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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

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.)**
200 Sidney Street - 4th Floor Cambridge, MA	**02139**
(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 October 28, 2022, the registrant had 124,591,741 shares of common stock, $0.001 par value per share, outstanding.

Seres Therapeutics, Inc.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or the Quarterly Report, contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this Quarterly Report, including 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, including the anticipated PDUFA target action date and potential FDA approval of SER-109, manufacturing activities and related timing, commercialization efforts and related timing, 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 are a development-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 our products, 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 limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

- Other than SER-109, we are early in our development efforts and may not be successful in our efforts to use our microbiome therapeutics platform to build a pipeline of product candidates and develop marketable drugs.
- Our product candidates are based on microbiome therapeutics, which is an unproven 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.
- Our 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, including SER-109, SER-287, and SER-301, 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.
- We rely on third parties for certain aspects of the manufacture of our product candidates for preclinical and clinical testing and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or that such quantities may not be available at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- Even if any of our product candidates receive marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, hospitals, third-party payors and others in the medical community necessary for commercial success.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- If we are unable to adequately protect our proprietary technology or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.
- The COVID-19 pandemic has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- We may expand our operational capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- 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.

PART I – FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (unaudited)

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 205,398	$ 180,002
Short term investments	27,605	110,704
Prepaid expenses and other current assets	14,510	12,922
Total current assets	247,513	303,628
Property and equipment, net	19,484	17,938
Operating lease assets	23,747	18,208
Restricted cash	8,185	8,000
Restricted investments	1,401	1,401
Long term investments	—	495
Other non-current assets	11,538	5,189
Total assets	$ 311,868	$ 354,859
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,449	$ 13,735
Accrued expenses and other current liabilities (1)	59,169	45,094
Operating lease liabilities	7,333	6,610
Deferred revenue - related party	4,868	16,819
Total current liabilities	81,819	82,258
Long term portion of note payable, net of discount	50,857	24,643
Operating lease liabilities, net of current portion	17,850	17,958
Deferred revenue, net of current portion - related party	92,796	86,998
Other long-term liabilities (2)	961	11,495
Total liabilities	244,283	223,352
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2022 and December 31, 2021; no shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at September 30, 2022 and December 31, 2021; 124,410,917 and 91,889,418 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	124	92
Additional paid-in capital	863,294	745,829
Accumulated other comprehensive loss	(118)	(60)
Accumulated deficit	(795,715)	(614,354)
Total stockholders' equity	67,585	131,507
Total liabilities and stockholders' equity	$ 311,868	$ 354,859

[1] Includes related party amounts of $34,112 and $21,098 at September 30, 2022 and December 31, 2021, respectively (see Note 11)
[2] Includes related party amounts of $0 and $10,585 at September 30, 2022 and December 31, 2021, respectively (see Note 11)

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue:				
Collaboration revenue - related party	$ 3,444	$ 126,725	$ 6,153	$ 136,636
Grant revenue	—	$ —	—	1,070
Total revenue	3,444	126,725	6,153	137,706
Operating expenses:				
Research and development expenses	43,116	39,882	126,700	105,139
General and administrative expenses	18,384	19,563	57,290	48,755
Collaboration (profit) loss sharing - related party	1,051	(1,127)	346	(1,127)
Total operating expenses	62,551	58,318	184,336	152,767
(Loss) income from operations	(59,107)	68,407	(178,183)	(15,061)
Other (expense) income:				
Interest income	865	590	1,644	2,385
Interest expense	(1,727)	(744)	(4,140)	(2,172)
Other expense	(33)	(35)	(682)	(729)
Total other (expense) income, net	(895)	(189)	(3,178)	(516)
Net (loss) income	$ (60,002)	$ 68,218	$ (181,361)	$ (15,577)
Net (loss) income per share attributable to common stockholders, basic	$ (0.49)	$ 0.74	$ (1.77)	$ (0.17)
Net (loss) income per share attributable to common stockholders, diluted	$ (0.49)	$ 0.72	$ (1.77)	$ (0.17)
Weighted average common shares outstanding, basic	122,527,275	91,757,614	102,380,700	91,649,035
Weighted average common shares outstanding, diluted	122,527,275	94,953,117	102,380,700	91,649,035
Other comprehensive income (loss):				
Unrealized gain (loss) on investments, net of tax of $0	140	(1)	(56)	58
Currency translation adjustment	(2)	—	(2)	—
Total other comprehensive income (loss)	138	(1)	(58)	58
Comprehensive (loss) income	$ (59,864)	$ 68,217	$ (181,419)	$ (15,519)

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total Stockholders' Equity
	Shares	Par Value				
Balance at December 31, 2020	91,459,239	$ 91	$ 723,482	$ (548,776)	$ (47)	$ 174,750
Issuance of common stock upon exercise of stock options	104,184	1	371	—	—	372
Issuance of common stock upon vesting of RSUs, net of tax withholdings	650	—	—	—	—	—
Issuance of common stock under ESPP	24,191	—	392	—	—	392
Stock-based compensation expense	—	—	3,624	—	—	3,624
Other comprehensive income	—	—	—	—	32	32
Net loss	—	—	—	(35,465)	—	(35,465)
Balance at March 31, 2021	91,588,264	$ 92	$ 727,869	$ (584,241)	$ (15)	$ 143,705
Issuance of common stock upon exercise of stock options	125,546	—	586	—	—	586
Stock-based compensation expense	—	—	5,078	—	—	5,078
Other comprehensive income	—	—	—	—	27	27
Net loss	—	—	—	(48,330)	—	(48,330)
Balance at June 30, 2021	91,713,810	$ 92	$ 733,533	$ (632,571)	$ 12	$ 101,066
Issuance of common stock upon exercise of stock options	51,938	—	174	—	—	174
Issuance of common stock under ESPP	76,226	—	435	—	—	435
Stock-based compensation expense	—	—	5,846	—	—	5,846
Unrealized loss on investments	—	—	—	—	(1)	(1)
Net income	—	—	—	68,218	—	68,218
Balance at September 30, 2021	91,841,974	$ 92	$ 739,988	$ (564,353)	$ 11	$ 175,738

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Par Value				
Balance at December 31, 2021	91,889,418	$ 92	$ 745,829	$ (614,354)	$ (60)	$ 131,507
Issuance of common stock upon exercise of stock options	92,478	—	257	—	—	257
Issuance of common stock upon vesting of RSUs, net of tax withholdings	69,195	—	—	—	—	—
Issuance of common stock under ESPP	159,214	—	892	—	—	892
Stock-based compensation expense	—	—	5,079	—	—	5,079
Other comprehensive loss	—	—	—	—	(155)	(155)
Net loss	—	—	—	(56,624)	—	(56,624)
Balance at March 31, 2022	92,210,305	$ 92	$ 752,057	$ (670,978)	$ (215)	$ 80,956
Issuance of common stock upon exercise of stock options	39,208	—	130	—	—	130
Issuance of common stock upon vesting of RSUs, net of tax withholdings	57,431	—	—	—	—	—
Stock-based compensation expense	—	—	6,748	—	—	6,748
Other comprehensive loss	—	—	—	—	(41)	(41)
Net loss	—	—	—	(64,735)	—	(64,735)
Balance at June 30, 2022	92,306,944	$ 92	$ 758,935	$ (735,713)	$ (256)	$ 23,058
Issuance of common stock net of issuance costs of $3,279	31,746,030	32	96,689			96,721
Issuance of common stock upon exercise of stock options	150,477	—	429	—	—	429
Issuance of common stock upon vesting of RSUs, net of tax withholdings	44,120	—	—	—	—	—
Issuance of common stock under ESPP	163,346	—	877	—	—	877
Stock-based compensation expense	—	—	6,364	—	—	6,364
Other comprehensive income	—	—	—	—	138	138
Net loss	—	—	—	(60,002)	—	(60,002)
Balance at September 30, 2022	124,410,917	$ 124	$ 863,294	$ (795,715)	$ (118)	$ 67,585

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

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

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (181,361)	$ (15,577)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Stock-based compensation expense	18,191	14,548
Depreciation and amortization expense	5,002	4,395
Non-cash operating lease cost	3,558	2,292
Amortization of premiums on investments	676	2,097
Amortization of debt issuance costs	553	368
Collaboration (profit) loss sharing - related party	346	(1,127)
Changes in operating assets and liabilities:		
Prepaid expenses and other current and other non-current assets	(12,899)	(5,001)
Accounts receivable	—	8,137
Deferred revenue - related party	(6,153)	2,863
Accounts payable	(3,250)	4,781
Operating lease liabilities	(3,520)	(2,185)
Accrued expenses and other current and long-term liabilities (3)	2,933	42,960
Net cash (used in) provided by operating activities	(175,924)	58,551
Cash flows from investing activities:		
Purchases of property and equipment	(6,360)	(7,988)
Purchases of investments	(36,138)	(66,342)
Sales and maturities of investments	119,000	125,982
Purchase of restricted investments	—	(750)
Net cash provided by investing activities	76,502	50,902
Cash flows from financing activities:		
Proceeds from exercise of stock options	816	1,131
Proceeds from issuance of common stock	100,000	—
Issuance costs paid for common stock	(3,279)	—
Issuance of common stock under ESPP	1,769	827
Proceeds from issuance of debt, net of issuance costs	27,606	—
Repayment of notes payable	(1,907)	—
Net cash provided by financing activities	125,005	1,958
Net increase in cash, cash equivalents, and restricted cash	25,583	111,411
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(2)	—
Cash, cash equivalents and restricted cash at beginning of period	188,002	116,049
Cash, cash equivalents and restricted cash at end of period	$ 213,583	$ 227,460
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,282	$ 1,836
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment purchases included in accounts payable and accrued expenses	$ 1,061	$ 316
Prepaid rent reclassified to right-of-use assets	$ 4,962	$ —
Lease liability arising from obtaining right-of-use assets	$ 4,370	$ 4,839

