Related Developments, as well as all other Developments conceived by me during the period of my employment and six (6) months thereafter. I acknowledge that all work performed by me as an employee of the Company is on a "work for hire" basis. I hereby waive all claims to any moral rights or other special rights which I may have or accrue in any Company-Related Developments. "Developments" mean inventions, discoveries, designs, developments, methods, modifications, improvements, processes, biological or chemical materials, algorithms, databases, computer programs, formulae, techniques, trade secrets, graphics or images, audio or visual works, and other works of authorship.

To preclude any possible uncertainty, I have set forth on Exhibit A attached hereto a complete list of Developments conceived by me before my employment that are not Company-Related Developments ("Prior Inventions"). I have also listed on Exhibit A all patent rights of which I am an inventor, other than those contained within Intellectual Property Rights ("Other Patent Rights"). If no such disclosure is attached, I represent that there are no Prior Inventions or Other Patent Rights. If, in the course of my employment with the Company, I incorporate a Prior Invention into a Company product, process or research or development program or other work done for the Company, I hereby grant to the Company a nonexclusive, royalty-free, fully paid-up, irrevocable, perpetual, worldwide license (with the full right to sublicense through multiple tiers) to make, have made, modify, use, offer for sale, import and sell such Prior Invention. Notwithstanding the foregoing, I will not incorporate, or permit to be incorporated, Prior Inventions in any Company-Related Development without the Company's prior written consent.

I understand that to the extent this Agreement is required to be construed in accordance with the laws of any state which precludes a requirement in an employee agreement to assign certain classes of inventions made by an employee, this Section will be interpreted not to apply to any invention which a court rules and/or the Company agrees falls within such classes.

16. **Documents and Other Materials**. I will keep and maintain adequate and current records of all Proprietary Information and Company-Related Developments conceived by me, which records will be available to and remain the sole property of the Company at all times. All files, letters, notes, memoranda, reports, records, data, sketches, drawings, notebooks, layouts, charts, quotations and proposals, specification sheets, program listings, blueprints, models, prototypes, materials or other written, photographic or other tangible material containing or embodying Proprietary Information, whether created by me or others, which come into my custody or possession, are the exclusive property of the Company to be used by me only in the performance of my duties for the Company. In the event of the termination of my employment for any reason, I will deliver to the Company all of the foregoing, and all other materials of any nature pertaining to the Proprietary Information of the Company and to my work, and will not take or keep in my possession any of the foregoing or any copies. Any property situated on the Company's premises and owned by the Company, including laboratory space, computers, disks and other storage media, filing cabinets or other work areas, is subject to inspection by the Company at any time with or without notice.

17. **Enforcement of Intellectual Property Rights**. I will cooperate fully with the Company, both during and after my employment with the Company, with respect to the procurement, maintenance and enforcement of Intellectual Property Rights, as well as all other patent rights, trademarks, copyrights and other intellectual property rights in all countries and territories worldwide owned by or licensed to the Company. I will sign, both during and after the term of this Agreement, all papers, including copyright applications, patent applications, declarations, oaths, assignments of priority rights, and powers of attorney, which the Company may deem necessary or desirable in order to protect its rights and interests in any Company-Related Development or Intellectual Property Rights. If the Company is unable, after reasonable effort, to secure my signature on any such papers, I hereby irrevocably designate and appoint each officer of the Company as my agent and attorney-in-fact to execute any such papers on my behalf, and to take any and all actions as the Company may deem necessary or desirable in order to protect its rights and interests in the same.

18. **Non-Competition and Non-Solicitation**. In order to protect the Company's Proprietary Information and good will, during my employment and for a period of twelve (12) months following the termination of my employment for any reason (the "Restricted Period"):

(a) in consideration of the offer of employment, my salary or wage, any bonus I may receive, and the equity granted to me in connection with commencement of employment with the Company, all of which I deem as fair and reasonable consideration for entering into this Agreement, I will not directly or indirectly, whether as owner, partner, shareholder, director, consultant, agent, employee, co-venturer or otherwise, engage, participate or invest in any business that develops, manufactures or markets microbiome therapeutics that are competitive with products or

services of the Company, or that the Company has under development, or that are the subject of active planning at any time during my employment (collectively, the "Competitive Products"); provided that this will not prohibit any possible investment in publicly traded stock of a company representing less than one percent of the stock of such company and provided further that this provision shall apply only if I am an exempt employee (as that term is defined by the Fair Labor Standards Act) or if and when I subsequently become an exempt employee; and

(b) I will not directly or indirectly, in any manner, other than for the benefit of the Company, (i) call upon, solicit, divert or take away any of the customers, business or prospective customers of the Company or any of its suppliers, and/or (ii) solicit, entice or attempt to persuade any other employee or consultant of the Company to leave the services of the Company for any reason.

I acknowledge and agree that if I violate any of the provisions of this Section, in addition to any other remedies to which the Company may be entitled in law or equity, the running of the Restricted Period will be extended by the time during which I engage in such violation(s) or up to twenty four (24) months, whichever is longer.

I acknowledge and agree that the provisions of this agreement shall apply during and following my employment by the Company and shall not be affected by any change in my job duties, whether material or immaterial.

I further acknowledge and agree that I have the right and have had the opportunity to consult with an attorney prior to signing this Agreement.

19. **Government Contracts**. I acknowledge that the Company may have from time to time agreements with other persons or with the United States Government or its agencies which impose obligations or restrictions on the Company regarding inventions made during the course of work under such agreements or regarding the confidential nature of such work. I agree to comply with any such obligations or restrictions upon the direction of the Company. In addition to the rights assigned under Section 5, I also assign to the Company (or any of its nominees) all rights which I have or acquired in any Developments, full title to which is required to be in the United States under any contract between the Company and the United States or any of its agencies.

20. **Prior Agreements**. I hereby represent that, except as I have fully disclosed previously in writing to the Company, I am not bound by the terms of any agreement with any previous employer or other party to refrain from using or disclosing any trade secret or confidential or proprietary information in the course of my employment with the Company or to refrain from competing, directly or indirectly, with the business of such previous employer or any other party. I further represent that my performance of all the terms of this Agreement as an employee of the Company does not and will not breach any agreement to keep in confidence proprietary information, knowledge or data acquired by me in confidence or in trust prior to my employment with the Company. I will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any previous employer or others.

21. **Remedies Upon Breach**. I understand that the restrictions contained in this Agreement are necessary for the protection of the business and goodwill of the Company and I consider them to be reasonable for such purpose. Any breach of this Agreement is likely to cause the Company substantial and irrevocable damage and therefore, in the event of such breach, the Company, in addition to such other remedies which may be available, will be entitled to specific performance and other injunctive relief.

22. **Use of Voice, Image and Likeness**. I give the Company permission to use my voice, image or likeness, with or without using my name, for the purposes of advertising and promoting the Company, or for other purposes deemed appropriate by the Company in its reasonable discretion, except to the extent expressly prohibited by law.

23. **Publications and Public Statements**. I will obtain the Company's written approval before publishing or submitting for publication any material that relates to my work at the Company and/or incorporates any Proprietary Information. To ensure that the Company delivers a consistent message about its products, services and operations to the public, and further in recognition that even positive statements may have a detrimental effect on the Company in certain securities transactions and other contexts, any statement about the Company which I create, publish or post during my period of employment and for six (6) months thereafter, on any media accessible by the public, including

but not limited to electronic bulletin boards and Internet-based chat rooms, must first be reviewed and approved by an officer of the Company before it is released in the public domain.

24. **No Employment Obligation**. I understand that this Agreement does not create an obligation on the Company or any other person to continue my employment. I acknowledge that, unless otherwise agreed in a formal written employment agreement signed on behalf of the Company by an authorized officer, my employment with the Company is at will and therefore may be terminated by the Company or me at any time and for any reason.

25. **Survival and Assignment by the Company**. I understand that my obligations under this Agreement will continue in accordance with its express terms regardless of any changes in my title, position, duties, salary, compensation or benefits or other terms and conditions of employment. I further understand that my obligations under this Agreement will continue following the termination of my employment regardless of the manner of such termination and will be binding upon my heirs, executors and administrators. The Company will have the right to assign this Agreement to its affiliates, successors and assigns. I expressly consent to be bound by the provisions of this Agreement for the benefit of the Company or any parent, subsidiary or affiliate to whose employ I may be transferred without the necessity that this Agreement be resigned at the time of such transfer.

26. **Disclosure to Future Employers**. I will provide a copy of this Agreement to any prospective employer, partner or co-venturer prior to entering into an employment, partnership or other business relationship with such person or entity.

27. **Defend Trade Secrets Act Notice of Immunity Rights.** I acknowledge that the Company has provided me with the following notice of immunity rights in compliance with the requirements of the Defend Trade Secrets Act: (i) I shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of Proprietary Information that is made in confidence to a Federal, State, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, (ii) I shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of Proprietary Information that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal and (iii) if I file a lawsuit for retaliation by the Company for reporting a suspected violation of law, I may disclose the Proprietary Information to my attorney and use the Proprietary Information in the court proceeding, if I file any document containing the Proprietary Information under seal, and do not disclose the Proprietary Information, except pursuant to court order.

28. **Exit Interview**. If and when I depart from the Company, I may be required to attend an exit interview and sign an "Employee Exit Acknowledgement" to reaffirm my acceptance and acknowledgement of the obligations set forth in this Agreement. During the Restricted Period following termination of my employment, I will notify the Company of any change in my address and of each subsequent employment or business activity, including the name and address of my employer or other post-Company employment plans and the nature of my activities.

29. **Severability**. In case any provisions (or portions thereof) contained in this Agreement will, for any reason, be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect the other provisions of this Agreement, and this Agreement will be construed as if such invalid, illegal or unenforceable provision had never been contained herein. If, moreover, any one or more of the provisions contained in this Agreement will for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it will be construed by limiting and reducing it, so as to be enforceable to the extent compatible with the applicable law as it will then appear.

30. **Entire Agreement**. This Agreement constitutes the entire and only agreement between the Company and me respecting the subject matter hereof, and supersedes all prior agreements and understandings, oral or written, between us concerning such subject matter. No modification, amendment, waiver or termination of this Agreement or of any provision hereof will be binding unless made in writing and signed by an authorized officer of the Company. Failure of the Company to insist upon strict compliance with any of the terms, covenants or conditions hereof will not be deemed a waiver of such terms, covenants or conditions. In the event of any inconsistency between this Agreement and any other contract between the Company and me, the provisions of this Agreement will prevail.

31. **Interpretation**. This Agreement will be deemed to be made and entered into in the Commonwealth of Massachusetts, and will in all respects be interpreted, enforced and governed under the laws of the Commonwealth of

Massachusetts. I hereby agree to consent to personal jurisdiction of the state and federal courts situated within Suffolk County, Massachusetts for purposes of enforcing this Agreement, and waive any objection that I might have to personal jurisdiction or venue in those courts. As used in this Agreement, "including" means "including but not limited to".

BY SIGNING BELOW, I CERTIFY THAT I HAVE READ THIS AGREEMENT CAREFULLY AND AM SATISFIED THAT I UNDERSTAND IT COMPLETELY.

IN WITNESS WHEREOF, the undersigned has executed this agreement as a sealed instrument as of the date set forth below.

Signed: _____
(Employee's full name)

Type or print name: _____

Date: _____

|US-DOCS\64377647.6||

EXHIBIT A

To: [_____]

From: _____

Date: _____

SUBJECT: **Prior Inventions**

The following is a complete list of all inventions or improvements relevant to the subject matter of my employment by the Company that have been made or conceived or first reduced to practice by me alone or jointly with others prior to my engagement by the Company:

No inventions or improvements

See below:

_____

_____

_____

_____

_____

_____

_____

Additional sheets attached

The following is a list of all patents, patent applications and other patent rights that I invented:

None

See below:

_____

_____

_____

_____

_____

_____

_____

|US-DOCS\122808486.1||

Exhibit 10.2

SERES THERAPEUTICS, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

(as amended effective March 19, 2024) (the "***Effective Date***")

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

I. CASH COMPENSATION

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

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

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

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

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

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

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

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

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

D. Annual Retainer Election.

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

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

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

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

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

II. EQUITY COMPENSATION

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

A. Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall receive an option to purchase 120,000 shares of the Company's common stock on the date of such initial election or appointment. The awards described in this Section II(A) shall be referred to as "***Initial Awards***." No Non-Employee Director shall be granted more than one Initial Award.

B. Subsequent Awards. A Non-Employee Director who (i) has been serving as a Non-Employee Director on the Board for at least six months as of the date of any annual meeting of the Company's stockholders after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall be automatically granted an option to purchase 60,000 Shares on the date of such annual meeting. The awards described in this Section II(B) shall be referred to as "***Subsequent Awards***." For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an annual meeting of the Company's stockholders shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Award on the date of such meeting as well.