[3]Includes related party amounts of $2,429 and $33,809 at September 30, 2022 and September 30, 2021, respectively (see Note 11)

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 microbiome therapeutics platform company developing 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 lead product candidate, SER-109, is designed to reduce further recurrences of *Clostridioides difficile* infection ("CDI"), a debilitating infection of the colon, in patients who have received antibiotic therapy for recurrent CDI by restructuring the colonic microbiome and changing its function. If approved by the U.S. Food and Drug Administration ("FDA"), the Company believes SER-109 will be a first-in-field oral microbiome drug. Building upon SER-109, the Company is developing therapeutic candidates, such as SER-155, to specifically target infections and antimicrobial resistance. SER-155, a microbiome therapeutic candidate consisting of a consortium of cultivated bacteria, is designed to reduce incidences of gastrointestinal infections, bloodstream infections and graft versus host disease ("GvHD") in patients receiving allogeneic hematopoietic stem cell transplantation ("allo-HSCT"). The Company is evaluating additional preclinical stage programs to reduce incidence of infection, which the Company refers to as Infection Protection, in indications such as cancer neutropenia, chronic liver disease, solid organ transplant, and antimicrobial resistant infections more broadly. The Company is also continuing its research activities in ulcerative colitis ("UC"), including evaluating the potential to utilize biomarker-based patient selection and stratification for future studies. In addition, the Company continues to leverage microbiome pharmacokinetic and pharmacodynamic data from across its clinical and preclinical portfolios, using its reverse translational microbiome therapeutic development platform to conduct research on various indications, including inflammatory and immune diseases, cancer, and metabolic diseases. The Company has built and deploys a reverse translational platform for the discovery and development of microbiome therapeutics. 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.

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 commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities.

The Company's product candidates are in development. 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. 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.

On June 29, 2022, the Company entered into securities purchase agreements with new and existing investors and certain directors and officers in a registered direct offering of an aggregate of 31,746,030 shares of common stock at a purchase price of $3.15 per share (the "Registered Direct Offering"). Total net proceeds to the Company were approximately $96,721, after deducting placement agent's fees and other estimated offering expenses. The closing date of the Registered Direct Offering was July 5, 2022.

Under Accounting Standards Update ("ASU") 2014-15, *Presentation of Financial Statements—Going Concern* (Subtopic 205-40) ("ASC 205-40"), the Company has the responsibility to evaluate whether conditions and/or events raise substantial doubt about its ability to meet its future financial obligations as they become due within one year after the date that the financial statements are issued. As required by ASC 205-40, this evaluation shall initially not take into consideration the potential mitigating effects of plans that have not been fully implemented as of the date the financial statements are issued.

As of September 30, 2022, the Company had an accumulated deficit of $795,715 and cash, cash equivalents and investments of $233,003. For the nine months ended September 30, 2022, the Company incurred a net loss of $181,361. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future. The Company expects that its cash, cash equivalents and investments as of September 30, 2022, will be sufficient to fund its operating expenses, capital expenditure requirements, and debt service obligations for at least the next 12 months from issuance of these condensed consolidated financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

The Company is eligible to receive contingent milestone payments under its license and collaboration 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") if certain development, regulatory approval or sales target milestones are achieved. NHSc Rx License GmbH is affiliated with Société des Produits Nestlé S.A., a significant stockholder of the Company. The milestone payments under each of the license and collaboration agreements are uncertain and there is no assurance that the Company will receive any of them. Until such time, if ever, as the Company can generate substantial product revenue, the Company will finance its cash needs through a combination of public or private equity offerings, debt financings, governmental funding, collaborations, strategic partnerships, or marketing, distribution or licensing arrangements with third parties. The Company may not be able to obtain funding on acceptable terms, or at all. If the Company is unable to raise additional funds as and when needed, it would have a negative impact on the Company's financial condition, which may require the Company to delay, reduce or eliminate certain research and development activities and reduce or eliminate discretionary operating expenses, which could constrain the Company's ability to pursue its business strategies.

Unaudited Interim Financial Information

The accompanying unaudited condensed consolidated financial statements as of September 30, 2022 and for the three and nine months ended September 30, 2022 and 2021 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, 2021 included in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2021, which was filed with the SEC on March 1, 2022 (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, 2021 was derived from audited annual financial statements, but does not contain all of the footnote disclosures from the annual financial statements. In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments which are necessary for a fair statement of the Company's financial position, results of operations, and cash flows for the periods presented. Such adjustments are of a normal and recurring nature. The results of operations for the three and nine months ended September 30, 2022 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2022.

2. Summary of Significant Accounting Policies

The significant accounting policies and estimates used in preparation of the condensed consolidated financial statements are described in the Company's audited financial statements as of and for the year ended December 31, 2021, and the notes thereto, which are included in the Annual Report. There have been no material changes to the Company's significant accounting policies during the nine months ended September 30, 2022.

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 condensed consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. In the 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.

Restricted Cash

The Company held restricted cash of $8,185 and $8,000 as of September 30, 2022 and December 31, 2021, respectively, which represents cash held for the benefit of the landlord for the Company's leases. The Company has classified the restricted cash as long-term on its consolidated balance sheet as the underlying leases are greater than 1 year.

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

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 205,398	$ 180,002
Restricted cash, non-current	8,185	8,000
Total cash, cash equivalents and restricted cash	$ 213,583	$ 188,002

Recently Adopted Accounting Standards

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes may result in earlier recognition of credit losses. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*, which narrowed the scope and changed the effective date for non-public entities for ASU 2016-13. The FASB subsequently issued supplemental guidance within ASU No. 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief* (“ASU 2019-05”). ASU 2019-05 provides an option to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost basis. For public entities that are Securities and Exchange Commission filers, excluding entities eligible to be smaller reporting companies, ASU 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. For all other entities, ASU 2016-13 is effective for annual periods beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. The Company adopted the new standard using a modified retrospective approach as of January 1, 2022. The adoption of this standard did not have a material impact on the Company's condensed 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 September 30, 2022 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 105,710	$ —	$ —	$ 105,710
Commercial paper	—	2,984	—	2,984
Investments:				
Corporate bonds	$ —	$ 5,692	$ —	$ 5,692
Government securities	—	21,913	—	21,913
	$ 105,710	$ 30,589	$ —	$ 136,299

	Fair Value Measurements as of December 31, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 70,322	$ —	$ —	$ 70,322
Commercial paper	—	3,999	—	3,999
Investments:				
Commercial paper	$ —	$ 6,250	$ —	$ 6,250
Corporate bonds	—	40,095	—	40,095
Government securities	—	64,854	—	64,854
	$ 70,322	$ 115,198	$ —	$ 185,520

Money market funds were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. Commercial paper, corporate bonds, and government securities were valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy. There were no transfers between Level 1 or Level 2 during the three and nine months ended September 30, 2022 and 2021.

As of September 30, 2022 and December 31, 2021, the Company held a restricted investment of $1,401 in both periods, which represent a certificate of deposit that is classified as Level 2 in the fair value hierarchy.

4. Investments

Investments by security type consisted of the following at September 30, 2022 and December 31, 2021 (in thousands):

	September 30, 2022			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Investments:				
Corporate bonds	$ 5,709	$ —	$ (17)	$ 5,692
Government securities	22,010	—	(97)	21,913
	$ 27,719	$ —	$ (114)	$ 27,605

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Investments:				
Commercial paper	$ 6,250	$ —	$ —	$ 6,250
Corporate bonds	40,123	—	(28)	40,095
Government securities	64,885	—	(31)	64,854
	$ 111,258	$ —	$ (59)	$ 111,199

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 and those investments with maturities greater than 12 months are considered non-current assets.

Excluded from the tables above are restricted investments of $1,401 and $1,401 as the cost approximates current fair value as of September 30, 2022 and December 31, 2021, respectively.

The amortized cost and fair value of investments in commercial paper, corporate bonds and government securities by contractual maturity, as of September 30, 2022 and December 31, 2021 were as follows (in thousands):

	Available-for-Sale as of September 30, 2022		Available-for-Sale as of December 31, 2021	
	Cost	Fair Value	Cost	Fair Value
Due in 1-year or less	$ 27,719	$ 27,605	$ 110,762	$ 110,704
Due after 1-year through 5-years	—	—	496	495
	$ 27,719	$ 27,605	$ 111,258	$ 111,199

5. Property and Equipment, Net

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

	September 30, 2022	December 31, 2021
Laboratory equipment	$ 22,623	$ 19,137
Computer equipment	3,432	3,255
Furniture and office equipment	1,958	1,219
Leasehold improvements	33,555	32,925
Construction in progress	3,186	1,670
	64,754	58,206
Less: Accumulated depreciation and amortization	(45,270)	(40,268)
	$ 19,484	$ 17,938

Depreciation and amortization expense was $1,747, $5,002, $1,493 and $4,395 for the three and nine months ended September 30, 2022 and 2021, respectively.

6. Accrued Expenses and Other Current Liabilities

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

	September 30, 2022	December 31, 2021
Development and manufacturing costs	$ 10,147	$ 11,147
Payroll and payroll-related costs	10,781	9,216
Liability related to 2021 License Agreement (Note 11)	34,112	21,098
Facility and other	4,129	3,633
	$ 59,169	$ 45,094

7. Leases

The Company leases real estate, primarily laboratory, office and manufacturing space. The Company's leases have remaining terms ranging from 1 year to 10 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 one year to five 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 July 2021, the Company entered into a lease agreement for a donor collection facility in Tempe, Arizona with a lease term of 10 years, commencing in March 2022, subject to certain renewal options, which are not deemed reasonably certain. Minimum lease payments total $4,052, net of tenant improvement allowance of $770, through the lease term. At lease commencement, the Company recorded a right-of-use asset of $5,900, which consists of the lease liability of $2,327 and $3,573 of leasehold improvements that revert back to the lessor at the termination of the lease.

In August 2021, the Company entered into a lease for additional laboratory space in Waltham, Massachusetts with a lease term of 10 years, commencing in March 2022, subject to certain renewal options, which are not deemed reasonably certain. Minimum lease payments total $2,449, net of tenant improvement allowance of $767, through the lease term. At lease commencement, the Company

recorded a right-of-use asset of $2,662, which consists of the lease liability of $1,273 and $1,389 of leasehold improvements that revert back to the lessor at the termination of the lease.

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

	September 30, 2022	December 31, 2021
Assets:		
Operating lease assets	$ 23,747	$ 18,208
Liabilities:		
Operating lease liabilities	$ 7,333	$ 6,610
Operating lease liabilities, net of current portion	17,850	17,958
Total operating lease liabilities	$ 25,183	$ 24,568

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating lease costs	$ 1,785	$ 1,278	$ 5,405	$ 3,595
Short-term lease costs	326	363	1,035	1,092
Variable lease costs	1,135	758	3,437	2,182
Sublease income	—	(437)	—	(1,361)
Total lease costs	$ 3,246	$ 1,962	$ 9,877	$ 5,508

During the three and nine months ended September 30, 2022 and 2021 the Company made cash payments for operating leases of $1,937, $5,382, $1,625 and $3,488, respectively.

As of September 30, 2022, future payments of operating lease liabilities are as follows (in thousands):

	As of September 30, 2022
2022 (remaining 3 months)	$ 2,386
2023	8,446
2024	3,387
2025	3,277
2026 and thereafter	16,199
Total future minimum lease payments	$ 33,695
Less: interest	(8,512)
Present value of operating lease liabilities	$ 25,183

As of September 30, 2022, the weighted average remaining lease term was 4.64 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 10%. As of September 30, 2021, the weighted average remaining lease term was 3.89 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 10%.

8. Note Payable

On October 29, 2019 (the "Closing Date"), the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Hercules Capital, Inc. ("Hercules") pursuant to which a term loan in an aggregate principal amount of up to $50,000 (the "Original Credit Facility") was available to the Company in three tranches, subject to certain terms and conditions. The first tranche of $25,000 was advanced to the Company on the Closing Date. The Company did not meet the milestone requirements for the second tranche under the Original Credit Facility, and as such, the additional amount up to $12,500 was not available for the Company to borrow. The Company elected not to borrow the third tranche of $12,500, which was available upon Hercules' approval until June 30, 2021.

Effective as of February 24, 2022 (the "Effective Date"), the Company entered into an Amendment to the Loan and Security Agreement (the "Amendment"), with the lenders party thereto (the "Lenders"), and Hercules in its capacity as the administrative agent

and the collateral agent for the Lenders, which amended the Original Credit Facility. Pursuant to the Amendment, term loans in an aggregate principal amount of up to $100,000 (the "New Credit Facility") became available to the Company in five tranches, subject to certain terms and conditions.

The first tranche in an aggregate principal amount of $25,000 was outstanding as of the Effective Date, after taking into account reborrowing by the Company on the Effective Date of a previously-repaid principal amount of approximately $2,900. The second tranche in an aggregate principal amount of $12,500 and the third tranche in an aggregate principal amount of $12,500 have been advanced to the Company and were outstanding as of the Effective Date. The fourth tranche in an aggregate principal amount of $25,000 is available upon satisfaction of certain conditions, including the approval by the FDA of a biologics license application in respect of SER-109 (the "Regulatory Approval Milestone") by no later than December 15, 2023. The fifth tranche in an aggregate principal amount of up to $25,000 is available through the Amortization Date (as defined below) upon satisfaction of certain conditions, including the Lenders' investment committee approval.

All advances outstanding under the New Credit Facility will bear interest at a rate equal to the greater of either (i) the Prime Rate (as reported in The Wall Street Journal) plus 6.40%, and (ii) 9.65%. For all advances outstanding under the New Credit Facility, the Company will make interest only payments through December 31, 2023, extendable to December 31, 2024 upon satisfaction of certain conditions (such applicable date, the "Amortization Date"). The principal balance and interest of the advances will be repaid in equal monthly installments after the Amortization Date and continuing through October 1, 2024, extendable to October 1, 2025, upon satisfaction of certain conditions (such applicable date, the "Maturity Date").

The Company may prepay advances under the New Credit Facility, in whole or in part, at any time subject to a prepayment charge equal to: (a) 2.0% of amounts so prepaid, if such prepayment occurs during the first year following the Effective Date; (b) 1.5% of the amount so prepaid, if such prepayment occurs during the second year following the Effective Date, and (c) 1.0% of the amount so prepaid, if such prepayment occurs during the third year following the Effective Date.

The Company will pay an end of term charge of 4.85% of the aggregate amount of the advances made under the Original Credit Facility on the earliest date of (i) November 1, 2023; (ii) the date that the Company prepays all of the outstanding principal in full, or (iii) the date the loan payments are accelerated due to an event of default. The Company will pay an additional end of term charge of 1.75% of the aggregate amount of the advances under the New Credit Facility (including the first tranche of $25,000) on the earliest date of (i) the Maturity Date; (ii) the date that the Company prepays all of the outstanding principal in full, or (iii) the date the loan payments are accelerated due to an event of default.

Other terms of the New Credit Facility remain generally identical to those under the Original Credit Facility, with certain covenants amended by the Amendment to provide the Company with additional operational flexibility, including the ability for the Company to issue up to $350,000 in convertible notes. The New Credit Facility includes a conditional liquidity covenant commencing on June 15, 2023, which ceases to apply if certain conditions are satisfied.

The New Credit Facility is secured by substantially all of the Company's assets, other than the Company's intellectual property. The Company has agreed to not pledge or secure its intellectual property to others.

The Company accounted for the New Credit Facility as a modification in accordance with the guidance in ASC 470-50, *Debt*. Amounts paid to the lenders were recorded as debt discount and a new effective interest rate was established. Upon issuance, the New Credit Facility was recorded as a liability with an initial carrying value of $50,586, net of debt issuance costs. The initial carrying value will be accreted to the repayment amount, which includes the outstanding principal plus the end of term charge, through interest expense using the effective interest rate method over the term of the debt. The effective interest rate in effect as of September 30, 2022 is 13.80%. As of September 30, 2022, the carrying value of the debt is $50,857, which is classified as a long-term liability on the condensed consolidated balance sheet. As of December 31, 2021, the carrying value of the debt was $24,643, which was classified as a long-term liability on the condensed consolidated balance sheet.

As of September 30, 2022 the future principal payments due under the arrangement, excluding interest and the end of term charge, are as follows (in thousands):

Year Ending December 31,	Principal
2022 (remaining 3 months)	$ —
2023	—
2024	50,000
Total	$ 50,000

During the three and nine months ended September 30, 2022 and 2021, the Company recognized $1,727, $4,140, $744 and $2,172, respectively, of interest expense related to the Loan Agreement, which is reflected in interest expense on the condensed consolidated statement of operations and comprehensive (loss) income.

9. Common Stock and Stock-Based Awards

On June 29, 2022, the Company entered into securities purchase agreements with new and existing investors and certain directors and officers in a registered direct offering of an aggregate of 31,746,030 shares of common stock at a purchase price of $3.15 per share. Total net proceeds to the Company were approximately $96,721, after deducting placement agent's fees and other estimated offering expenses. Net proceeds included an aggregate of $27,525 received from Flagship Pioneering Fund VII, L.P. and Nutritional Health LTP Fund, L.P., affiliates of Flagship Pioneering ("Flagship"), one of the Company's significant stockholders, in exchange for 8,738,243 shares. The closing date of the Registered Direct Offering was July 5, 2022.

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. As of September 30, 2022, the Company had not sold any shares of common stock under the Sales Agreement.

Stock Options

The following table summarizes the Company's stock option activity since December 31, 2021:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2021	11,517,189	$ 11.10	7.42	$ 28,006,768
Granted	4,391,197	$ 6.89		
Exercised	(282,163)	$ 2.89		
Forfeited	(717,514)	$ 10.48		
Outstanding as of September 30, 2022	14,908,709	$ 10.05	7.46	$ 16,414,140
Options exercisable as of September 30, 2022	7,057,137	$ 10.31	6.00	$ 10,814,736

The weighted average grant-date fair value of stock options granted during the three and nine months ended September 30, 2022 and 2021 was $4.07, $5.53, $10.08 and $17.89 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. As of September 30, 2022, none of these options were exercisable because none of the specified performance targets had been achieved. Because achievement of the specified performance targets was not deemed probable as of September 30, 2022, the Company did not record any expense for these stock options from the dates of issuance through September 30, 2022.

Restricted Stock Units

The Company has granted restricted stock units ("RSUs") with time-based vesting conditions. The table below summarizes the Company's restricted stock unit activity since December 31, 2021:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted stock units as of December 31, 2021	734,755	$ 17.68
Granted	1,224,494	$ 6.97
Vested	(170,846)	$ 20.87
Forfeited	(187,115)	$ 12.18
Unvested restricted stock units as of September 30, 2022	1,601,288	$ 9.79

The Company has granted RSUs with service-based vesting conditions. RSUs represent the right to receive shares of common stock upon meeting specified vesting requirements. Unvested shares of restricted common stock may not be sold or transferred by the holder. These restrictions lapse according to the service-based vesting conditions of each award. During the nine months ended

September 30, 2022, the Company granted 1,224,494 RSUs. 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.