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

D. Terms of Awards Granted to Non-Employee Directors

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

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

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

* * * * *

Exhibit 10.3

Separation Agreement and Release

This Separation Agreement and Release ("Agreement") is made by and between David Arkowitz ("Executive") and Seres Therapeutics, Inc. (the "Company") (collectively referred to as the "Parties" or individually referred to as a "Party"). Capitalized terms used but not defined in this Agreement shall have the meanings set forth in the Employment Agreement (as defined below).

WHEREAS, the Parties have previously entered into that certain Amended and Restated Employment Agreement, dated as of May 10, 2021 (the "Employment Agreement"); and

WHEREAS, in connection with Executive's termination of employment with the Company or a subsidiary or affiliate of the Company effective March 15, 2024 (the "Separation Date"), the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive's employment with or separation from the Company or its subsidiaries or affiliates but, for the avoidance of doubt, nothing herein will be deemed to release any rights or remedies in connection with Executive's ownership of vested equity securities of the Company or Executive's right to indemnification by the Company or any of its affiliates pursuant to contract or applicable law (collectively, the "Retained Claims").

NOW, THEREFORE, in consideration of the severance payments and benefits described in Section 4 of the Employment Agreement, which, pursuant to the Employment Agreement, are conditioned on Executive's execution and non-revocation of this Agreement, and in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

1. Severance Payments and Benefits; Salary and Benefits. The Company agrees to provide Executive with the severance payments and benefits described in Section 4(b) of the Employment Agreement, payable at the times set forth in, and subject to the terms and conditions of, the Employment Agreement. In addition, to the extent not already paid, and subject to the terms and conditions of the Employment Agreement, the Company shall pay or provide to Executive all other payments or benefits described in Section 3(c) of the Employment Agreement, subject to and in accordance with the terms thereof. 3.

2. Release of Claims. Executive agrees that, other than with respect to the Retained Claims, the foregoing consideration represents settlement in full of all outstanding obligations owed to Executive by the Company, any of its direct or indirect subsidiaries and affiliates, and any of its or their respective current and former officers, directors, equity holders, managers, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, insurers, trustees, divisions, and subsidiaries and predecessor and successor corporations and assigns (collectively, the "Releasees"). Executive, on Executive's own behalf and on behalf of any of Executive's affiliated companies or entities and any of Executive's or their respective heirs, family members, executors, agents, and assigns, other than with respect to the Retained Claims, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, or cause of action relating to any matters of any kind, whether presently known or unknown,

suspected or unsuspected, that Executive may possess against any of the Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the date Executive signs this Agreement, including, without limitation:

(a) any and all claims relating to or arising from Executive's employment or service relationship with the Company or any of its direct or indirect subsidiaries or affiliates and the termination of that relationship;

(b) any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of any shares of stock or other equity interests of the Company or any of its affiliates, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state law, and securities fraud under any state or federal law;

(c) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

(d) any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Labor Standards Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; and the Sarbanes-Oxley Act of 2002;

(e) any and all claims for violation of the federal or any state constitution;

(f) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

(g) any claim for any loss, cost, damage, or expense arising out of any dispute over the non-withholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement;

(h) any and all claims arising out of the wage and hour and wage payments laws and regulations of the state or states in which Executive has provided service to the Company or any of its affiliates (including without limitation the Massachusetts Payment of Wages Law); and

(i) any and all claims for attorneys' fees and costs.

Executive agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not release claims that cannot be released as a matter of law, including, but not limited to, Executive's right to report possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation (including Executive's right to receive an award for information provided to any such government agencies), Executive's right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company (with the understanding that Executive's release of claims herein bars Executive from recovering monetary or other individual relief from the Company or any Releasee in connection with any charge, investigation or proceeding, or any related complaint or lawsuit, filed by Executive or by anyone else on Executive's behalf before the federal Equal Employment Opportunity Commission or a comparable state or local agency), claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims to continued participation in certain of the Company's group benefit plans pursuant to the terms and conditions of COBRA, claims to any benefit entitlements vested as the date of separation of Executive's employment, pursuant to written terms of any employee benefit plan of the Company or its affiliates and Executive's right under applicable law, and any Retained Claims. This release further does not release claims for breach of Section 3(c), Section 4(b) or Section 4(c) of the Employment Agreement.

3. Acknowledgment of Waiver of Claims under ADEA. Executive understands and acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive understands and agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Executive signs this Agreement. Executive understands and acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further understands and acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney prior to executing this Agreement; (b) Executive has 45 days within which to consider this Agreement, and the Parties expressly agree that such time period to review this Agreement shall not be extended upon any material or immaterial changes to this Agreement; (c) Executive has seven business days following Executive's execution of this Agreement to revoke this Agreement pursuant to written notice to the Chief Legal Officer of the Company; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the 45 day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement.

4. Post-Termination Obligations. Executive reaffirms Executive's continuing obligations under the Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement (the "Proprietary Information Agreement") between Executive and the Company dated as of May 10, 2021, and, without limiting the foregoing, Executive remakes the non-competition covenants set forth in the Proprietary Information Agreement as if set forth herein. In addition, Executive agrees to refrain from Disparaging (as defined below) the Company and its affiliates, including their respective services, technologies, practices, directors and officers. The Company agrees to instruct its officers and directors to refrain from Disparaging Executive. Nothing in this Section shall preclude any Party from making truthful statements that are reasonably necessary to comply with applicable law, regulation or legal process, or to defend or enforce a Party's rights under this Agreement or the Employment Agreement. For purposes of this Agreement, "Disparaging" means making remarks, comments or statements, whether written or oral, that impugn the character, integrity, reputation or abilities of the individual or entity being disparaged.

5. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

6 No Oral Modification. This Agreement may only be amended in a writing signed by Executive and a duly authorized officer of the Company.

7. Governing Law; Dispute Resolution. This Agreement shall be subject to the provisions of Sections 9(a), 9(c) and 9(i) of the Employment Agreement.

8. Effective Date. This Agreement may not be signed by Executive before the Separation Date. Executive has seven business days after Executive signs this Agreement to revoke it and this Agreement will become effective upon the expiration of such seven business day period, so long as it has been signed by the Parties and has not been revoked by Executive before that date.

9. Protected Disclosures. In accordance with 18 U.S.C. §1833, notwithstanding anything to the contrary in this Agreement, the Employment Agreement, the Proprietary Information Agreement or any other agreement between Executive and the Company or any of its subsidiaries in effect as of the date Executive receives this Agreement (together, the "Subject Documents"): (a) Executive will not be in breach of the Subject Documents, and shall not be held criminally or civilly liable under any federal or state trade secret law (i) for the disclosure of a trade secret that is made in confidence to a federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (ii) for the disclosure of a trade secret that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; and (b) if Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Executive may disclose the trade secret to Executive's attorney, and may use the trade secret information in the court proceeding, if Executive files any document containing the trade secret under seal, and does not disclose the trade secret, except pursuant to court order. Furthermore, the Parties agree that nothing in the Subject

Documents prohibits Executive from (i) communicating directly with, cooperating with, or providing information to, or receiving financial awards from, any federal, state or local government agency, including without limitation the U.S. Securities and Exchange Commission, the U.S. Commodity Futures Trading Commission, the U.S. Department of Justice, the U.S. Equal Employment Opportunity Commission, or the U.S. National Labor Relations Board, without notifying or seeking permission from the Company, or (ii) discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination based on a protected characteristic or any other conduct that Employee has reason to believe is unlawful.

10. Voluntary Execution of Agreement. Executive understands and agrees that Executive executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive acknowledges that: (a) Executive has read this Agreement; (b) Executive has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement; (c) Executive has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel; (d) Executive understands the terms and consequences of this Agreement and of the releases it contains; and (e) Executive is fully aware of the legal and binding effect of this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

Dated: March 15, 2024

/s/ David Arkowitz
David Arkowitz

SERES THERAPEUTICS, INC.

Dated: March 15, 2024

By:/s/ Thomas J. DesRosier
Name: Thomas J. DesRosier
Title: EVP, Chief Legal Officer

Exhibit 10.4

SERES THERAPEUTICS, INC. ADVISORY AGREEMENT

THIS ADVISORY AGREEMENT (this "**Agreement**") is made and effective as of March 15, 2024 (the "**Effective Date**") by and between David Arkowitz, an individual ("**Advisor**"), whose address is set forth on the signature page below and SERES THERAPEUTICS, Inc., a Delaware corporation (along with its affiliated companies, the "**Company**") (collectively referred to as the "**Parties**" or individually referred to as a "**Party**").

WHEREAS, the Parties have previously entered into that certain Separation Agreement and Release dated as of March 15, 2024 (the "**Separation Agreement**"), which sets forth certain terms and conditions of Advisor's separation from employment with the Company effective March 15, 2024 (the "**Separation Date**"); and

WHEREAS, the Company seeks to retain Advisor's services on and following the Effective Date on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, the Company and Advisor hereby agree as follows:

1. Services. The Company hereby engages Advisor to provide to the Company, and Advisor agrees to provide to the Company under the terms and conditions of this Agreement, advisory services as reasonably requested by the Company from time to time (hereinafter the "**Services**"). Notwithstanding the foregoing, the parties intend for Advisor's separation from employment with the Company to constitute a "separation from service" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended ("**Section 409A**"), and accordingly, in no event will the level of bona fide services that Advisor performs under this Agreement exceed twenty percent (20%) of the average level of bona fide services performed by Advisor for the Company over the thirty-six (36) month period immediately preceding the Separation Date.

2. Time Commitment/Compensation.

   (a) Time Commitment. In general, Advisor is expected to provide up to 10 hours of Services per month throughout the term of this Agreement.

   (b) Compensation. Company shall pay Advisor $500.00 per hour for each hour spent by Advisor in the performance of Services for Company, payable within 45 days of the end of each month upon presentation of a Company approved invoice by Advisor, fully detailing the time spent and tasks performed by Advisor. Invoices should reference this Agreement and should be submitted to: Accounts Payable, Seres Therapeutics, Inc, 101 Cambridge Park Drive, Cambridge, MA 02140 or via email at billing@seresthrerapeutics.com. Further, any stock options and restricted stock options issued to Advisor's during his employment with the Company will continue to vest during the performance of Services under this Agreement and shall be deemed to constitute continued service to the Company under and for purposes of the stock options and restricted stock options of the Company that were granted to Advisor prior to the Separation Date.

3. Expenses. The Company will reimburse Advisor for reasonable and necessary out-of-pocket expenses incurred by Advisor in the performance of the Services, provided such out-of-pocket expenses are approved in advance by an officer of the Company and further are supported by reasonable documentation. Such expenses will include reasonable travel expenses of Advisor to the Company's offices.

4. Independent Contractor. Advisor is not, nor will Advisor be deemed to be at any time during the term of this Agreement, an employee of the Company, and therefore Advisor will not be entitled to any benefits provided by the Company to its employees (including such items as health and disability benefits, but except as otherwise provided in the Separation Agreement with respect to continued medical, dental or vision coverage pursuant to COBRA), even if it is later determined that Advisor is a common law employee of Company or any of its affiliates for any purpose. Advisor's status and relationship with the Company will be that of an independent contractor and consultant. Advisor will not state or imply, directly or indirectly, that Advisor is empowered to bind the Company without the Company's prior written consent. Nothing herein will create, expressly or by implication, a partnership, joint venture or other association between the parties. Advisor will be solely responsible for payment of all charges and taxes arising from his or her

5. Term of Agreement. The term of this Agreement and Advisor's Services hereunder will commence as of the Effective Date of this Agreement and, unless terminated earlier as a result of the death, physical incapacity or mental incompetence of Advisor, which will result in automatic termination, or unless terminated pursuant to Section 6, it will continue in effect until September 15, 2024 (the "**Initial Term**"). The term of this Agreement may be extended beyond the Initial Term for additional periods upon mutual written agreement of the parties. Upon expiration or termination of this Agreement all obligations of the parties hereunder shall cease except that the provisions of Sections 7 through 13 will survive the termination or expiration of this Agreement for any reason. The period from the Effective Date through the expiration or termination of this Agreement, regardless of the time or reason for such termination, shall be referred to herein as the "**Term**".

6. Termination. Either Party may, without prejudice to any right or remedy it may have due to any failure of the other Party to perform its obligations under this Agreement, terminate the Term immediately by written notice to the other Party in the event of a material breach of this Agreement by such other Party. The Company may terminate the Term at any time by written notice to Advisor. If prior to the expiration of the Initial Term the Company terminates the Term other than due to Advisor's material breach of this Agreement, Advisor shall be entitled to the continued exercisability of Advisor's options to purchase shares of the Company's common stock set forth in Section 2 of this Agreement as if Advisor had continued providing the Services until the expiration of the Initial Term. In the event of termination under this Section 6 at any time, the Advisor shall be entitled to payment for expenses incurred prior to the effective date of termination and shall have no further rights under this Agreement. Such payments shall constitute full settlement of any and all claims of the Advisor of every description against the Company under this Agreement.

7. Representations and Warranties of Advisor. Advisor represents and warrants to the Company that (i) with respect to any information, know-how, knowledge or data disclosed by Advisor to the Company or any other third party in the performance of this Agreement, Advisor has the full and unrestricted right to disclose the same; and (ii) Advisor is free to undertake the Services required by this Agreement, and there is, and will be, no conflict of interest between Advisor's performance of this Agreement and any obligation Advisor may have to other parties.

8. Covenants of Advisor. Notwithstanding anything herein to the contrary, Advisor agrees to continue to abide by the terms of the Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement previously entered into between Advisor and the Company (the "**Proprietary Information Agreement**"), which are hereby incorporated by reference into this Agreement, and which shall apply in addition to the other covenants set forth in this Agreement.

9. Confidentiality. Advisor agrees to hold all Confidential Information (as hereinafter defined) of the Company (or other parties whose Confidential Information the Company has in its possession under obligations of confidentiality) in trust and strict confidence and, except as may be authorized by the Company in writing, will not use for any purpose other than the performance of the Services under this

Agreement, nor disclose such Confidential Information to any person, association, company, entity or other organization (whether for profit or not for profit).

As used herein, "Confidential Information" means all knowledge and information which Advisor has acquired or may acquire as a result of, or related to his or her relationship with theCompany, including but not limited to, Works (as defined below) information concerning the Company's business, finances, operations, strategic planning, research and development activities, products, molecules, organisms, laboratory materials, prototypes, cell lines, inventions, research developments, improvements, processes, trade secrets, services, cost and pricing policies, formulae, diagrams, schematics, notes, data, memoranda, methods, know-how, techniques, inventions, and marketing strategies. Confidential Information will also include information received by the Company from third parties under an obligation of confidentiality. Notwithstanding the foregoing sentence, such Confidential Information does not include (i) information which is or becomes publicly available (except as may be disclosed by Advisor in violation of this Agreement), (ii) information acquired by Advisor from a third-party source other than the Company or any of its employees, advisors or shareholders, which source legally acquired such information under no obligation of confidentiality, or (iii) information of a general nature and specifically information regarding the microbiome therapeutics field known to Advisor prior to advising the Company or acquired by Advisor during the term hereof by reason of his or her other business activities. This Agreement shall not prohibit Advisor from disclosing Confidential Information to the extent required for Advisor to comply with a court or governmental order, provided that Advisor provides prior written notice of such required disclosure to the Company and cooperates in reasonable and lawful actions by the Company to avoid and/or minimize the extent of such disclosure.

10. Ownership of Work Product. Advisor will communicate in writing and disclose to the Company promptly and fully all concepts, inventions, formulae, molecules, organisms, trade secrets, know-how, technical or business innovations, writings or other works of authorship and patents or patent rights created, reduced to practice, or conceived by Advisor (whether or not patentable or copyrightable and whether made solely by Advisor or jointly with others), which result from the Services that Advisor performs for the Company or which result from use of Confidential Information (along with all patent, copyright and other proprietary rights arising therefrom, collectively the "**Works**").

Advisor will make and maintain adequate and current written records of all Works, which records will be available to and remain the property of the Company at all times. The Works will be and remain the sole and exclusive property of the Company or its nominees whether or not patented or copyrighted and without regard to any termination of this Agreement. The Works are being created at the instance of the Company and will be deemed to be "works made for hire" under the United States copyright laws. Advisor hereby assigns and, to the extent any such assignment cannot be made at present, hereby agrees to assign to the Company, without further compensation, all right, title and interest in and to all Works. Advisor will assist the Company in any reasonable manner to obtain for its own benefit patents, copyrights and other proprietary rights in any and all countries with respect to the Works, and Advisor will execute and deliver, when requested, patent and other applications and assignments thereof. In the event Advisor's signature on any assignment of the Works or patent or other application or assignment thereof with respect to the Works cannot be obtained within five (5) days after the Company's request therefor, Advisor hereby designates the Company as his agent for, and grants to the Company a power of attorney, which power of attorney shall be deemed coupled with an interest, solely for the purpose of effecting the execution of such documents. Advisor will further assist the Company at the Company's expense, and including compensation at Advisor's then current hourly consulting rate, in every proper way to enforce any patents, copyrights and other legal protections obtained, including testifying in any suit or proceeding.

11. Company Data. Any data or other materials furnished by the Company for use by Advisor in connection with the Services will remain the sole property of the Company and will be held in trust

and confidence by Advisor in accordance with Section 9 as Confidential Information. The

Company may obtain the return of the Company data or other materials furnished to Advisor upon written notice to Advisor requesting such return, and in any event Advisor will promptly return such data or materials upon termination of this Agreement.

12. Advertising. Advisor will not in any way or in any form publicize or advertise in any manner the fact that Advisor is performing the services called for by this Agreement without the prior written consent of the Company.

13. Restriction on Solicitation. During the Term and for one year thereafter, Advisor will not recruit or otherwise solicit, entice and induce any employee of the Company to terminate their employment with, or otherwise cease their relationships with the Company.

14. Trade Secrets. In accordance with 18 U.S.C. §1833, notwithstanding anything to the contrary in this Agreement, the Proprietary Information Agreement or any other agreement between Advisor and the Company or any of its subsidiaries in effect as of the Effective Date (together, the "**Subject Documents**"): (a) Advisor will not be in breach of the Subject Document, and shall not be held criminally or civilly liable under any federal or state trade secret law (i) for the disclosure of a trade secret that is made in confidence to a federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (ii) for the disclosure of a trade secret that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; and (b) if Advisor files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Advisor may disclose the trade secret to Advisor's attorney, and may use the trade secret information in the court proceeding, if Advisor files any document containing the trade secret under seal, and does not disclose the trade secret, except pursuant to court order. Furthermore, the Parties agree that nothing in the Subject Documents prohibits Executive from (i) communicating directly with, cooperating with, or providing information to, or receiving financial awards from, any federal, state or local government agency, including without limitation the U.S. Securities and Exchange Commission, the U.S. Commodity Futures Trading Commission, the U.S. Department of Justice, the U.S. Equal Employment Opportunity Commission, or the U.S. National Labor Relations Board, without notifying or seeking permission from the Company or (ii) discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination based on a protected characteristic or any other conduct that Employee has reason to believe is unlawful.

15. Assignment. The rights and liabilities of the parties hereto shall bind and inure to the benefit of their respective successors, heirs, executors and administrators, as the case may be; provided that, as the Company has specifically contracted for Advisor's Services, Advisor may not assign or delegate Advisor's obligations under this Agreement either in whole or in part without the prior written consent of the Company. The Company may assign its rights and obligations hereunder to any person or entity that succeeds to all or substantially all of the Company's business. Any assignment not in accordance with this Section 15 shall be void.

16. Miscellaneous. This Agreement (together with all exhibits hereto), the Separation Agreement and the Proprietary Information Agreement, contain the entire understanding of the parties with respect to the matters contained herein, and supersedes all proposals and agreements, written or oral, and all other communications between the parties relating to the subject matter of this Agreement. This Agreement will be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without regard to its conflict of laws rules that would result in the application of the laws of another jurisdiction. Advisor and the Company each hereby submit to the exclusive personal jurisdiction of the federal and state courts located in Massachusetts in connection with any disputes as to the meaning, effect, performance or validity

of this Agreement or arising out of, related to, or in any way connected with, this Agreement or Advisor's relationship with the Company. This Agreement may not be modified or amended except in

writing signed or executed by Advisor and the Company. In the event any provision of this Agreement is held to be unenforceable or invalid because it is overbroad or too far reaching, such provision will be deemed to be revised so that it applies to the maximum extent permitted by law.

IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed as of the date first set forth above.

ADVISOR SERES THERAPEUTICS, INC.

/s/ David Arkowitz /s/ Tom DesRosier

David Arkowitz Name: Tom DesRosier

Date: March 15, 2024 Title: EVP, CLO

Date: March 15, 2024

Exhibit 10.5

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

CONFIDENTIAL

September 15, 2015

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (the "**Agreement**"), effective as of September 15, 2015 (the "**Effective Date**"), is made and entered into by and between Seres Therapeutics, Inc. (formerly Seres Health, Inc.), a corporation organized and existing under the laws of Delaware, having its principal place of business at 215 First Street, Cambridge MA 02142, USA ("**Seres**"); and GenIbet BioPharmaceuticals, SA, a corporation organized and existing under the laws of Portugal, having its principal place of business at Edifício da Unidade Piloto do IBET, Estação Agronómica Nacional, Avenida da República, 2780-157 Oeiras, Portugal ("**GenIbet**"). Seres and GenIbet may be referred to herein individually as a "**Party**" or collectively as the "**Parties**."

WHEREAS, Seres desires to have SER-109, SER-262, SER-287 and other products (each a "**Product**" and collectively, the "**Products**") manufactured by a third party for purposes of conducting clinical trials and commercial supply;

WHEREAS, GenIbet has expertise and cGMP-compliant facilities for the manufacture of products similar to the Products at its manufacturing facility located at Edifício da Unidade Piloto do IBET, Estação Agronómica Nacional, Avenida da República, 2780-157 Oeiras, Portugal (the "**Facility**");

WHEREAS, GenIbet desires to modify a manufacturing suite for the manufacture of the Products and to supply such Products to Seres, all in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and obligations set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. DEFINITIONS

Capitalized terms used but not defined in this Agreement shall have the meaning given in Exhibit 1.

2. AREAS

2.1 Dedicated Area in GenIbet's Facility.

2.1.1 GenIbet shall modify the dedicated bacterial suite (including fermentation, and purification rooms), the non-dedicated preparation room and access hallways as depicted on Exhibit 2 in the Facility for the performance of the activities relating to the Manufacture of the Products under this Agreement (the "**Seres Dedicated Area**"), and the raw materials and product storage areas depicted on Exhibit 2 in accordance with the construction plans and requirements attached hereto as Exhibit 2.

|||

2.1.2 GenIbet shall complete the construction, qualification and commissioning of the initial Seres Dedicated Area on or before [***] (the "**Deadline**"). The Deadline shall be equitably adjusted to reflect delays resulting solely from changes requested by Seres under Section 5 or otherwise by mutual agreement of the Parties.

2.1.3 GenIbet shall notify Seres upon completion of the Seres Dedicated Area that it is ready for acceptance. GenIbet shall provide Seres with all test results, evidence of conformance to applicable cGMP requirements, evidence of health, safety and environmental compliance as required under Section 9.7 hereof, and such other information reasonably requested by Seres for it to determine whether to accept or reject the Seres Dedicated Area.

2.1.4 Seres may only reject the Seres Dedicated Area if it does not fully comply with the agreed Project Plan and requirements of Exhibit 2. In this case, GenIbet shall correct the deficiencies so that the Seres Dedicated Area fully complies with the Project Plan and requirements of Exhibit 2 as promptly as possible and shall notify Seres that it is ready for acceptance. The date on which Seres accepts the Seres Dedicated Area is the "**Area Acceptance Date**". If the Area Acceptance Date is more than [***] after the Deadline, Seres may terminate this Agreement without liability or elect in its sole discretion to renegotiate the terms of this Agreement.

2.1.5 The use of the Seres Dedicated Area during the Term (as defined in Section 15.1) is solely for the purpose of Manufacturing the Products and for related activities benefitting Seres, and GenIbet shall not use the Seres Dedicated Area for any other purpose not approved in advance by Seres in writing. GenIbet agrees to make the Seres Dedicated Area available to Seres personnel and their designees as and when requested by Seres, provided that (i) the total number of people inside the units at the same time complies, at all times, with the provisions of cGMP; (ii) Seres personnel and their designees do not, at any time or in any way, compromise the Manufacturing process, and (iii) Seres personnel are trained in GenIbet SOPs required for their presence in the unit during Manufacturing.

2.2 Non-Dedicated Area in GenIbet's Facility

2.2.1 GenIbet will provide Seres with cGMP-compliant space that is sufficient for the Manufacture of Products in accordance with this Agreement, including (i) a preparation room; and (ii) storage spaces for Raw Materials, Consumables, process intermediates and Product (collectively, the "**Non-Dedicated Area**").

2.2.2 The storage spaces within the Non-Dedicated Area will have the appropriate environmental controls for temperature and humidity to meet the environmental storage requirements per the most relevant material specifications defined by the vendor or relevant pharmacopeia. These requirements shall be further specified in the appropriate documents and the Quality Agreements.

2.2.3 GenIbet's use of the Non-Dedicated Area for its other projects will not compromise: (i) Seres's Manufacturing schedule in the Seres Dedicated Area or the quality of the Raw Materials, Consumables, process intermediates and Product; or (ii) the cGMP compliance status of the Facility and activities related to the Manufacture of Product.