During the year ended December 31, 2021, the Company granted performance-based restricted stock awards to two employees for the purchase of an aggregate of 85,000 shares of common stock with a grant date fair value of $9.59 per share and 40,000 shares with a grant date fair value of $20.35 per share. These restricted stock awards vest only upon achievement of specified performance targets. As of September 30, 2022, none of these awards were vested because none of the specified performance targets had been achieved. Because achievement of the specified performance targets was not deemed probable as of September 30, 2022, the Company did not record any expense for these awards from the dates of issuance through September 30, 2022.

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) income (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development expenses	$ 3,474	$ 2,718	$ 9,500	$ 7,564
General and administrative expenses	2,890	3,128	8,691	6,984
	$ 6,364	$ 5,846	$ 18,191	$ 14,548

10. Net (Loss) Income per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Basic Earnings Per Share:				
Numerator:				
Net (loss) income	$ (60,002)	$ 68,218	$ (181,361)	$ (15,577)
(Loss) income attributable to common stockholders - basic	$ (60,002)	$ 68,218	$ (181,361)	$ (15,577)
Denominator:				
Weighted-average shares outstanding	122,527,275	91,757,614	102,380,700	91,649,035
Net (loss) income per share applicable to common stockholders - basic	$ (0.49)	$ 0.74	$ (1.77)	$ (0.17)
Diluted Earnings Per Share				
Numerator:				
Net (loss) income	$ (60,002)	$ 68,218	$ (181,361)	$ (15,577)
(Loss) income attributable to common stockholders - basic	$ (60,002)	$ 68,218	$ (181,361)	$ (15,577)
Denominator:				
Weighted-average shares outstanding	122,527,275	91,757,614	102,380,700	91,649,035
Dilutive impact from:				
Stock options to purchase common stock	—	3,186,762	—	—
Unvested restricted stock units	—	8,741	—	—
Weighted-average shares outstanding - diluted	122,527,275	94,953,117	102,380,700	91,649,035
Net (loss) income per share applicable to common stockholders - diluted	$ (0.49)	$ 0.72	$ (1.77)	$ (0.17)
Anti-dilutive potential common stock equivalents excluded from the calculation of net loss (income) per share:				
Stock options to purchase common stock	14,908,709	7,716,681	14,908,709	10,903,443
Unvested restricted stock units	1,601,288	549,455	1,601,288	558,196
Shares issuable under ESPP	62,010	—	20,897	—

The anti-dilutive potential common stock equivalents for the three and nine months ended September 30, 2022 and 2021 were excluded from the computation of diluted net income per share attributable to common stockholders because those stock options to purchase common stock and restricted stock units had an anti-dilutive impact due to the assumed proceeds per share using the treasury stock method being greater than the average fair value of the Company's common shares for those periods.

11. Collaboration Revenue

License Agreement with NHSc Rx License GmbH (Nestlé)

Summary of Agreement

In July 2021, the Company entered into a license agreement (the "2021 License Agreement") with NHSc Pharma Partners, succeeded by NHSc Rx License GmbH (together with Société des Produits Nestlé S.A., their affiliates, and their subsidiaries, "Nestlé"). Under the terms of the 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 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) the Company's SER-109 product candidate 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 is responsible for completing development of SER-109 in the 2021 Field in the United States until first regulatory approval for SER-109 is obtained.

Nestlé has the sole right to commercialize SER-109 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 will be responsible for the manufacturing and supply for commercialization under a supply agreement that will be entered into between the parties. Both parties will perform pre-launch activities of SER-109 prior to the first commercial sale in the United States. The Company is responsible for funding the pre-launch activities until first commercial sale of SER-109 in the 2021 Licensed Territory and in accordance with a pre-launch plan, up to a specified cap. Following first commercial sale of SER-109, the Company will be entitled to an amount equal to 50% of the commercial profits.

In connection with the 2021 License Agreement, the Company received an upfront payment of $175,000. The Company is eligible to receive additional payments of up to $360,000 if certain regulatory and sales milestones are achieved. The potential future milestone payments include up to $135,000 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 (i) with twelve months' prior written notice, effective only on or after the third anniversary of first commercial sale of the first 2021 Collaboration Product in the 2021 Licensed Territory, (ii) if first commercial sale of the first 2021 Collaboration Product in the 2021 Licensed Territory has not occurred by the fifth anniversary of the effective date of the 2021 License Agreement, with one hundred eighty days' prior written notice, which must be provided during a specified period set forth in the 2021 License Agreement, or (iii) if regulatory approval for SER-109 is not granted after submission by the Company of a filing seeking first regulatory approval as set forth in the development and regulatory activity plan, and the parties fail to agree on further development of SER-109 in accordance with the terms of the 2021 License Agreement, with one hundred eighty days' prior written notice, which must be provided within a specified period set forth in the 2021 License Agreement. 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),* 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 SER-109 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 SER-109 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 SER-109 and the services to obtain regulatory approval of SER-109 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 SER-109 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 SER-109 are not complex or specialized, could be performed by another qualified third party, are not expected to significantly modify or customize the license given that SER-109 is late-stage intellectual property that has completed clinical development and the services are expected to be 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 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 deliverables under Topic 606. The Company and Nestlé are both active participants in the pre-launch activities and commercialization activities and are exposed to significant risks and rewards that are dependent on the commercial success of the activities in the arrangement.

The up-front payment of $175,000 compensated the Company for: (i) the co-exclusive license for SER-109 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 SER-109 in the United States and (iii) pre-launch activities performed by Nestlé and the Company until the first commercial sale of SER-109 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 SER-109 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.

The Company determined that any variable consideration related to 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 Topic 606 transaction price of $139,500 has been allocated to the co-exclusive license for SER-109 and the services performed in accordance with the development and regulatory activity plan to obtain regulatory approval of SER-109 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 three and nine months ended September 30, 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 is being recognized over time as the services are performed. During the three and nine months ended September 30, 2022 and 2021, the Company recognized $1,497, $3,678, $1,265, and $1,265, of collaboration revenue - related party, respectively, related to the services performance obligation under the 2021 License Agreement.

The amount allocated to the Topic 808 unit of accounting relates to the pre-launch activities performed prior to the first commercial sale of SER-109 and was determined to be $35,500 based on standalone selling price.

The Company recorded the $35,500 in total liabilities on its condensed consolidated balance sheet at the inception of the arrangement. On a quarterly basis, the Company and Nestlé provide financial information about the pre-launch activities performed by both parties. The Company reduces the $35,500 liability as the pre-launch activities are performed and it makes payments to Nestlé for the pre-launch costs Nestlé incurs. As of September 30, 2022, there was $34,112 included in accrued expenses and other current liabilities which represents Nestlé incurred costs not yet reimbursed.

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) income. In the three and nine months ended September 30, 2022 and 2021, the Company recognized $1,182, $4,355, $1,117, and $1,117, respectively, in research and development expenses and $1,676, $6,290, $1,701, and $1,701, respectively, in general and administrative expenses associated with pre-launch activities performed.

As the Company and Nestlé are both active participants in the pre-launch activities, the sharing of 50% of the pre-launch costs will be recognized in collaboration (profit) loss sharing - related party in the Company's condensed consolidated statements of operations and comprehensive (loss) income. The Company recorded $1,051 and $346 of expense in the collaboration (profit) loss sharing line for the three and nine months ended September 30, 2022, respectively, compared to income of $1,127 for the same periods in the prior year.

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 for the treatment of CDI and IBD, including SER-109, 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 letter agreement also provides scenarios under which Nestlé's reimbursement to the Company for certain Phase 3 development costs would be reduced or delayed depending on the outcomes of the SER-287 Phase 2b study.

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 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 September 30, 2022, the aggregate amount of the transaction price allocated to the performance obligation of the 2016 License Agreement was approximately $200,000.

During the three and nine months ended September 30, 2022 and 2021, using the cost-to-cost method, which best depicts the transfer of control to the customer, the Company recognized $1,947, $2,475, $(5,883) and $4,028 of collaboration revenue – related party, respectively.

As of September 30, 2022 and December 31, 2021, there was $97,664 and $103,817, respectively, of deferred revenue related to the unsatisfied portion of the performance obligation under the Nestlé agreements. As of September 30, 2022, 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) income.

Contract Balances from Contracts with Customers

The following table presents changes in the Company's contract liabilities during the nine months ended September 30, 2022 and 2021 (in thousands):

	Balance as of December 31, 2021	Additions	Deductions	Balance as of September 30, 2022
Nine Months Ended September 30, 2022				
Contract liabilities:				
Deferred revenue - related party	$ 103,817	—	(6,153)	$ 97,664

	Balance as of December 31, 2020	Additions	Deductions	Balance as of September 30, 2021
Nine Months Ended September 30, 2021				
Contract liabilities:				
Deferred revenue - related party	$ 108,174	8,157	(5,294)	$ 111,037

During the three and nine months ended September 30, 2022 and 2021 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue recognized in the period from:				
Amounts included in the contract liability at the beginning of the period	$ 3,444	$ (4,618)	$ 6,153	$ 4,028

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.

12. Commitments and Contingencies

Leases

Refer to Note 7 “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 condensed consolidated financial statements as of September 30, 2022 or December 31, 2021.

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 condensed consolidated financial statements as of September 30, 2022 or December 31, 2021.

13. Income Taxes

The Company did not provide for any income taxes in its condensed consolidated statement of operations and comprehensive (loss) income for the three and nine months ended September 30, 2022 and 2021.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize its deferred tax assets. Management has considered the Company’s history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of September 30, 2022 and December 31, 2021. Management reevaluates the positive and negative evidence at each reporting period.

As of September 30, 2022 and December 31, 2021, the Company had no accrued interest or tax penalties recorded. The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The Company is currently under examination by the Internal Revenue Service ("IRS") for the period ended December 31, 2018 related to its R&D tax credits. The Company's tax years are still open under statute from 2011 to present. All years may be examined to the extent the tax credit or net operating loss carryforwards are used in future periods.

14. Related Party Transactions

As described in Note 11, 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 and nine months ended September 30, 2022 and 2021, the Company recognized $1,497, $3,678, $132,608, and $132,608, respectively, of related party revenue associated with the 2021 License Agreement. As of September 30, 2022 and December 31, 2021, there was $2,411 and $6,089 of deferred revenue related to the 2021 License Agreement, respectively, which is classified as current in the condensed consolidated balance sheets. As of September 30, 2022 and December 31, 2021 there was $34,112 and $31,683 included in accrued expenses and other liabilities related to the 2021 License Agreement. The Company made no

payments to Nestlé during the three and nine months ended September 30, 2022. There is no amount due from Nestlé as of September 30, 2022.

As described in Note 11, 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 and nine months ended September 30, 2022 and 2021, the Company recognized $1,947, $2,475, $(5,883), and $4,028, respectively, of related party revenue associated with the 2016 License Agreement. As of September 30, 2022 and December 31, 2021 there was $95,253 and $97,728 of deferred revenue related to the 2016 License Agreement, which is classified as current or non-current in the condensed consolidated balance sheets. The Company has made no payments to Nestlé during the three and nine months ended September 30, 2022. There was no amount due from Nestlé as of September 30, 2022.

As described in Note 9, the Company entered into a securities purchase agreement with Flagship Pioneering Fund VII, L.P. and Nutritional Health LTP Fund, L.P., affiliates of Flagship, one of the Company's significant stockholders, for the sale of 8,738,243 shares of its common stock at a purchase price of $3.15 per share as part of the Registered Direct Offering, which closed on July 5, 2022. The Company received proceeds from Flagship of $27,525.

In July 2022, the Company entered into a Pledge and Utilization Agreement with Flagship Pioneering Labs TPC, Inc., an affiliate of Flagship, for an option to lease certain manufacturing space. The Company paid $833 for this option which is classified in other non-current assets on the Company's condensed consolidated balance sheet as of September 30, 2022.

In July 2019, the Company entered into a sublease agreement with Flagship to sublease a portion of its office and laboratory space in Cambridge, Massachusetts. The term of the sublease agreement commenced in July 2019 and ended in November 2021. Under this agreement, the Company recorded other income of $437 and $1,361 during the three and nine months ended September 30, 2021, respectively. The Company received cash payments of $437 and $1,361 during the three and nine months ended September 30, 2021, respectively.

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 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 microbiome therapeutics company developing 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. We have an advanced drug pipeline with late-stage clinical assets that are formulated for oral delivery and a differentiated microbiome therapeutics drug discovery and development platform including good manufacturing practices, or GMP, manufacturing capabilities for this novel drug modality.

Our highest priority is preparing for potential commercialization of SER-109, an investigational oral microbiome therapeutic in development for recurrent *Clostridioides difficile* infection, or CDI. The FDA recently accepted for review our BLA for SER-109. The BLA has been granted Priority Review designation with a Prescription Drug User Fee Act, or PDUFA, target action date of April 26, 2023. If approved by the FDA, we plan to launch SER-109 with our collaborator, Aimmune Therapeutics, Inc., a Nestlé Health Science company, soon after approval.

We are also designing microbiome therapeutics to decolonize pathogens and modulate host function to reduce and prevent infections. We believe that the scientific and clinical data from our SER-109 program validate this novel approach, 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. We are evaluating SER-155 in a Phase 1b study in patients receiving allogeneic hematopoietic stem cell transplantation, or allo-HSCT, to reduce incidences of gastrointestinal infections, bloodstream infections and graft-versus-host disease, or GvHD. We are also evaluating additional preclinical stage programs to reduce incidence of infections in indications such as cancer neutropenia, chronic liver disease, solid organ transplant, and reduce antimicrobial resistant infections more broadly.

We continue our research activities in ulcerative colitis, or UC, including evaluating the potential to utilize biomarker-based patient selection and stratification for future studies. We have completed preliminary analysis of data from the first cohort of the SER-301 Phase 1b study, which included 15 subjects. Evaluation of the first cohort data by an independent Data Safety Monitoring Board indicated that it would be safe to proceed to the placebo-controlled second cohort. While efficacy was not a defined endpoint in the first cohort, evaluation of clinical outcome data collected as part of the study indicated that no subjects in the first cohort achieved clinical remission as defined by the FDA using the Three-Component Modified Mayo Score after 10 weeks of treatment, though there were improvements in one or more individual components (endoscopic, stool frequency and rectal bleeding subscores) in some patients. Strains in SER-301 were observed to engraft in subjects across the trial period, and based on the assessment of metabolomic data, SER-301 demonstrated pharmacological properties consistent with its design and led to baseline-dependent modulation of the metabolic landscape in the gastrointestinal tract of patients treated. In April 2022, we announced our decision not to proceed with the planned SER-301 Phase 1b second study cohort. We continue to conduct analyses of data from our UC clinical stage programs to inform next steps for further development in UC and irritable bowel disease more broadly.

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 conduct research on various indications, including inflammatory and immune diseases, cancer, and metabolic diseases.

We have built and deploy a reverse translational platform for the discovery and development of microbiome therapeutics. 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.

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.

Many of our product candidates are still in preclinical development or early-stage discovery. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Since our inception, we have incurred significant operating losses. Our net loss was $181.4 million for the nine months ended September 30, 2022. As of September 30, 2022, we had an accumulated deficit of $795.7 million and cash, cash equivalents and investments totaling $233.0 million. We expect that our existing cash, cash equivalents and investments will be sufficient to fund our operating expenses, capital expenditure requirements and debt service obligations for at least the next 12-months from issuance of our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

While we plan to focus our investment on our highest priority clinical programs in the near-term, our expenses may increase substantially in connection with our ongoing and planned activities, particularly as we:

- complete the clinical development, seek regulatory approval, and prepare for commercialization of SER-109 for patients with recurrent CDI;
- continue the clinical development of SER-155 to reduce incidences of gastrointestinal infections, bloodstream infections and GvHD in patients receiving allo-HSCT;
- continue evaluating preclinical stage programs to reduce incidence of infection, in indications such as cancer neutropenia, chronic liver disease, solid organ transplant, and antimicrobial resistant infections more broadly;
- continue translational research activities, informed by the SER-287 Phase 2b and SER-301 Phase 1b study data, to evaluate the potential to utilize biomarker-based patient selection and stratification in future clinical development efforts;
- make strategic investments in our research discovery and development platforms and capabilities to advance our priority programs;
- make strategic investments in manufacturing capabilities;
- maintain and augment our intellectual property portfolio and opportunistically acquire complementary intellectual property;
- potentially establish a sales and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products 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.

In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, 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 bio companies' stock have been highly volatile as a result of the COVID-19 pandemic and the continued increase 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.

SER-109

SER-109 is an oral microbiome therapeutic candidate consisting of a consortium of purified Firmicutes spores. The SER-109 manufacturing purification process is designed to remove unwanted microbes in an effort to reduce the risk of pathogen transmission beyond donor screening alone. SER-109 is designed to reduce recurrent CDI in patients with a history of CDI by modulating the microbiome to a state that resists *C. difficile* germination and growth. SER-109, if approved, is intended to treat individuals with recurrent CDI, a patient population which includes nearly 170,000 cases per year in the United States.

The Phase 3 ECOSPOR III study 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 sustained clinical response 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 number-needed-to treat was 3.6. 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; $p < 0.001$ and $p < 0.002$ for the test sequence), and thereby consistent with the results seen at eight weeks. Results across stratifications of age and antibiotics remained similar. The study's efficacy results related to the primary endpoint from all analyses exceeded the statistical threshold previously provided in consultation with the FDA that could allow this single clinical study to fulfill efficacy requirements for a BLA. The efficacy 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.

In June 2022, we announced confirmatory results from the ECOSPOR IV open-label study. 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. In ECOSPOR IV, subjects treated with SER-109 had a recurrence rate of 8.7% at eight weeks, which indicates a 91.3% sustained clinical response, consistent with the 88% rate observed in the ECOSPOR III study. Subjects with a first recurrence of CDI (29% of subjects in the ECOSPOR IV study) had a CDI recurrence rate of 6.5%, and subjects with ≥ two prior CDI episodes (ECOSPOR III inclusion criteria) had a CDI recurrence rate of 9.7% at eight weeks. At 24 weeks, 13.7% of all subjects treated with SER-109 had a recurrence of CDI. In addition to data from the ECOSPOR III study, the ECOSPOR IV data will be included as part of the rolling submission of the BLA to the FDA. We expect the ECOSPOR III data alone to serve as the basis for efficacy in our BLA submission and the FDA requested safety data from at least 300 subjects treated with SER-109 at the commercial dose as the basis for safety. Safety data across both ECOSPOR IV and ECOSPOR III are expected to fulfill this requirement and complete our Phase 3 program for SER-109.

The FDA recently accepted for review our BLA for SER-109. The BLA has been granted Priority Review designation with a PDUFA target action date of April 26, 2023. If approved by the FDA, we plan to launch SER-109 with our collaborator, Aimmune Therapeutics, Inc., a Nestlé Health Science company, soon after approval.

In November 2021, we initiated a SER-109 expanded access program across the United States. The program is designed to enable eligible adults with recurrent CDI to obtain access to SER-109 prior to a potential FDA product approval.

In addition, we plan on initiating a Phase 3 trial in the European Union, or EU, in order to expand access to the EU market upon potential approval.