2.3 Seres Specialized Equipment.

2.3.1 Seres has or may provide the specialized equipment (non-permanent installation equipment) identified on Exhibit 2 for use by GenIbet in Manufacturing Product on behalf of Seres (the "**Specialized Equipment**"). GenIbet agrees not to use the Specialized Equipment in performing services for itself or for third parties.

2.3.2 GenIbet shall maintain the Specialized Equipment in accordance with the manufacturer's recommendations (other than as agreed with Seres) provided that the latest version of such recommendations is provided by Seres to GenIbet, as required to maintain the Specialized Equipment in accordance with this Agreement and the applicable Quality Agreement and otherwise in accordance with the maintenance plan set forth in the Product Manufacturing Plan.

2.4 Facility Closures. Within [***] after the Effective Date and on [***] thereafter, GenIbet shall propose to Seres a schedule showing all national and corporate holidays and Facility shutdowns for the next 12 months for Seres' review and approval. GenIbet shall not close the Facility on any day other than the dates identified in such schedule without Seres' prior approval.

3. DESCRIPTION OF WORK

3.1 Manufacture and Supply.

3.1.1 From and after the Area Acceptance Date, GenIbet shall Manufacture and supply to Seres the Products in accordance with a Master Batch Record. Notwithstanding the foregoing, before GenIbet commences Manufacture of a Product hereunder, the Parties shall agree in writing upon a Product Manufacturing Plan. Within [***] of the Effective Date, the Parties will agree a global Product Manufacturing Plan for SER-109, which will be incorporated into this Agreement as Exhibit 3.

3.1.2 The specifications for a Product set forth in the applicable Product Manufacturing Plan and/or Master Batch Record may be amended by Seres from time to time in accordance with Section 5.

3.2 Forecasts and Purchase Orders.

3.2.1 Within [***] after the Effective Date, Seres shall provide to GenIbet a non-binding [***] forecast of its estimated requests for each Product and update it within [***] after each calendar [***] (beginning on [***], so that GenIbet shall [***] rolling forecast as to the needs of Seres). Following receipt of each forecast, and without limiting its obligations to supply the Product in accordance with this Agreement, GenIbet shall promptly provide Seres [***] GenIbet's ability to provide the Product in accordance with such forecast.

3.2.2 Seres shall submit in writing or electronically purchase orders ("**Purchase Orders**") for the Product to GenIbet. If Seres submits a Purchase Order to GenIbet without providing at least the Minimum Lead Time, GenIbet will not be required to deliver the ordered Product by the requested delivery date, but will use Commercially Reasonable Efforts to deliver the Product in the Purchase Order on the requested date, but in any event shall deliver the Product within the applicable Minimum Lead Time. The "**Minimum Lead Time**" for SER-109 is [***], and for other Products shall be as set forth in the applicable Product Manufacturing Plan.

|||

3.2.3 Unless GenIbet expressly notifies Seres otherwise, GenIbet shall be deemed to have accepted any and all such Purchase Orders from Seres; provided that Purchase Orders (other than the Last Time Buy under Section 15.7.5) that exceed the forecasts by more than [***]% in any calendar quarter for the purchase of the Product shall not bind GenIbet for the excess quantity until such Purchase Orders for such excess quantity are accepted by GenIbet. Each Purchase Order shall identify the Product being ordered, the quantity being ordered and the desired shipping date.

3.3 Staffing Plan.

3.3.1 Within [***] after the Effective Date, GenIbet shall prepare for Seres' review and approval a reasonable staffing plan. The staffing plan will include: at least [***], at least [***]. The [***] shall be agreed to by the Parties and stipulated in the applicable Purchase Order. Notwithstanding the foregoing, GenIbet shall employ a sufficient number of trained employees to ensure that GenIbet is able to meet its obligations under this Agreement, including Manufacture and delivery of Products in accordance with this Agreement (including delivery of the Products on or before the delivery date specified in the applicable Purchase Order).

3.3.2 GenIbet shall use Commercially Reasonable Efforts to guarantee that any absences due to illness and vacation of the trained personnel will not affect the compliance of its obligations, up to and including retaining appropriately experienced and trained staff for overtime work at its own expense.

3.3.3 The persons dedicated to Manufacture of Product may work on the manufacture of products for GenIbet or its other customers upon approval from Seres, which shall not be unreasonably withheld or delayed. Work for other customers shall not compromise cGMP compliance or delivery dates for the Products.

4. MATERIALS

4.1 Supply of Proprietary Materials. Except as otherwise set forth in the applicable Product Manufacturing Plan, Seres or its designees shall obtain and supply to GenIbet those certain proprietary Materials specified in the Product Manufacturing Plan and/or Master Batch Record as necessary to Manufacture the Product, within the deadlines foreseen in the Master Batch Record. Seres shall further provide to GenIbet such data and information as necessary to apprise GenIbet of the proper storage and safe handling requirements for the Materials delivered by Seres or its designees.

4.2 Non-Proprietary Materials. Seres or its designees shall instruct GenIbet regarding non-proprietary materials which will need to be obtained directly by GenIbet, including, but not limited to, type of materials, supplier/place of purchase and proper storage and safe handling requirements.

4.3 Inspection and Storage of Materials. GenIbet shall handle and store the Materials in accordance with this Agreement and the applicable Quality Agreement. GenIbet shall inspect and release test the Materials to ensure that they meet the Materials specifications set forth in the applicable Master Batch Record. GenIbet shall retain aliquots of each Material shipment per the Master Batch Record to enable regulatory compliance and investigations.

5. CHANGES TO PRODUCT AND/OR SERES DEDICATED AREA.

5.1 Each Party promptly shall notify the other Party of new regulatory requirements of which it becomes aware which may reasonably be expected to impact the requirements for the Manufacture of Product under this Agreement and which are required by an applicable Regulatory Authority or Applicable Law, and shall confer with each other with respect to the best means to comply with such requirements. GenIbet shall have no obligation to Manufacture Product in compliance with the requirements of a Regulatory Authority not explicitly specified in the Product Manufacturing Plan and/or Master Batch Record.

5.2 If changes to the Seres Dedicated Area, Product Manufacturing Plan, and/or Master Batch Record are required of the Parties as a result of requirements set forth by a Regulatory Authority, and such changes apply solely to the Seres Dedicated Area and Manufacture and supply of one or more Products, then Seres and GenIbet will review such requirements and agree in writing to changes to the Seres Dedicated Area, Product Manufacturing Plan, and Master Batch Record, and [***].

5.3 If changes resulting from the requirements of a Regulatory Authority apply generally to one or more Products as well as to other products produced by GenIbet for itself or for third parties, or to the Non-Dedicated Area, then Seres and GenIbet will review such requirements and agree in writing to changes to the Non-Dedicated Area, Product Manufacturing Plan, and Master Batch Record, and [***].

5.4 Subject to the foregoing, and notwithstanding anything to the contrary herein, GenIbet shall not make any changes to the Seres Dedicated Area, Non-Dedicated Area, Product Manufacturing Plan, and/or Master Batch Record that would reasonably be expected to have an impact on Seres or the Products [***].

6. MANUFACTURE

6.1 Testing Prior to Delivery. GenIbet shall conduct in-process testing of each Batch of Product according to the applicable Master Batch Record prior to delivery of such Batch by GenIbet to Seres or its designee. Unless exclusively due to any act or omission by Seres, if an in-process Batch of Product is not compliant with the Master Batch Record, GenIbet shall, [***], handle, store, transport, treat and dispose of such Product according to all applicable laws, directives, codes, rules, regulations, ordinances, orders, permits, licenses, consents and other authorizations (including but not limited to the environment and employee health and safety). Notwithstanding the foregoing, if reprocessing, rework or reproduction is allowed pursuant to Seres' regulatory submissions or approved by Seres, it shall be performed in accordance with the Quality Agreement and cGMP and, unless such reprocessing, rework, or reproduction results from Seres' acts or omissions, [***] in connection with such reprocessing, rework or reproduction.

6.2 Facility. GenIbet shall Manufacture each Product at the Facility, utilizing the Seres Dedicated and Non-Dedicated Areas. GenIbet shall maintain, [***], the Facility (including, without limitation, the Seres Dedicated Area) in a state of repair and operating efficiency consistent with the requirements of cGMP and other Applicable Law.

6.3 In the event any change in the Product Manufacturing Plan for a Product requested by Seres or mandated by Applicable Law or any increase in order volume requested by Seres results in any regulatory or other costs to GenIbet, or requires that GenIbet make any expenditures at the Facility or within the Seres Dedicated Area or Non-Dedicated Area, such costs and expenditures shall be [***].

6.4 Acceptance and Rejection

|||

6.4.1 GenIbet shall deliver to Seres, concurrently with the delivery of each Batch of Product, a Certificate of Compliance and such other documents and materials required to be delivered under the applicable Quality Agreement. Within [***] after delivery of any Batch of Product to Seres, Seres shall examine such Batch to determine whether the Product conforms to the Master Batch Record. No claims for non-compliance with the Master Batch Record or shortage in quantity of any individual shipment of any Product shall be valid unless made by written notice given within [***] from the date of delivery, except in the case of latent defects (defects not reasonably ascertainable upon a physical inspection of the Batch), in which case such claims shall be made in writing within [***]. Any such notice shall describe [***]. Failure to deliver a notice of non-conformance in the manner contemplated in this Section 6.4.1 shall constitute an acceptance of the applicable Batch by Seres.

6.4.2 If Seres notifies GenIbet under Section 6.4.1 that a shipment of Product has failed, in whole or in part, to meet the Master Batch Record, Seres will conduct [***]. If Seres determines that any part of the shipment fails to meet the Master Batch Record, Seres will provide [***] the results of Seres' testing; it being understood and agreed [***] proprietary.

6.4.3 If the affected Product fails to conform to the Master Batch Record, GenIbet shall make up any shortfall and/or replace any non-conforming Product or rework any rejected Product, if applicable, [***]; provided that GenIbet shall have no liability or obligation to Seres under this Section 6.4.3 if any such defect or non-conformance is not due to [***]. Upon GenIbet's instructions, Seres shall destroy or return, in either case at [***], any non-conforming Product; provided that if it is determined that any such defect or non-conformance is not due to [***].

6.5 Delivery. GenIbet shall deliver all Product FCA (Incoterms 2010) at the Facility. To the extent that Seres complies with the delivery dates regarding the supply to GenIbet of Materials and Specialized Equipment, GenIbet shall deliver to Seres the amount of Product specified in each Purchase Order no later than the dates specified therein. On or before the delivery date specified in the applicable Purchase Order, GenIbet shall, as directed by Seres, deliver the Product to a carrier designated by Seres or into storage at the Facility. All Purchase Orders shall be filled in compliance with the terms and conditions of this Agreement and the Master Batch Record, including any packaging, handling, storage and labeling requirements set forth on the Master Batch Record.

6.6 Storage. GenIbet will store Products [***] after GenIbet's release or the period required by applicable cGMPs, whichever is longer (the "**Storage Period**"). The Storage Period may be extended only if agreed to by the Parties in writing. After the Storage Period, if GenIbet agrees to store Product longer, then GenIbet may charge the storage fees as set forth in Exhibit 4. GenIbet shall store all Products in accordance with Applicable Law and Seres' reasonable instructions. Notwithstanding anything to the contrary in the foregoing, with respect to Product intended for commercial distribution, GenIbet shall maintain the amount of safety stock (the "**Safety Stock**") of each Batch of Product in quantities to be agreed upon by the Parties in good faith at least [***] prior to the first expected delivery date of Product for commercial distribution. Such Safety Stock shall be stored in accordance Seres' reasonable instructions and cGMPs, and shall be maintained for the period required by cGMPs, unless the Product Manufacturing Plan sets forth a longer period.

6.7 [***].

7. INTELLECTUAL PROPERTY

7.1 Existing Intellectual Property. Except as the Parties may otherwise expressly agree in writing, each Party shall continue to own its existing patents, trademarks, copyrights, trade secrets and other intellectual property, without conferring any interests therein on the other Party. Without limiting the generality of the preceding sentence, as between GenIbet and Seres, Seres shall own all right, title and interest arising under Applicable Law in and to all Products, Seres technology and labeling and trademarks associated therewith, including any improvements and modifications relating thereto, and any Inventions based on Seres' Confidential Information (collectively, **"Seres Intellectual Property"**). Neither GenIbet nor any third party shall acquire any right, title or interest in Seres' Intellectual Property by virtue of this Agreement or otherwise, except to the extent expressly provided herein. GenIbet hereby assigns (and will cause its personnel and any third parties involved in the performance of its obligations hereunder to assign) to Seres, without further compensation being due, any right, title and interest they may have in any Seres Intellectual Property. GenIbet agrees to take such steps and execute such documents as may be reasonably requested by Seres to perfect Seres' ownership of Seres' Intellectual Property.