SER-155

SER-155, an oral microbiome therapeutic candidate consisting of a consortium of cultivated bacteria, is designed to decrease infection and translocation of antibiotic resistant bacteria in the gastrointestinal tract and modulate host immune responses to decrease 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 are significantly more likely to die due to infection and/or lethal GvHD. SER-155 was designed using our reverse translational discovery platform to reduce incidences of gastrointestinal infections, bloodstream infections and GvHD in patients receiving allo-HSCT. The SER-155 Phase 1b study is designed to include approximately 70 patients in both an open-label and a randomized, double-blind, placebo-controlled cohort that will evaluate safety and tolerability before and after HSCT. Additionally, the engraftment of SER-155 bacteria (a measure of pharmacokinetics) and the efficacy of SER-155 in preventing infections and GvHD will be evaluated.

In November 2022, we announced the completion of enrollment of cohort 1 of the Phase 1b clinical study of SER-155 designed to evaluate safety, microbiome alterations, and the impact on infections and/or GvHD associated with SER-155 in adult subjects who are undergoing allo-HSCT. We anticipate conducting a pre-planned meeting with the study's Data and Safety Monitoring Board to review SER-155 cohort 1 safety data by the end of the year. In addition, we plan to announce initial safety and pharmacological data

from cohort 1, including drug bacterial species engraftment, in early 2023. The study is being conducted at a number of leading cancer centers across the U.S.

SER-301

SER-301 is an oral microbiome therapeutics candidate comprised of a consortium of cultivated bacteria for the treatment of mild-to-moderate UC. SER-301 is a consortium of cultivated bacteria designed using our reverse translational discovery platform that incorporates analysis of microbiome biomarkers from human clinical data and preclinical assessments using human cell-based assays and *in vitro/ex vivo* and *in vivo* disease models. The design of SER-301 incorporates insights obtained from the SER-287 Phase 1b clinical and microbiome results, as well as from our clinical portfolio more broadly, and additional functional data from preclinical assessments, in an effort to optimize desired pharmacological properties.

SER-301 is designed to reduce induction of pro-inflammatory activity, improve epithelial barrier integrity and TNF-α driven inflammation in intestinal epithelial cells, or IECs, and modulate UC-relevant anti-inflammatory, innate and adaptive immune pathways. SER-301 is being produced by our advanced fermentation, formulation and delivery platforms. It includes strains delivered in spore form, as well as strains fermented in non-spore (vegetative) form and delivered using enterically-protected technology designed to release in the colon.

The SER-301 Phase 1b study was designed to include approximately 65 subjects with mild-to-moderate UC distributed across two cohorts. We have completed preliminary analysis of data from the first cohort of the SER-301 Phase 1b study, which included 15 subjects. Evaluation of the first cohort data by an independent Data Safety Monitoring Board indicated that it would be safe to proceed to the placebo-controlled second cohort. While efficacy was not a defined endpoint in the first cohort, evaluation of clinical outcome data collected as part of the study indicated that no subjects in the first cohort achieved clinical remission as defined by the FDA using the Three-Component Modified Mayo Score after 10 weeks of treatment, though there were improvements in one or more individual components (endoscopic, stool frequency and rectal bleeding subscores) in some patients. Strains in SER-301 were observed to engraft in subjects across the trial period with the number of engrafting strains exceeding expectations at multiple sampling time points. A dual formulation was evaluated in the first cohort and the extent of engraftment across subjects was correlated with whether bacteria were formulated as bacterial spores versus vegetative strains; the former demonstrating stronger engraftment across all patients.

Based on the assessment of metabolomic data, SER-301 demonstrated pharmacological properties consistent with its design and led to baseline-dependent modulation of the metabolic landscape in the gastrointestinal tract of patients treated; changes were observed in short-chain and medium-chain fatty acids, tryptophan-derived metabolites, bile acids, and other microbe-associated metabolites, as well as host metabolites associated with a non-disease state. These SER-301 metabolomic results were encouraging compared with the results observed in the SER-287 Phase 2b study, in which the metabolic changes were not observed in general across subjects administered with SER-287. Additionally, changes in disease-relevant metabolites in SER-301 were observed to be greater in a definable subpopulation of patients.

The degree of metabolic changes observed following SER-301 administration appeared to be dependent on the baseline metabolic profile of the study subjects, providing support for the potential for microbiome therapeutics to be developed in biomarker-identified UC patient subpopulations.

In April 2022, we announced our decision not to proceed with the planned SER-301 Phase 1b second study cohort. We continue to conduct analyses of data from our UC clinical stage programs to inform next steps for further development.

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, our portfolio includes an option to license foundational intellectual property related to the use of bacteria in combination with checkpoint inhibitors from MD Anderson. The patents and applications included in our portfolio cover both composition of matter and methods (e.g., method of treating). Our intellectual property rights related to SER-109, SER-155, SER-287 and SER-301 extend through 2034. We plan on continuing to broaden our patent portfolio. Currently, we have 24 active patent application families, which includes 22 nationalized applications and two pending at the PCT stage. To date, we have obtained 24 issued U.S. patents.

Regulatory Exclusivity

If we obtain marketing approval for any of our product candidates, we expect to receive marketing exclusivity against biosimilar products. For a new biological composition approved by the FDA, a 12-year period of exclusivity in the United States may be obtained. In Europe, the European Medicines Agency awards 10 years of exclusivity for new molecular entities.

Financial Operations Overview

Revenue

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

Operating Expenses

Our operating expenses since inception have consisted primarily of research and development activities and general and administrative costs.

Research and Development Expenses

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

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

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

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

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase in the foreseeable future as we complete clinical development, scale up manufacturing operations, seek regulatory approval, and prepare for commercialization of SER-109, continue conducting analyses of data from our UC clinical stage programs to inform next steps for further development, continue to discover and develop additional product candidates, including SER-155 and pursue later stages of clinical development of our product candidates.

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 professional service fees for marketing and market access activities in preparation for the commercial launch of SER-109; legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our headcount and expand our infrastructure to support the potential growth in our research and development activities and the potential commercialization of our product candidates, and as we conduct pre-launch activities to prepare for commercialization of SER-109. We also may 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

Collaboration (profit) loss sharing – related party includes 50% sharing of the profit or loss related to the pre-launch activities and commercialization activities associated with the 2021 License Agreement with NHSc Rx License GmbH as discussed in Note 11 to our condensed consolidated financial statements.

Other Income (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.

Other (Expense) Income

Other (expense) income primarily consists of amortization of premiums on investments and sublease income.

Income Taxes

Since our inception in 2010, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. We did not provide for any income taxes in the three and nine months ended September 30, 2022 or 2021.

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, 2021, filed with the SEC on March 1, 2022, or the Annual Report, are considered by management to be the most important to an understanding of the consolidated financial statements because of their significance to the portrayal of our financial condition and results of operations. There have been no material changes to that information disclosed in our Annual Report during the three and nine months ended September 30, 2022.

Results of Operations

Comparison of Three Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		
	2022	2021	Change
	(in thousands)		
Revenue:			
Collaboration revenue - related party	$ 3,444	$ 126,725	$ (123,281)
Total revenue	3,444	126,725	(123,281)
Operating expenses:			
Research and development	43,116	39,882	3,234
General and administrative	18,384	19,563	(1,179)
Collaboration (profit) loss sharing - related party	1,051	(1,127)	2,178
Total operating expenses	62,551	58,318	4,233
(Loss) income from operations	(59,107)	68,407	(127,514)
Other (expense) income:			
Interest income	865	590	275
Interest expense	(1,727)	(744)	(983)
Other expense	(33)	(35)	2
Total other (expense) income, net	(895)	(189)	(706)
Net (loss) income	$ (60,002)	$ 68,218	$ (128,220)

Revenue

Total revenue was $3.4 million and $126.7 million for the three months ended September 30, 2022 and 2021, respectively. The decrease in revenue as compared to the prior period was primarily due to the collaboration revenue that was recognized during the third quarter of 2021 upon on the transfer of control of the license by the company to Nestlé, pursuant to the 2021 License Agreement. For additional information, see Note 11 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report. The decrease in revenue was partially offset by an increase of $7.8 million in revenue recognized under the 2016 License Agreement as compared to the prior period.

Research and Development Expenses

	Three Months Ended September 30,		
	2022	2021	Change
	(in thousands)		
Microbiome therapeutics platforms	$ 8,552	$ 9,366	$ (814)
SER-109	12,372	13,309	(937)
SER-287	795	1,568	(773)
Early stage programs	1,460	1,446	14
Total direct research and development expenses	23,179	25,689	(2,510)
Personnel-related (including stock-based compensation)	19,937	14,193	5,744
Total research and development expenses	$ 43,116	$ 39,882	$ 3,234

Research and development expenses were $43.1 million for the three months ended September 30, 2022 and $39.9 million for the three months ended September 30, 2021. The increase of $3.2 million was primarily due to the following:

- an increase in personnel-related costs of $5.7 million primarily due to an increase of $4.9 million in salaries, bonus, payroll taxes and employee benefits expenses and an increase of $0.8 million in stock-based compensation expense as a result of increased headcount;

partially offset by the following:

- a decrease of $0.9 million in expenses related to our SER-109 program due to a decrease in clinical trial costs,
- a decrease of $0.8 million in expenses related to our SER-287 program due to a decrease in clinical trial costs of $0.4 million and a decrease in analytical testing of $0.4 million; and
- a decrease of $0.8 million in research expenses related to our microbiome therapeutics platforms, primarily due to a decrease in facilities costs, lab supplies, and consumables of $1.4 million and a decrease in professional fees of $0.5 million, partially offset by increases in consulting expenses and analytical testing of $0.4 million and $0.6 million, respectively.