7.2 License.

7.2.1 Subject to the terms of this Agreement, Seres will grant GenIbet on the Area Acceptance Date a non-exclusive, royalty-free, revocable license to (i) make the Products in the Seres Dedicated Area; and (ii) use the trademarks of Seres identified in the Product Manufacturing Plan solely in connection with its labeling of Products, in each case during the Term and solely at the Facility. Such licenses shall not be sublicensable, assignable or transferable in whole or in part. GenIbet's use of Seres' trademarks shall comply with Seres' usage guidelines. GenIbet hereby assigns to Seres all goodwill associated with the use of Seres' trademarks. In the event that GenIbet becomes aware of any possible or actual infringement by a third party of Seres' Intellectual Property, it shall provide immediate written notice to Seres.

7.2.2 GenIbet hereby grants (and shall cause any third party licensors of Licensed Know-How to grant) Seres a non-exclusive, transferable, royalty-free, irrevocable, perpetual, worldwide license to use and modify any GenIbet Intellectual Property, together with a right to sublicense the GenIbet Intellectual Property and Licensed Know-How to any third party manufacturer solely for purposes of manufacturing products for Seres and its Affiliates and business partners. "**GenIbet Intellectual Property**" means any processes or know-how owned by or licensed to GenIbet that GenIbet uses to Manufacture the Products for Seres under this Agreement.

7.3 Technology Transfer. Subject to the terms of this Agreement, Seres shall promptly provide GenIbet all the documentation, information, Specialized Equipment (including specifications therefor), and materials that are necessary for the Manufacture of the Products. All such documentation, information, Equipment and materials shall remain the sole and exclusive property of Seres.

7.4 Disclaimer. Except as otherwise expressly provided herein, nothing contained in this Agreement shall be construed or interpreted, either expressly or by implication, or otherwise, as: (i) a grant, transfer or other conveyance by either Party to the other of any right, title, license or other interest of any kind in any of its Inventions or other intellectual property, (ii) creating an obligation on the part of either Party to make any such grant, transfer or other conveyance or (iii) requiring either Party to participate with the other Party in any cooperative development program or project of any kind or to continue with any such program or project.

|||

7.5 Confidentiality of Intellectual Property. Intellectual Property shall be deemed to be the Confidential Information of the Party owning such Intellectual Property. The protection of each Party's Confidential Information is described in Section 11.

8. SUBCONTRACTORS

GenIbet shall not subcontract its obligations under this Agreement (other than with respect to the construction of Seres Dedicated Area) without the prior written consent of Seres, which consent shall not be unreasonably withheld or delayed. [***]. GenIbet shall cause its subcontractors to execute agreements with provisions substantially similar to the provisions in Sections 7, 11, and 12.2. Seres may revoke its approval of a subcontractor if the subcontractor breaches Section 7, 11, and 12.2 in any material respect.

9. REGULATORY AND QUALITY MATTERS

9.1 Permits, Registrations and Licenses.

9.1.1 Seres will be responsible, [***], for obtaining, maintaining, updating and remaining in compliance with all permits, licenses and other authorizations during the Term of this Agreement, which are necessary or required under federal, state, and local laws, rules and regulations which are applicable to the use of Product Manufactured by GenIbet hereunder. GenIbet will be responsible for, [***], obtaining and maintaining all generally required permits, registrations and licenses applicable to the Facility and to the production of pharmaceutical and biological products generally to the extent required for GenIbet to carry out its regulatory and Manufacturing obligations hereunder.

9.1.2 Without limitation on the foregoing in Section 9.1.1, GenIbet will prepare and deliver to Seres a Site Master File (SMF) in accordance with the Quality Agreement. Seres may utilize the SMF only in connection with the preparation of regulatory filings related to the Products. Any other use of the SMF by Seres shall require the prior written approval of GenIbet.

9.2 Quality Agreement. Within [***] of the Effective Date, the Parties shall agree in writing to a revised Clinical Quality Agreement and within [***] of the Effective Date, the Parties shall agree in writing to a Commercial Quality Agreement. [***]. The Quality Agreements are intended to supplement this Agreement, and shall be incorporated in this Agreement in its entirety, except that in the event of a conflict between any term, condition or provision of this Agreement and any term, condition or provision of the Quality Agreements, the applicable term, condition or provision of the Quality Agreement shall control unless specifically set forth otherwise in this Agreement or otherwise agreed in writing by the Parties.

9.3 Facility Audits. Representatives (including internal and external auditors) of Seres and its Affiliates (a) shall upon [***] review GenIbet's quality control procedures; and (b) may, during normal business hours and [***], conduct a supplier audit of the Facility and Seres Dedicated Area. GenIbet shall make available the Facility, Seres Dedicated Area and its personnel to representatives (including internal and external auditors) of Seres and its Affiliates for purposes of verifying that the Products are being Manufactured and supplied in accordance with the applicable Specifications and Applicable Law and that GenIbet is in compliance with the terms of this Agreement. GenIbet shall promptly remedy or cause the remedy of any deficiencies that may be noted in any such audit.

9.4 Inspections by Regulatory Authorities. Seres shall give GenIbet advance notice, to the extent that advance notice is given to Seres, of any site visit to the Facility by any Government Authority, the

purpose of which is to inspect the Manufacture of any Product or the compliance status of the Facility under Applicable Law, in accordance with the terms and conditions of the Quality Agreements. In any event, GenIbet shall advise Seres of the occurrence of any such visit immediately upon such visit, and GenIbet shall furnish to Seres all material information supplied to, or supplied by, any Government Authority, including the Form 483 (and foreign equivalent) observations and responses, to the extent that such information relates to such Product or the ability of GenIbet to comply with the terms of this Agreement or Applicable Law. In addition, and without limitation on the foregoing, to the extent permitted by the applicable Government Authority, representatives of Seres shall be permitted to participate in any such site visit by a Government Authority, and GenIbet shall provide Seres with a reasonable opportunity to review and comment upon any response to the Government Authority to the extent the response relates to Product prior to delivery to the Government Authority.

9.5 Adverse Event Reporting. Seres shall be responsible for reporting adverse events and complaints with respect to any Product (including the Materials), and for responding to any such reports and complaints, in accordance with the terms and conditions of the applicable Quality Agreement. GenIbet shall promptly notify Seres of any information GenIbet receives related to an adverse event or complaint.

9.6 Recalls. In the event Seres is required to recall any Product, or elects to institute a voluntary recall, Seres will be responsible for coordinating such recall. Seres will promptly notify GenIbet of such recall and provide GenIbet with a copy of all documents relating to such recall. GenIbet will cooperate with Seres in connection with any recall, [***], unless the recall is determined to have been necessitated by [***] to perform the Manufacturing activities at issue in accordance with Applicable Law or this Agreement. [***] will be responsible for all of the costs and expenses of recalls (including but not limited to costs associated with receiving and administering the recalled Product and notification of the recall to those persons whom Seres deems appropriate)), except for recalls determined to have been necessitated by [***] to perform the Manufacturing activities at issue in accordance with Applicable Law or this Agreement, in which case [***] will be responsible for all of the costs and expenses of such recalls.

9.7 Health, Safety and Environmental Compliance. All Manufacturing operations are to be performed using appropriate safety measures and containment techniques as dictated by Applicable Law and industry standards. GenIbet shall be solely responsible for implementing and maintaining health and safety procedures for the Manufacture of Product and performance of services under this Agreement and for the handling of any materials or hazardous waste used in or generated by such activities. GenIbet, in consultation with Seres, shall develop safety and handling procedures for Materials and Product; provided, however, that Seres shall have no responsibility for GenIbet's health and safety program. The generation, collection, storage, handling, transportation, movement and release of hazardous materials and waste generated in connection with the Manufacture of Product and other services under this Agreement shall be the responsibility of GenIbet at GenIbet's cost and expense, unless otherwise agreed to in writing by the Parties for special situations or conditions. Without limiting other legally applicable requirements, GenIbet shall prepare, execute and maintain, as the generator of waste, all licenses, registrations, approvals, authorizations, notices, shipping documents and waste manifests required under Applicable Law.

9.8 Distribution within European Union. In the event that Seres seeks to distribute Product, including as an investigational medicinal product, within the European Union or any member states thereof, Seres will be responsible [***] for obtaining all permits, licenses and other authorizations required by Applicable Law.

10. CHARGES, INVOICING, PAYMENT AND TAXES

10.1 Charges.

10.1.1 The Charges under this Agreement are set forth in Exhibit 4.

10.1.2 The Charges under Section 1 of Exhibit 4 shall be adjusted [***] for fluctuations in the exchange rate between the United States Dollar and the Euro. The adjustment shall be as follows:

(Current Exchange Rate - Baseline Exchange Rate) / Baseline Exchange Rate, where

"Baseline Exchange Rate" means the Euro to Dollar exchange rate, as quoted in the Wall Street Journal published [***].

"Current Exchange Rate" means the Euro to Dollar exchange rate, as quoted in the Wall Street Journal published [***].

10.2 Invoicing.

10.2.1 GenIbet shall promptly invoice Seres for the fixed monthly charges under Section 1 of Exhibit 4 and the [***] under Section 2 of Exhibit 4 on a monthly basis in arrears. GenIbet shall send invoices to [***].

10.2.2 GenIbet shall invoice Seres for the per-Batch charges [***] for each Batch in accordance with Section 3 of Exhibit 4.

10.3 Payment Terms. Except as otherwise stated in Exhibit 4, Seres shall pay all undisputed amounts pursuant to this Agreement within [***] after receipt of an invoice therefor from GenIbet by direct wire transfer of United States Dollars in immediately available funds in the requisite amount to [***].

10.4 Disputed Amounts. In the event of any dispute on the amounts, [***].

10.5 Taxes

10.5.1 Retained Taxes. Each Party will be responsible for the payment of any taxes, levies and charges on its own personal and real property, business and franchise and privilege taxes on its business, and for taxes based on its net income or gross receipts ("**Income Taxes**"), in each case that are imposed by applicable Government Authorities (collectively, the "**Retained Taxes**"). If required by Applicable Law, Seres will be entitled to withhold an amount in respect of any Income Tax from any payment to GenIbet only to the extent GenIbet does not benefit of any exemption of withholding tax under applicable tax treaties or to the limit of any reduced withholding tax GenIbet may benefit under applicable tax treaties. Seres shall inform GenIbet in writing in advance of any such required tax withholding, as well as, of any reduced withholding tax or exemption of withholding tax GenIbet may benefit under applicable tax treaties and the respective formalities. If any amounts in respect of Income Taxes are withheld by Seres, Seres shall pay such amounts over to the applicable Governmental Authority and provide documentation to GenIbet evidencing such payment.

|||

10.5.2Export/Import Taxes. [***] shall be responsible for the taxes, duties, tariffs, consular fees, levies, penalties, and other charges imposed by applicable Governmental Authorities on the import or export of the of Products ("**Export/Import Taxes**") to the extent such Party is responsible for such amounts in accordance with the Incoterms® 2010 delivery terms set forth in Section 6.5.

10.5.3Other Taxes. [***] shall be responsible for all goods, VAT, sales, use, consumption and other similar taxes, levies and charges (other than Retained Taxes and Export/Import Taxes) imposed by applicable Governmental Authorities in connection with the delivery of the Products to Seres or any invoice. [***].

1.1.1EU VAT Directive. Cross-Border sales of Products may fall within Article 44 of the EU VAT Directive or the relevant equivalent national provision, so that GenIbet is not required to charge VAT. In such case, with respect to each applicable jurisdiction, [***].

1.1.1Cooperation. Each Party shall cooperate, as reasonably requested by the other, to minimize the amount of all amounts payable to Government Authorities under this Section 10.5, including by claiming any available exemption or any available refund, credit or other recovery, and by executing and filing any invoices, forms or certificates reasonably required, in each case, to the extent that doing so would not adversely affect such Party.

10.6Audits. GenIbet shall maintain full and accurate financial records pertaining to amounts invoiced under this Agreement on a consistent basis and in accordance with GAAP for [***] after their creation or such longer period as may be required under Applicable Law. Such records shall include [***]. Upon Seres' request, GenIbet will provide Seres or its independent auditor with access to [***].

10.7Foreign Corrupt Practices Act. The Parties confirm that any compensation payable hereunder does not constitute remuneration or other means to attempt to corruptly influence a Government Official (as such term is defined in the U.S. Foreign Corrupt Practices Act of 1977 (the "**FCPA**")) to act in his official capacity to assist either Seres or GenIbet in obtaining or retaining business. In connection with each Party's obligations under this Agreement, and to the extent the FCPA applies to either Party's obligations under this Agreement, neither Seres nor GenIbet has made or offered, or hereafter will make or offer, directly or indirectly, any payment or inducement to a Government Official with the intent to corruptly influence a Government Official to act in his official capacity to assist either Seres or GenIbet in obtaining or retaining business. In connection with this Agreement, neither Party will give to or accept from any other person anything of value in order to obtain an improper business advantage. Any breach of the foregoing provision will be deemed a material breach of this Agreement that is not capable of relief and will entitle the nonbreaching Party to terminate this Agreement with immediate effect.

11. CONFIDENTIALITY

11.1Confidentiality Obligations. Each Party agrees that such Party will use reasonable efforts to keep confidential any Confidential Information of the other Party. The foregoing obligations will not apply to any information to the extent that:

11.1.1 Was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure;

11.1.2 Was generally available to the public or was otherwise part of the public domain at the time of its disclosure to the receiving Party;

11.1.3 Became generally available to the public or otherwise becomes part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; or

11.1.4 Was subsequently lawfully disclosed to the receiving Party by a third party other than in contravention of a confidentiality obligation of such third party to the disclosing Party.

Each Party may disclose the other Party's Confidential Information to the extent such disclosure is reasonably necessary for prosecuting or defending litigation, advising investors and the investment community of the results of activities hereunder (subject to the prior written consent of the other Party, which consent will not be unreasonably withheld), complying with applicable governmental regulations, granting a permitted sublicense of its rights hereunder or otherwise in performing its obligations or exercising its rights hereunder. If a Party is required to make any such disclosure of the other Party's Confidential Information, it will give reasonable advance notice to that other Party of such disclosure requirement, will cooperate with the other Party in its efforts to secure confidential treatment of such Confidential Information prior to its disclosure, and, except to the extent inappropriate in the case of patent applications, will use all reasonable efforts to secure confidential treatment of such information prior to its disclosure (whether through protective orders or confidentiality agreements or otherwise).

11.2Public Announcement; Agreement Terms. Except to the extent required by Applicable Law, neither Party shall make any public announcements concerning this Agreement or the terms hereof without the prior written consent of the other Party. The terms and conditions of this Agreement shall be Confidential Information of the Parties.

12. REPRESENTATIONS, WARRANTIES, UNDERTAKINGS, AND COVENANTS

12.1By Each Party. Each Party represents, warrants, undertakes and covenants to the other that: (i) it is duly organized and validly existing under the laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement; (ii) it has all necessary power and authority to execute and deliver this Agreement, to perform its obligations hereunder and to consummate the transactions contemplated hereby; (c) its execution and delivery of this Agreement have been duly and validly authorized by all necessary action, and no other proceedings on its part are necessary to authorize this Agreement or to consummate the transactions contemplated hereby; and (iii) this Agreement has been duly authorized and validly executed and delivered by it and constitutes a legal, valid and binding obligation on it, enforceable against it in accordance with the terms of this Agreement.

12.2By GenIbet. GenIbet represents, warrants, undertakes and covenants that: [***].

12.3Disclaimer of Warranties. EXCEPT AS SPECIFICALLY SET FORTH IN THIS SECTION 12, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR USE, NON-INFRINGEMENT AND ANY OTHER STATUTORY WARRANTY.

13. INDEMNIFICATION

13.1Indemnification by Seres. Seres shall indemnify, defend and hold GenIbet and its Affiliates, agents, employees, officers and directors (the "**GenIbet Indemnitees**") harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneys' fees) arising out of third party claims or suits related to: (a) Seres' performance of, or failure to perform, its obligations under this Agreement; (b) breach by Seres of any of its representations, warranties, covenants and undertakings under this Agreement; and (c) GenIbet's use of the Seres Intellectual Property in the manner expressly permitted under this Agreement; provided, however, that Seres' obligations pursuant to this Section 13.1 will not apply to the extent such claims or suits result from the acts or omissions of any of the GenIbet Indemnitees or to the extent such claims or suits are the responsibility of GenIbet under Section 13.2.

13.2Indemnification by GenIbet. GenIbet shall indemnify, defend and hold Seres and its Affiliates and business partners, and their respective agents, employees, officers and directors (the "**Seres Indemnitees**") harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneys' fees) arising out of Third Party claims or suits related to: (a) GenIbet's performance of, or failure to perform, its obligations under this Agreement; (b) breach by GenIbet of any of its representations, warranties, covenants and undertakings under this Agreement; and (c) [***].

13.3Notification of Claim . A Party seeking indemnification shall: (a) promptly notify ("**Claim Notice**") the indemnifying Party as soon as it becomes aware of a claim or suit for which indemnification may be sought pursuant hereto (provided that the failure to give a Claim Notice promptly shall not prejudice the rights of an indemnified Party except to the extent that the failure to give such prompt notice materially adversely affects the ability of the indemnifying Party to defend the claim or suit); (b) cooperate with the indemnifying Party in the defense of such claim or suit, at the expense of the indemnifying Party; and (c) if the indemnifying Party confirms in writing to the indemnified Party its intention to defend such claim or suit within [***] after receipt of the Claim Notice, permit the indemnifying Party to control the defense of such claim or suit, including without limitation the right to select defense counsel; provided that if the indemnifying Party fails to (i) provide such confirmation in writing within the [***] period; or (ii) diligently and reasonably defend such suit or claim at any time, its right to defend the claim or suit shall terminate immediately upon [***] written notice to the indemnifying Party and the indemnified Party may assume the defense of such claim or suit [***]. In no event, however, may the indemnifying Party [***].

14. DISPUTE RESOLUTION

14.1 Any dispute arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination, shall be referred to and finally resolved by arbitration under the [***], which Rules are deemed to be incorporated by reference into this clause.

14.2 The number of arbitrators shall be [***]. The seat, or legal place, of arbitration shall be [***]. The language to be used in the arbitral proceedings shall be English.

14.3 The Parties further consent to the jurisdiction of any state court located within a district that encompasses assets of a Party against which a judgment has been rendered for the enforcement of such judgment or award against the assets of such Party.

|||

15. TERM AND TERMINATION

15.1Term. This Agreement will commence upon the Effective Date and shall continue in full force and effect for the period of [***] after the Effective Date, unless terminated earlier in accordance with this Agreement or extended in accordance with this Section 15.1 (the "**Term**"). Seres may extend the Term [***] on the then-current terms and conditions.

15.2Termination for Convenience. Subject to the early termination fees in Section 15.3 of this Agreement, Seres may terminate this Agreement [***].

15.3Early Termination Fees. In the event that Seres terminates the Agreement under Section 15.2 prior to the third anniversary of the Effective Date has expired, the following early termination fees will apply:

15.3.1[***];

15.3.2[***];

15.3.3[***].

15.4Termination for Cause.

15.4.1 Seres may terminate this Agreement upon a date set forth in a notice of termination if GenIbet breaches a material obligation under this Agreement and fails to cure it within [***] after notice of termination by Seres. Any such notice shall describe, in detail, the breach of the material obligation.

15.4.2 GenIbet may terminate this Agreement upon a date set forth in a notice of termination if Seres fails to make any payment in accordance with Section 10.3 and Exhibit 4 and fails to cure such failure within [***] after notice of termination.

15.5Termination for Insolvency. To the extent permitted under Applicable Law, within [***] after receiving notice of any of the following events, GenIbet with respect to Seres, and Seres with respect to GenIbet, shall have the right to terminate this Agreement forthwith on written notice: (a) dissolving or ceasing to do business; (b) making an assignment for the benefit of creditors; (c) being subject to the institution of insolvency, receivership, bankruptcy or other proceedings for settlement of debts, provided such proceedings have not been vacated within [***] and are being actively contested by such other Party; or (d) effecting a reorganization of its business or affairs using any creditor protection legislation.

15.6Termination for Change of Control. Seres may [***] if there is a Change of Control of GenIbet.

15.7Effect of Expiration or Termination.

1.1.1 In the event of termination or expiration of this Agreement, the Parties will endeavor to transition the Manufacturing services and technology transfer in such a manner as to not cause unreasonable inconvenience to either Party. The Parties will reasonably cooperate during such period to continue any such ongoing services and GenIbet shall perform such

functions reasonably necessary or required in connection with the orderly wind-down of any active project as required by the terms of this Agreement and Applicable Law.

1.1.1 Promptly upon a termination of this Agreement or at the request of the disclosing Party, the receiving Party shall return to the disclosing Party all Confidential Information of the disclosing Party in its possession, except for one copy that may be retained solely for archive purposes in a confidential legal file. Furthermore, GenIbet shall promptly return all Seres-supplied Materials, Seres-supplied or paid-for equipment (including the Specialized Equipment), records, Product, retained samples, reference standards, data, reports and other property, information and/or know-how in recorded form that was provided by Seres, or generated in the performance of the services under this Agreement, that are owned by or licensed to Seres, excepting that required to be retained by Applicable Law, litigation holds or for regulatory compliance.

1.1.2 In the event of termination by GenIbet pursuant to Section 15.4 (Termination for Cause), Seres shall pay GenIbet for Manufacturing and other services completed up to the effective date of such termination within [***] of Seres' receipt of all results, reports, data, samples, and other deliverables to be provided pursuant to this Agreement. In the event the funds received by GenIbet prior to such termination exceed costs incurred to the date of termination, GenIbet shall refund the difference to Seres within [***] after the effective date of termination.

1.1.3 Upon any termination of this Agreement other than for GenIbet's material breach, Seres: (i) shall purchase from GenIbet any existing inventories of Product conforming to the Master Batch Record and Manufactured in accordance with cGMP and the Master Batch Record, at the then-current per-Batch charge for the Manufacture of such Product under Section 3 of Exhibit 4; and (ii) may either: (a) purchase any Product in process held by GenIbet as of the date of the termination, at a price to be mutually agreed (it being understood that such price shall reflect, on a *pro rata* basis, work performed and non-cancelable, out-of-pocket expenses actually incurred by GenIbet with respect to the Manufacture of such in-process Product); or (b) reimburse GenIbet for all work performed and non-cancelable costs, and out-of-pocket expenses incurred by GenIbet and direct GenIbet to dispose of such material at [***] cost.

1.1.4 Upon a termination of this Agreement under Section 15.6, GenIbet (or its successor) shall: (i) continue to fill orders for Products submitted during the Run-Down Period; and (ii) fill a final order (the "**Last Time Buy**") for Products notwithstanding the then-current forecast. GenIbet or its successor will maintain the ability to produce up to 24 Drug Substance and 24 Drug Product lots for a Last Time Buy during the Run-Down Period. The "**Run-Down Period**" means the 12 month period commencing on the effective date of termination.

1.2 Survival. The following Sections of this Agreement shall survive its termination for any reason: 2.1.4, 2.3, 6.6, 7, 9, 10, 11, 12, 13, 14, 15, 16, 17.3, 17.5, 17.6, 17.7, 17.8, 17.9, 17.10, 17.11, and 17.12.

2. INSURANCE

15.8 GenIbet shall provide the following insurance coverage in the amounts specified:

2.1.1[***].

|||

2.1.2[***].

2.1.3[***].

15.9 The foregoing insurance covers shall be primary and non-contributing with respect to any other insurance or self-insurance that may be maintained by Seres and its Affiliates. [***]. GenIbet shall cause its insurers to issue a letter from the applicable insurer that evidences that the covers and policy endorsements required under this Agreement are maintained in force. The insurers selected by GenIbet shall have an [***] rating of [***] or better.

15.10 In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained during the entire Term and for a period of not less than [***] following the termination or expiration of the Term. During the Term and such [***] period, GenIbet shall use Commercially Reasonable Efforts not to permit any insurance set forth in Section 16.1 to be reduced, expired or canceled without the prior written consent of Seres**.**.

3. MISCELLANEOUS

3.1 Independent Contractors. This Agreement does not create a joint venture, partnership, employment relationship or other agency relationship between the Parties or their Affiliates. Neither Party shall be obligated with respect to any transaction and no obligation or rights or liabilities of any kind whatsoever are created (or shall be deemed to be created) as a result of this Agreement, or any other written or oral statement or any further actions by the Parties, except in the case of this Agreement for the provisions expressly contained herein.

3.2 Assignment. Except to the extent and in the manner provided in this Section 17.2, the Parties agree that their rights and obligations under this Agreement may not be transferred or assigned to a third party without the prior written consent of the other Parties, which consent may be withheld in each such other Party's sole discretion. Any assignment not in conformance with this Section 17.2 shall be null, void and of no legal effect. Notwithstanding the foregoing:

3.2.1a Party may transfer or assign its rights and obligations under this Agreement, without consent, to a successor to all or substantially all of its business or assets relating to this Agreement whether by sale, merger, operation of law or otherwise;

3.2.2 Seres may transfer or assign its rights and obligations under this Agreement without consent to an Affiliate; and

3.2.3 GenIbet may transfer or assign its rights and obligations under this Agreement without consent to an Affiliate that is at least as creditworthy as GenIbet.

3.3 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the express provisions of this Agreement.