General and Administrative Expenses

	Three Months Ended September 30,		
	2022	2021	Change
		(in thousands)	
Personnel related (including stock-based compensation)	$ 7,663	$ 6,792	$ 871
Professional fees	6,832	10,586	(3,754)
Facility-related and other	3,889	2,185	1,704
Total general and administrative expenses	$ 18,384	$ 19,563	$ (1,179)

General and administrative expenses were $18.4 million for three months ended September 30, 2022 compared to $19.6 million for the three months ended September 30, 2021. The decrease of $1.2 million was primarily due to the following:

- a decrease in professional fees of $3.8 million primarily due to decrease in professional services and consulting fees of $3.3 million and a decrease in recruiting expenses of $0.6 million;

partially offset by the following:

- an increase in personnel related costs of $0.9 million primarily due to an increase in salaries, bonus, payroll taxes and employee benefits expenses as a result of increased headcount;
- an increase in facility-related and other costs of $1.7 million primarily due to increases in license costs and office supplies of $2.2 million, partially offset by a decrease in IT-related expenses of $0.5 million.

Collaboration (Profit) Loss Sharing - related party

Collaboration (profit) loss sharing – related party resulted in a $1.1 million expense to us for the three months ended September 30, 2022, compared to $1.1 million of income for the three months ended September 30, 2021. For the three months ended September 30, 2022 and 2021, we incurred $2.9 million and $2.8 million, respectively, of pre-launch expenses which we recorded within research and development expense or general and administrative expense based on the nature of the underlying expense. Our collaborative partner incurred $5.0 million and $0.6 million of pre-launch expenses for the three months ended September 30, 2022 and 2021, respectively. Therefore, the $1.1 million of expense recorded in the three months ended September 30, 2022 represents the sharing of 50% of the pre-launch expenses and represents a loss to us because we performed less of the pre-launch activities than our collaborative partner.

Other (Expense) Income, Net

Other (expense) income, net for the three months ended September 30, 2022 and 2021 was $0.9 million of expense and $0.2 million of expense, respectively. The increase in other (expense) income, net was primarily due to an increase in interest expense of $1.0 million, partially offset by an increase in interest income of $0.3 million.

Comparison of Nine Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		
	2022	2021	Change
		(in thousands)	
Revenue:			
Collaboration revenue - related party	$ 6,153	$ 136,636	$ (130,483)
Grant revenue	—	1,070	(1,070)
Total revenue	6,153	137,706	(131,553)
Operating expenses:			
Research and development	126,700	105,139	21,561
General and administrative	57,290	48,755	8,535
Collaboration (profit) loss sharing - related party	346	(1,127)	1,473
Total operating expenses	184,336	152,767	31,569
Loss from operations	(178,183)	(15,061)	(163,122)
Other (expense) income:			
Interest income	1,644	2,385	(741)
Interest expense	(4,140)	(2,172)	(1,968)
Other expense	(682)	(729)	47
Total other (expense) income, net	(3,178)	(516)	(2,662)
Net loss	$ (181,361)	$ (15,577)	$ (165,784)

Revenue

Total revenue was $6.2 million and $137.7 million for the nine months ended September 30, 2022 and 2021, respectively. The decrease in revenue as compared to the prior period was primarily due to the collaboration revenue that was recognized during the third quarter of 2021 upon on the transfer of control of the license by the company to Nestlé, pursuant to the 2021 License Agreement. For additional information, see Note 11 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report. Additionally, we recorded a decrease in collaboration revenue of $1.6 million as compared to the prior period under the 2016 License Agreement. Revenue for the nine months ended September 30, 2021 also included $1.1 million of grant revenue related to our CARB-X grant for SER-155. We graduated from the CARB-X program in May 2021 and will receive no additional funding.

Research and Development Expenses

	Nine Months Ended September 30,		
	2022	2021	Change
	(in thousands)		
Microbiome therapeutics platforms	$ 25,126	$ 24,964	$ 162
SER-109	37,384	31,709	5,675
SER-287	1,614	7,976	(6,362)
Early stage programs	4,876	3,719	1,157
Total direct research and development expenses	69,000	68,368	632
Personnel-related (including stock-based compensation)	57,700	36,771	20,929
Total research and development expenses	$ 126,700	$ 105,139	$ 21,561

Research and development expenses were $126.7 million for the nine months ended September 30, 2022 and $105.1 million for the nine months ended September 30, 2021. The increase of $21.6 million was primarily due to the following:

- an increase in personnel-related costs of $20.9 million primarily due to an increase of $19.0 million in salaries, bonus, payroll taxes and employee benefits expenses and an increase of $1.9 million in stock-based compensation expense as a result of increased headcount;
- an increase of $5.7 million in expenses related to our SER-109 program primarily due to increases in facilities costs, lab supplies, and consumables of $6.1 million and consulting expenses of $0.8 million, partially offset by a decrease in clinical trial costs of $1.4 million; and
- an increase of $1.2 million in expenses for our early stage programs primarily due to an increase in consulting expenses of $1.1 million and an increase in professional fees of $0.1 million; and
- partially offset by a decrease of $6.4 million in expenses for our SER-287 program primarily due to a decrease in clinical trial costs of $5.7 million and a decrease in analytical testing of $0.8 million, as we continue to evaluate the data from our UC clinical stage programs, including SER-287, to inform next steps for further development.

General and Administrative Expenses

	Nine Months Ended September 30,		
	2022	2021	Change
	(in thousands)		
Personnel related (including stock-based compensation)	$ 22,999	$ 16,520	$ 6,479
Professional fees	22,998	25,533	(2,535)
Facility-related and other	11,293	6,702	4,591
Total general and administrative expenses	$ 57,290	$ 48,755	$ 8,535

General and administrative expenses were $57.3 million for the nine months ended September 30, 2022 compared to $48.8 million for the nine months ended September 30, 2021. The increase of $8.5 million was primarily due to the following:

- an increase in personnel related costs of $6.5 million primarily due to an increase of $4.8 million in salaries, bonus, payroll taxes and employee benefits expenses and an increase of $1.7 million in stock-based compensation expense as a result of increased headcount; and
- a decrease in professional fees of $2.5 million primarily due to decreases in professional services and consulting fees;
- an increase in facility-related and other costs of $4.6 million primarily due to increases in technology license costs and office supplies and IT-related expenses.

Collaboration (Profit) Loss Sharing - related party

Collaboration (profit) loss sharing – related party resulted in a $0.3 million expense to us for the nine months ended September 30, 2022, compared to $1.1 million of income for the nine months ended September 30, 2021. For the nine months ended

September 30, 2022 and 2021, we incurred $10.6 million and $2.8 million of pre-launch expenses which we recorded within research and development expense or general and administrative expense based on the nature of the underlying expense. Our collaborative partner incurred $11.3 million and $0.6 million of pre-launch expenses for the nine months ended September 30, 2022 and 2021. Therefore, the $0.3 million of expense recorded represents the sharing of 50% of the pre-launch expenses and represents a loss to us because we performed less of the pre-launch activities than our collaborative partner.

Other (Expense) Income, Net

Other (expense) income, net for the nine months ended September 30, 2022 and 2021 was $3.2 million of expense and $0.5 million of expense, respectively. The increase in other (expense) income, net was primarily due to an increase in interest expense of $2.0 million and a decrease in interest income of $0.7 million.

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. Our research and development and general and administrative expenses may continue to increase and, as a result, we will need additional capital to fund our operations, which we may obtain from additional financings, public offerings, research funding, additional collaborations, contract and grant revenue or other sources.

On June 29, 2022, we entered into securities purchase agreements with new and existing investors and certain directors and officers in a registered direct offering, or the Registered Direct Offering, of an aggregate of 31,746,030 shares of our common stock at a purchase price of $3.15 per share for total net proceeds of approximately $96.7 million, after deducting placement agent's fees and other estimated offering expenses. Net proceeds included an aggregate of $27.5 million received from Flagship Pioneering Fund VII, L.P. and Nutritional Health LTP Fund, L.P., affiliates of Flagship Pioneering, or Flagship, one of the our significant stockholders, in exchange for 8,738,243 shares. The closing date of the Registered Direct Offering was July 5, 2022.

In May 2021, we entered into a Sales Agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, to sell shares of our common stock, with aggregate gross sales proceeds of up to $150.0 million, from time to time, through an "at the market" equity offering program under which Cowen acts as sales agent. As of September 30, 2022, we have not sold any shares of common stock under the Sales Agreement.

As of September 30, 2022, we had cash, cash equivalents and investments totaling $233.0 million and an accumulated deficit of $795.7 million. Based on our current plans and forecasted expenses, we believe that our cash, cash equivalents and investments as of September 30, 2022, will enable us to fund our operating expenses, capital expenditure requirements, and debt service obligations for at least the next 12 months from the issuance of our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

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 SER-109, 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 SER-109 (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. The Letter Agreement also provides scenarios under which Nestlé's reimbursement to us for certain Phase 3 development costs would be reduced or delayed depending on the outcomes of the SER-287 Phase 2b study. 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, and Nestlé agreed to bear the cost of such activities to support approval of 2016 Collaboration Products in the 2016 Licensed Territory.

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 SER-109 and for Phase 3 clinical trials for SER-109. 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 SER-109 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 SER-109 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 our SER-109 product candidate) 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) our SER-109 product candidate 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 are responsible for, and will use commercially reasonable efforts in, conducting development of SER-109 in the 2021 Field in the United States until first regulatory approval for SER-109 is 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 2021 Collaboration Products in the 2021 Field in the 2021 Licensed Territory, at its cost, except that expenses incurred for regulatory activities approved by a joint steering committee pursuant to a life cycle management plan for 2021 Collaboration Products are shared equally between the parties. We will be solely responsible for manufacturing and supplying 2021 Collaboration Products for development in the 2021 Field in the 2021 Licensed Territory.