3.4 Force Majeure. Neither Party shall be liable to the other Party for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by earthquake, riot, civil commotion, war, terrorist acts, flood, the other Party's non-performance, or other event that is both beyond the reasonable control of the respective Party and could not be avoided through

|||

reasonable precautions. The Party affected by such force majeure event will provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and will use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable. If there is a force majeure event, the Party affected by the force majeure event is excused from any default or delay for as long as and to the extent that: (i) such circumstances prevail; (ii) the affected Party is not at fault in causing the force majeure event and could not have avoided the default or delay through the use of reasonable precautions; (iii) the affected Party continues to use its Commercially Reasonable Efforts to recommence performance. If the performance by GenIbet of any obligation under this Agreement is delayed owing to a force majeure for any continuous period of more than [***], Seres shall have the right to either (i) [***]; or (ii) [***].

3.5 Entire Agreement of the Parties; Amendments; Waiver. This Agreement constitutes and contains the entire understanding and agreement of the Parties respecting the subject matter hereof and cancels and supersedes any and all prior and contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. No waiver, modification or amendment of this Agreement will be valid or effective unless made in writing and signed by each of the Parties. No waiver, modification or amendment of any other provision of this Agreement will be valid or effective unless made in writing and signed by both Parties. A waiver by either Party of any of the terms and conditions of this Agreement in any instance will not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach hereof.

3.6 Captions. The captions to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement.

3.7 Governing Law. This Agreement shall be governed by, and construed and interpreted, in accordance with the internal laws of the [***] without giving effect to any choice of law rule that would cause the application of the laws of any jurisdiction. It is hereby agreed that the United Nations' Convention on Contracts for the International Sale of goods shall have no application to this Agreement and it is hereby specifically excluded.

3.8 Notices and Deliveries. Any notice, request, delivery, approval or consent required or permitted to be given under this Agreement will be in writing and will be deemed to have been sufficiently given if delivered in person, transmitted by facsimile (receipt verified) or by express courier service (signature required) or [***] after it was sent by registered letter, return receipt requested (or its equivalent), provided that no postal strike or other disruption is then in effect or comes into effect within [***] after such mailing, to the Party to which it is directed at its address or facsimile number shown below or such other address or facsimile number as such Party will have last given by notice to the other Parties.

If to Seres, addressed to:

Seres Therapeutics, Inc.
215 First St., Suite 100
Cambridge, MA 02142, USA
Attention: [***]
Fax:+16179450268

If to GenIbet, addressed to:

GenIbet Biopharmaceuticals
Estação Agronómica Nacional
Avenida da Rebública, 2780-157 Oeiras,Portugal
Attention: [***]
Fax:+351214469480

3.9 No Consequential Damages.

3.9.1 SUBJECT TO SECTION 17.9.2, IN NO EVENT WILL ANY PARTY OR ANY OF ITS RESPECTIVE AFFILIATES BE LIABLE TO THE ANY OTHER PARTY OR ANY OF ITS AFFILIATES FOR: (I) SPECIAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, LOSS OF PROFITS OR REVENUE; OR (II) DIRECT DAMAGES IN EXCESS OF THE AMOUNTS PAID OR PAYABLE UNDER THIS AGREEMENT.

15.10.1 Section 17.9.1 shall not apply to a Party's obligations under [***].

3.10 Cumulative Remedies. All rights, remedies, undertakings, obligations and agreements contained in this Agreement will be cumulative and none of them will be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

3.11 Severability. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under Applicable Law, but if any provision of this Agreement is held to be prohibited by or invalid under Applicable Law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. The Parties will make a good faith effort to replace the invalid or unenforceable provision with a valid one so long as the essential benefits of this Agreement remain enforceable and obtainable.

3.12 Counterparts. This Agreement may be executed simultaneously in any number of counterparts, any one of which need not contain the signature of more than one Party but all such counterparts taken together will constitute one and the same agreement.

[Signature page follows]

|||

In Witness Whereof, the Parties have caused this Agreement to be executed by their respective duly authorized officers as of the Effective Date, each copy of which will for all purposes be deemed to be an original.

Seres Therapeutics, Inc.

By: /s/ Roger Pomerantz

Name: Roger Pomerantz, M.D.

Title: President and Chief Executive Officer

GenIbet BioPharmaceuticals

By: /s/ [***]

Name: [***]

Title: [***]

By: /s/ [***]

Name: [***]

Title: [***]

Exhibit 1

Definitions

As used in the Agreement, the following terms are defined as indicated:

"Active Pharmaceutical Ingredient" or **"API"** means the active pharmaceutical or biological ingredient as further set forth in the applicable Product Manufacturing Plan.

"Affiliate" means with respect to either Party, any business entity controlling, controlled by, or under common control with such Party. For the purpose of this definition only, "control" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract or otherwise, or (b) the ownership, directly or indirectly, of at least fifty percent (50%) of the voting securities or other ownership interest of a business entity; provided that, if local law requires a minimum percentage of local ownership, control will be established by direct or indirect beneficial ownership of one hundred per cent (100%) of the maximum ownership percentage that may, under such local law, be owned by foreign interests.

"**Applicable Law**" shall mean all international, national, federal, state, provincial and local laws, statutes, codes, guidelines, rules, regulations, ordinances, orders, decrees or other pronouncements of any governmental, administrative or judicial authority that apply to either of the Parties' respective obligations hereunder, including cGMP.

"Batch" shall mean a specific quantity of product that (a) is intended to have uniform character and quality within specified limits, and (b) is Manufactured according to a single manufacturing order during the same cycle of manufacture as further specified in the applicable Product Manufacturing Plan.

"Certificate of Compliance" means a document signed by the designated quality manager of GenIbet in connection with the Manufacture of a Batch of Product that evidences such Batch's compliance with cGMPs and Master Batch Record.

"Change of Control" means the occurrence of any one of the following: (a) any person (as the term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act)) is or becomes the beneficial owner (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of voting securities of GenIbet representing more than 50% of GenIbet's outstanding voting securities or rights to acquire such securities; (b) any sale, lease, exchange or other transfer (in one transaction or a series of transactions) of the Facility or all or substantially all of the assets of GenIbet; or (c) a plan of liquidation of the Company or an agreement for the sale or liquidation of the Company is approved and completed.

"Commercially Reasonable Efforts" mean taking such steps and performing in such a manner as a well-managed company would undertake where such company was acting in a determined, prudent, and reasonable manner to achieve the particular result provided always that such steps are within the reasonable control of the Party required to exert such efforts.

"Confidential Information" means any and all non-public and proprietary information that is specifically designated as such and that is disclosed by any Party to any other Party in written or other

similar form in connection with this Agreement; provided, however, that in the case of such information that is disclosed orally, the disclosing party shall deliver the required designation in writing to the receiving Party within 30 days after such disclosure.

"Consumables" shall mean the consumable products and packaging supplies and components, including, without limitation, all of the raw materials and packaging supplied required by GenIbet to Manufacture a Product as set forth in the applicable Product Manufacturing Plan.

"Control" means, with respect to an item or an intellectual property right, possession of the ability, whether arising by ownership or license, to grant a license or sublicense as provided for in this Agreement under such item or right without violating the terms of any written agreement with any Third Party.

"Current Good Manufacturing Practices" or **"cGMP"** shall mean the following to the extent having jurisdiction over the Manufacture of a Product and/or the Facility and Seres Dedicated Area: (a) the good manufacturing practices required by the FDA and set forth in the FD&C Act or FDA regulations (including without limitation 21 CFR 210 and 211); (b) the Commission Directive 2003/94/EC, laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use, and any amendment thereto; (c) the Commission Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products, and any amendment thereto; (d) the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, on the Community code relating to medicinal products for human use, and any amendment thereto; (e) the Guidelines on Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, approved by the European Commission and currently provided for at Eudralex - Volume 4 and any amendment thereto; (f) any local laws, statutes, codes, guidelines, rules, regulations, ordinances, orders, decrees or other pronouncements of any governmental, administrative authority enacting and/or implementing and/or regulating the provisions of (b) to (e), and (f) the PICS guidelines to good manufacturing practices in effect at any time during the Term of this Agreement. For the avoidance of doubt, when reference is made herein to "any amendment thereto" it shall include acts which supersede and replace the ones expressly provided for.

"Drug Product" shall mean the Drug Substance in its finished dosage form that is produced in accordance with the Master Batch Record.

"Drug Substance" shall mean the substance that is produced in accordance with the Master Batch Record and intended to be used in the manufacture of a drug product.

"FDA" shall mean the United States Food and Drug Administration or any successor entity thereto.

"FD&C Act" shall mean the United States Federal Food, Drug and Cosmetic Act, as may be amended from time to time.

"Government Authority TC "Government Authority" \f C \l "5" " means any supranational, national, regional, state or local government, court, governmental agency, authority, board, bureau, instrumentality, or regulatory body.

|||

“Intellectual Property” shall mean ideas, concepts, discoveries, inventions, developments, know-how, trade secrets, techniques, methodologies, modifications, innovations, improvements, writings, documentation, data and rights (whether or not protectable under state, federal or foreign patent, trademark, copyright or similar laws) or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable.

“Inventions” shall mean any inventions, discoveries, innovations, methods, improvements, processes, techniques or other valuable developments, whether patentable or copyrightable or not, relating to Product, the API or their manufacture, arising out of the performance of services under this Agreement by GenIbet and/or any use of either Seres Intellectual Property and/or the API. For the avoidance of doubt, Inventions include Process Inventions, as defined below.

“Licensed Know-How TC "Government Authority" \f C \l “5” ” shall mean any and all technology, information, expertise, know-how, and/or trade secrets Controlled by GenIbet that is necessary or useful for the manufacture of the Product and/or the manufacture, use, sale, offer for sale, and importation of the Products.

“Manufacture,” “Manufacturing,” and **“Manufactured**” shall mean all operations of GenIbet in the scheduling, production, manufacturing, processing, packaging, labeling, testing, storage, quality control testing (including in-process, release, and stability testing when applicable) and release of Product.

“Master Batch Record” or **“MBR”** shall mean, with respect to each Product to be Manufactured hereunder, a formal set of instructions given by Seres for the Manufacture of each such Product. The MBR shall be developed and maintained in GenIbet’s standard format by GenIbet, as per Seres’ instructions and using master formulation and technical support.

“Materials” as used in this Agreement shall collectively mean all materials required for Manufacture of Product, including the API, Consumables, and Raw Materials.

“Process Inventions” shall mean any Inventions that are new manufacturing technologies, methods, processes or techniques, or are improvements to existing manufacturing technologies, methods, processes or techniques, and that are generally applicable to pharmaceutical products. For purposes of clarity, Process Inventions shall not include such Inventions that (i) are only applicable to Product, Seres Technology, the intellectual property of a collaborator and/or the API and/or (ii) require the use of Product, Seres Technology, the intellectual property of a collaborator and/or the API.

“Product Manufacturing Plan” shall mean an addendum to this Agreement for each Product Manufactured hereunder, which may include, without limitation, the Product, Product Specifications, Materials, Materials Specifications, Regulatory Authorities, the countries where such Product will be used in clinical trials, and pricing for such Product Manufactured under this Agreement.

“Purchase Order” shall mean written orders from Seres to GenIbet which shall specify (a) the quantity of Product ordered, (b) the minimum number of employees and their status (e.g., full-time dedicated or part-time dedicated) to be engaged, (c) shipping instructions (e.g. choice of container, temperature requirements), (d) requested delivery dates, and (e) delivery destinations.

|||

“Quality Agreement” shall mean individually, either the Clinical Quality Agreement or Commercial Quality Agreement and “**Quality Agreements**” shall mean the Clinical Quality Agreement and Commercial Quality Agreement collectively, both of which are addenda to this Agreement under which the Parties allocate the pharmaceutical responsibilities, as further set forth in Section 8.2.

“Raw Materials” shall mean all excipients, inactive ingredients and other substances used by GenIbet in the Manufacture of a Product, with the exception of API and Consumables, as specified in the applicable Product Manufacturing Plan.

“Regulatory Authority” shall mean those agencies or authorities responsible for regulation of the Product in the country where the Product is Manufactured and/or used in clinical trials.

“Site Master File” shall mean a document prepared by GenIbet containing specific and factual GMP information about the production and/or control of pharmaceutical manufacturing operations carried out at the Facility and any closely integrated operations at adjacent and nearby buildings.

“SOP” means GenIbet’s standard operating procedures applicable to the Manufacture of the Product.

Exhibit 2

Seres Dedicated Area Project Plan

[***]

Attachment 2-1

Dedicated Area

[***]

Attachment 3

Product Manufacturing Plan for SER-109

[***]

|||

Exhibit 4

Charges

[***]

|||

200 Sidney Street
Cambridge, MA 02139
Tel: 617-945-9626
www.serestherapeutics.com

September 14, 2020

GenIbet Biopharmaceuticals SA Via Email: [***]
Estação Acronómica Nacional
Avenida da República ACKNOWLEDGEMENT REQUESTED
2780-157 Oeiras, PORTUGAL

Attention: [***]

Re: Supply Agreement effective September 15, 2015, as subsequently amended and extended (the "Agreement") by and between Seres Therapeutics, Inc. ("Seres") and GenIbet BioPharmaceuticals SA ("GenIbet").

Dear [***]:

Pursuant to Section 15.1 of the Agreement, this letter serves as notice that Seres will extend the Term of the Agreement for an additional [***] on the now-current terms and conditions.

Please confirm receipt of this letter via email to [***]

Regards,

/s/John G. Aunins
John Auniņš, Ph.D.
Chief Technical Officer and Executive Vice President, CMC

|||

200 Sidney Street
Cambridge, MA 02139
Tel: 617-945-9626
www.serestherapeutics.com

September 07, 2021

GenIbet Biopharmaceuticals SA
Estação Acronómica Nacional
Avenida da República
2780-157 Oeiras, PORTUGAL
Attention: [***]

Via Email: [***]

Re: Supply Agreement effective September 15, 2015, as subsequently amended and extended (the "Agreement") by and between Seres Therapeutics, Inc. ("Seres") and GenIbet BioPharmaceuticals SA ("GenIbet").

Dear [***]:

Pursuant to Section 15.1 of the Agreement, this letter serves as notice that Seres will extend the Term of the Agreement through [***], on the now-current terms and conditions.

Please confirm receipt of this letter by providing your e-signature below.

Best Regards,

/s/ David S. Ege
David S. Ege
EVP & Chief Technical Officer

Accepted and Agreed:

/s/[***]
[***]

|||

III

200 Sidney Street
Cambridge, MA 02139
Tel: 617-945-9626
www.serestherapeutics.com

December 6, 2021

GenIbet Biopharmaceuticals SA
Estação Acronómica Nacional
Avenida da República
2780-157 Oeiras, PORTUGAL
Attention: [***]

Via Email: [***]

Re: Supply Agreement effective September 15, 2015, as subsequently amended and extended (the "Agreement") by and between Seres Therapeutics, Inc. ("Seres") and GenIbet BioPharmaceuticals SA ("GenIbet").

Dear [***]:

Pursuant to Section 15.1 of the Agreement, this letter serves as notice that Seres will extend the Term of the Agreement through [***], on the now-current terms and conditions.

Please confirm receipt of this letter by providing your e-signature below.

Best Regards,

/s/David S. Ege
David S. Ege
EVP & Chief Technical Officer

Accepted and Agreed:

/s/[***]
[***]
12/9/2021

|||

200 Sidney Street
Cambridge, MA 02139
Tel: 617-945-9626
www.serestherapeutics.com

March 22, 2022

Sent via email: [***]

GenIbet Biopharmaceuticals SA
Estação Acronómica Nacional
Avenida da República
2780-157 Oeiras, PORTUGAL
Attention: [***]

Re: Supply Agreement effective September 15, 2015, as subsequently amended and extended (the "Agreement") by and between Seres Therapeutics, Inc. ("Seres") and GenIbet BioPharmaceuticals SA ("GenIbet").

Dear [***]:

Pursuant to Section 15.1 of the Agreement, this letter serves as notice that Seres will extend the Term of the Agreement through June 30, 2023, on the now-current terms and conditions.

Best Regards,

/s/David S. Ege
David S. Ege
EVP & Chief Technical Officer

|||

200 Sidney Street
Cambridge, MA 02139
Tel: 617-945-9626
www.serestherapeutics.com

March 6, 2023

GenIbet Biopharmaceuticals SA **Via Email:** [***] **and Federal Express**
Estação Acronómica Nacional Avenida da República
2780-157 Oeiras, PORTUGAL
Attention: Raquel Fortunato

Re: Supply Agreement effective September 15, 2015, as subsequently amended and extended (the "Agreement") by and between Seres Therapeutics, Inc. ("Seres") and GenIbet BioPharmaceuticals SA ("GenIbet").

Dear [***]:

Pursuant to Section 15.1 of the Agreement, this letter serves as notice that Seres will extend the Term of the Agreement through June 30, 2024, on the now-current terms and conditions.

Best Regards,

/s/David S. Ege
David S. Ege
EVP & Chief Technical Officer

|||

101 Cambridge Park Drive
Cambridge, MA 02140
Tel: 617-945-9626
www.serestherapeutics.com

March 6, 2024

GenIbet Biopharmaceuticals SA **Via Email:** [***] **and Federal Express**
Estação Acronómica Nacional Avenida da República
2780-157 Oeiras, PORTUGAL
Attention: Raquel Fortunato

Re: Supply Agreement effective September 15, 2015, as subsequently amended and extended (the "Agreement") by and between Seres Therapeutics, Inc. ("Seres") and GenIbet BioPharmaceuticals SA ("GenIbet").

Dear [***]:

Pursuant to Section 15.1 of the Agreement, this letter serves as notice that Seres will extend the Term of the Agreement through June 30, 2025, on the now-current terms and conditions.

Best Regards,

/s/David S. Ege
David S. Ege
EVP & Chief Technical Officer

|||

SERES THERAPEUTICS, INC.
2015 INCENTIVE AWARD PLAN

STOCK OPTION GRANT NOTICE

Capitalized terms not specifically defined in this Stock Option Grant Notice (the "***Grant Notice***") have the meanings given to them in the 2015 Incentive Award Plan (as amended from time to time, the "***Plan***") of Seres Therapeutics, Inc. (the "***Company***").

The Company hereby grants to the participant listed below ("***Participant***") the stock option described in this Grant Notice (the "***Option***"), subject to the terms and conditions of the Plan and the Stock Option Agreement attached hereto as **Exhibit A** (the "***Agreement***"), both of which are incorporated into this Grant Notice by reference.

Participant:	[_____]
Grant Date:	[_____]
Exercise Price per Share:	[_____]
Shares Subject to the Option:	[_____]
Final Expiration Date:	[_____]
Vesting Schedule:	Subject to the terms of the Agreement, the Option will vest and become exercisable as to (i) 50% of the underlying Shares upon achievement of a 30-day trailing average public market closing price per share of Common Stock greater than or equal to $3.00 (the "***First Performance Condition***") and (ii) as to the remaining 50% of the underlying Shares upon achievement of a 30-day trailing average public market closing price per share of Common Stock greater than or equal to $5.00 (the "***Second Performance Condition***" and each of the First Performance Condition and the Second Performance Condition, a "***Performance Condition***"), provided that if a Performance Condition is achieved prior to the first anniversary of the Grant Date, the portion of the Option eligible to vest upon achievement of such Performance Condition shall instead vest upon the first anniversary of the Grant Date.
Type of Option:	Non-Qualified Stock Option

By Participant's signature below, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

SERES THERAPEUTICS, INC.	**PARTICIPANT**
By:	
Print Name:	[Name]
Title:	

|US-DOCS\148207996.2||

Exhibit A

STOCK OPTION AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

ARTICLE I.
GENERAL

1.1 Grant of Option. Pursuant to the Grant Notice to which this Agreement is attached, the Company has granted to Participant the Option effective as of the grant date set forth in the Grant Notice (the "***Grant Date***").

1.2 Incorporation of Terms of Plan. The Option is subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

ARTICLE II.
PERIOD OF EXERCISABILITY

2.1 Commencement of Exercisability.

(a) Subject to Sections 2.1(b), (c) and (d), the Option will vest and become exercisable according to the vesting schedule in the Grant Notice (the "***Vesting Schedule***") except that any fraction of a Share as to which the Option would be vested or exercisable will be accumulated and will vest and become exercisable only when a whole Share has accumulated.

(b) Notwithstanding Section 2.1(a) but subject to Section 2.1(d), if a Change in Control occurs before a Performance Target has been attained and the cash consideration payable per Share in such Change in Control, or if the consideration payable per Share in such Change in Control is not 100% cash, the public market closing price per Share on the final trading day before the Change in Control (in either case, the "***CIC Price***"), equals or exceeds such Performance Target, then

(i) if such Change in Control occurs on or after the first anniversary of the Grant Date, immediately before such Change in Control, the Option will vest as to the portion of the Option that was eligible to vest upon attainment of such Performance Target, or

(ii) if such Change in Control occurs before the first anniversary of the Grant Date, the applicable Performance Target will be deemed satisfied as of immediately before such Change in Control and the portion of the Option that was eligible to vest upon the attainment of such Performance Target will convert to time-based vesting and vest on the first anniversary of the Grant Date (subject to Section VIII(e) of the Plan).

(c) Notwithstanding Section 2.1(a), if a Change in Control occurs before a Performance Target has been attained and the CIC Price is less than such Performance Target, the Option will be forfeited and cancelled as of immediately before such Change in Control as to the portion of the Option that was eligible to vest upon attainment of such Performance Target.

(d) Notwithstanding anything in the Grant Notice, the Plan or this Agreement to the contrary, unless the Administrator otherwise determines, the Option will immediately expire and be forfeited as to any portion that is not vested and exercisable as of Participant's Termination of Service for any reason; provided that if Participant's employment is terminated by the Company without Cause or by Participant

for Good Reason (as such terms are defined in Participant's employment agreement with the Company) on or within the sixty (60) days preceding or twelve (12) months following the date of a Change in Control and Participant executes a separation and release agreement in substantially the form attached to such employment agreement during the time periods set forth therein, then:

(i) if such termination of employment occurs within the sixty (60) days preceding the date of the Change in Control, any portion of the Option that would have become vested or converted to time-based vesting under Section 2.1(b) if Participant had remained employed through the occurrence of the Change in Control, shall vest immediately before such Change in Control (and for the avoidance of doubt, such portion of the Option shall remain outstanding following such termination and eligible to vest under Section 2.1(b) if such Change in Control occurs and shall be forfeited if such Change in Control does not occur or such portion of the Option does not vest upon such Change in Control), and

(ii) if such termination of employment occurs on or within twelve (12) months following the date of the Change in Control, any portion of the Option that was outstanding and unvested as of immediately before such termination of employment shall vest upon such termination of employment.

2.2 Duration of Exercisability. The Vesting Schedule is cumulative. Any portion of the Option which vests and becomes exercisable will remain vested and exercisable until the Option expires. The Option will be forfeited immediately upon its expiration.

2.3 Expiration of Option. The Option may not be exercised to any extent by anyone after, and will expire on, the first of the following to occur:

(a) The final expiration date in the Grant Notice;

(b) Except as the Administrator may otherwise approve, the expiration of three (3) months from the date of Participant's Termination of Service, unless Participant's Termination of Service is for Cause or by reason of Participant's death or Disability;

(c) Except as the Administrator may otherwise approve, the expiration of one (1) year from the date of Participant's Termination of Service by reason of Participant's death or Disability; and

(d) Except as the Administrator may otherwise approve, Participant's Termination of Service for Cause.

As used in this Agreement, "***Cause***" means (i) if Participant is a party to a written employment or consulting agreement with the Company or its Subsidiary in which the term "cause" is defined (a "***Relevant Agreement***"), "Cause" as defined in the Relevant Agreement, and (ii) if no Relevant Agreement exists, (A) the Administrator's determination that Participant failed to substantially perform Participant's duties (other than a failure resulting from Participant's Disability); (B) the Administrator's determination that Participant failed to carry out, or comply with any lawful and reasonable directive of the Board or Participant's immediate supervisor; (C) Participant's conviction, plea of no contest, plea of nolo contendere, or imposition of unadjudicated probation for any felony or indictable offense or crime involving moral turpitude; (D) Participant's unlawful use (including being under the influence) or possession of illegal drugs on the premises of the Company or any of its Subsidiaries or while performing Participant's duties and responsibilities for the Company or any of its Subsidiaries; or (E) Participant's commission of an act of fraud, embezzlement, misappropriation, misconduct, or breach of fiduciary duty against the Company or any of its Subsidiaries.

ARTICLE III.
EXERCISE OF OPTION

3.1 Person Eligible to Exercise. During Participant's lifetime, only Participant may exercise the Option. After Participant's death, any exercisable portion of the Option may, prior to the time the Option expires, be exercised by Participant's Designated Beneficiary as provided in the Plan.

3.2 Partial Exercise. Any exercisable portion of the Option or the entire Option, if then wholly exercisable, may be exercised, in whole or in part, according to the procedures in the Plan at any time prior to the time the Option or portion thereof expires, except that the Option may only be exercised for whole Shares.

3.3 Tax Withholding.

(a) The Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the Option as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise issuable under the Option.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the Option, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the Option. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or exercise of the Option or the subsequent sale of Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure the Option to reduce or eliminate Participant's tax liability.

ARTICLE IV.
OTHER PROVISIONS

4.1 Adjustments. Participant acknowledges that the Option is subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.

4.2 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant (or, if Participant is then deceased, to the person entitled to exercise the Option) at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

4.3 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

4.4 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

4.5 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

4.6 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement and the Option will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

4.7 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

4.8 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

4.9 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the Option, and rights no greater than the right to receive the Shares as a general unsecured creditor with respect to the Option, as and when exercised pursuant to the terms hereof.

4.10 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

4.11 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

(a)

* * * * *

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: May 8, 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: May 8, 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 March 31, 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.

May 8, 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 March 31, 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.

May 8, 2024

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