Nestlé has the sole right to commercialize the 2021 Collaboration Products 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 the 2021 Collaboration Products in the 2021 Licensed Territory in accordance with the commercialization plan. Both parties will perform medical affairs activities for 2021 Collaboration Products in the 2021 Licensed Territory in accordance with a medical affairs plan. We will be solely responsible for the manufacturing and supply of 2021 Collaboration Products for commercialization under a supply agreement that will be entered into between the parties. We are responsible for commercialization and medical affairs activities costs incurred by the parties until first commercial sale of the first 2021 Collaboration Product in the 2021 Licensed Territory and in accordance with a pre-launch plan, up to a specified cap. Following first commercial sale of the first 2021 Collaboration Product, we will be entitled to a royalty in an amount equal to approximately 50% of the commercial profits.

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-cancellable 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 SER-109, $10.0 million upon Canadian regulatory approval of SER-109, 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 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 (i) with twelve months' prior written notice, effective only on or after the third anniversary of first commercial sale of the first 2021 Collaboration Product in the 2021 Licensed Territory, (ii) if first commercial sale of the first 2021 Collaboration Product in the 2021 Licensed Territory has not occurred by the fifth anniversary of the effective date of the 2021 License Agreement, with one hundred eighty days' prior written notice, which must be provided during a specified period set forth in the 2021 License Agreement, or (iii) if regulatory approval for SER-109 is not granted after submission by us of a filing seeking first regulatory approval as set forth in the development and regulatory activity plan, and the parties fail to agree on further development of SER-109 in accordance with the terms of the 2021 License Agreement, with one hundred eighty days' prior written notice, which must be provided within a specified period set forth in the 2021 License Agreement. 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, or the Bacthera Agreement, with BacThera AG, or Bacthera, a joint venture between Chr. Hansen and a Lonza Group affiliate. 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, which is currently under construction; and (ii) provide manufacturing services to us for our SER-109 product and, if agreed by the parties, SER-287 product.

Under the terms of the Bacthera Agreement, we agreed to pay Bacthera a total of at least 240 million CHF (or approximately $262 million) for the initial term of the agreement, inclusive of the construction fees and annual operating fees. The construction fees 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.

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 with 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. We did not meet the milestone requirements for the second tranche under the Original Credit Facility, and as such, the additional second tranche amount of up to $12.5 million was not available for us to borrow. We elected not to borrow the third tranche of $12.5 million, which was available upon Hercules' approval until June 30, 2021. Commitments of Hercules to lend to us under the Original Credit Facility are

subject to amendments made pursuant to the Second Amendment, as defined below. See "Amendment to Loan and Security Agreement with Hercules" below.

The Original Credit Facility also includes events of default, the occurrence and continuance of which provide Hercules with the right to demand immediate repayment of all principal and unpaid interest, and to exercise remedies against us and the collateral. These events of default include, among other things and subject to customary exceptions: (i) insolvency, liquidation, bankruptcy or similar events; (ii) failure to pay any debts due under the loan and security agreement with Hercules or other loan documents on a timely basis; (iii) failure to observe certain covenants under the loan and security agreement with Hercules; (v) occurrence of a material adverse effect; (vi) material misrepresentation by us; (vii) occurrence of any default under any other agreement involving material indebtedness; and (viii) certain material money judgments.

On April 16, 2020, we entered into an amendment to the loan and security agreement with Hercules, 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, or the Effective Date, we entered into a Second Amendment to the Original Credit Facility (as amended by the First Amendment), or the New Credit Facility, pursuant to which term loans in an aggregate principal amount of up to $100.0 million have become available to us in five tranches including the first tranche under the Original Credit Facility, subject to certain terms and conditions.

The first tranche in an aggregate principal amount of $25.0 million is outstanding as of the Effective Date, after taking into account reborrowing by us on the Effective Date of a previously-repaid principal amount of approximately $2.9 million. The second tranche in an aggregate principal amount of $12.5 million and the third tranche in an aggregate principal amount of $12.5 million have been advanced to us and were outstanding as of the Effective Date. The fourth tranche in an aggregate principal amount of $25.0 million is available upon satisfaction of certain conditions, including the approval by the FDA of a biologics license application in respect of SER-109, or the Regulatory Approval Milestone, by no later than December 15, 2023. The fifth tranche in an aggregate principal amount of up to $25.0 million is available through the Amortization Date (as defined below) upon satisfaction of certain conditions, including the Lenders' investment committee approval.

All advances outstanding under the New Credit Facility bear interest at a rate equal to the greater of either (i) the Prime Rate (as reported in The Wall Street Journal) plus 6.40%, and (ii) 9.65%. For all advances outstanding under the New Credit Facility, we will make interest only payments through December 31, 2023, extendable to December 31, 2024 upon satisfaction of certain conditions, such applicable date, the Amortization Date. The principal balance and interest of the advances will be repaid in equal monthly installments after the Amortization Date and continuing through October 1, 2024, extendable to October 1, 2025, upon satisfaction of certain conditions, such applicable date, the Maturity Date.

We may prepay advances under the New Credit Facility, in whole or in part, at any time subject to a prepayment charge equal to: (a) 2.0% of amounts so prepaid, if such prepayment occurs during the first year following the Effective Date; (b) 1.5% of the amount so prepaid, if such prepayment occurs during the second year following the Effective Date, and (c) 1.0% of the amount so prepaid, if such prepayment occurs during the third year following the Effective Date.

We will pay an end of term charge of 4.85% of the aggregate amount of the advances made under the Old Credit Facility on the earliest date of (i) November 1, 2023; (ii) the date that we prepay all of the outstanding principal in full, or (iii) the date the loan payments are accelerated due to an event of default. We will pay an additional end of term charge of 1.75% of the aggregate amount of the advances under the New Credit Facility (including the first tranche of $25.0 million) on the earliest date of (i) the Maturity Date; (ii) the date that we prepay all of the outstanding principal in full, or (iii) the date the loan payments are accelerated due to an event of default.

Other terms of the New Credit Facility remain generally identical to those under the Old Credit Facility, with certain covenants amended by the Second Amendment to provide us with additional operational flexibility, including the ability for us to issue up to $350.0 million in convertible notes. The New Credit Facility includes a conditional liquidity covenant commencing on June 15, 2023, which ceases to apply if certain conditions including the Regulatory Approval Milestone are satisfied.

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

As of September 30, 2022 and December 31, 2021, the outstanding principal under the New Credit Facility was $50.0 million and $24.1 million, respectively. For a further description of the New Credit Facility, see Note 8 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Cash Flows

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

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Cash (used in) provided by operating activities	$ (175,924)	$ 58,551
Cash provided by investing activities	76,502	50,902
Cash provided by financing activities	125,005	1,958
Net decrease in cash, cash equivalents and restricted cash	$ 25,583	$ 111,411

Operating Activities

During the nine months ended September 30, 2022, operating activities used $175.9 million of cash, primarily due to a net loss of $181.4 million and changes in our operating assets and liabilities of $22.9 million, partially offset by non-cash charges of $28.3 million. Non-cash charges consisted of stock-based compensation expense of $18.2 million, $3.6 million related to the amortization of right-of-use assets, $5.0 million of depreciation and amortization, and $0.7 million of net amortization of premium related to our investments, $0.6 million of non-cash interest expense, and loss sharing under the 2021 License Agreement with Nestlé of $0.3 million. Changes in our operating assets and liabilities during the nine months ended September 30, 2022 consisted of an increase in accrued expenses and other current and long-term liabilities of $2.9 million, a decrease in accounts payable of $3.3 million, a decrease in deferred revenue of $6.2 million, an increase in prepaid expenses and other current and other non-current assets of $12.9 million and a decrease in operating lease liabilities of $3.5 million. The increase in other current and other non-current assets is primarily driven by an increase in prepaid expenses of $7.3 million related to the Bacthera Agreement.

During the nine months ended September 30, 2021, operating activities provided $58.6 million of cash, primarily due to cash provided by changes in our operating assets and liabilities of $51.6 million and non-cash charges of $22.6 million, partially offset by a net loss of $15.6 million. Net cash provided by changes in our operating assets and liabilities during the nine months ended September 30, 2021 consisted of an increase in accrued expenses and other current and long-term liabilities of $43.0 million, an increase in accounts payable of $4.8 million, an increase in deferred revenue of $2.9 million, and a decrease in accounts receivable of $8.1 million. These increases were partially offset by an increase in prepaid expenses and other current and long-term assets of $5.0 million and a decrease in operating lease liabilities of $2.2 million. The increase in accrued expenses and other current and long-term liabilities was primarily due to an increase of $33.8 million which represents an amount owed to Nestlé for pre-launch activities in conjunction with the 2021 License Agreement. The increase in accounts payable was due to the timing of payments. The increase in deferred revenue was primarily due to the 2021 License Agreement. The decrease in accounts receivable is due to our receipt of receivables due during the quarter. The increase in prepaid expenses and other current and long-term assets was due to timing of payments to vendors. The decrease in operating lease liabilities was due to the cash payment of lease obligations.

Investing Activities

During the nine months ended September 30, 2022, net cash provided by investing activities was $76.5 million, consisting of sales and maturities of investments of $119.0 million, partially offset by purchases of investments of $36.1 million and purchases of property and equipment of $6.4 million.

During the nine months ended September 30, 2021, net cash provided by investing activities was $50.9 million, consisting of sales and maturities of investments of $126.0 million, partially offset by purchases of investments of $66.3 million and purchases of property and equipment of $8.0 million and purchases of restricted investments of $0.8 million.

Financing Activities

During the nine months ended September 30, 2022, net cash provided by financing activities was $125.0 million, consisting of $96.7 million of net proceeds received from the Registered Direct Offering that we completed in July 2022 and $27.6 million of proceeds received from the New Credit Facility, net of issuance costs. We also received $0.8 million from the issuance of common stock associated with the exercise of stock options, and $1.8 million in connection with the issuance of common stock under our 2015 Employee Stock Purchase Plan, or ESPP. These payments were partially offset by principal payments under the Original Credit

Facility of $1.9 million.

During the nine months ended September 30, 2021, net cash provided by financing activities was $2.0 million, consisting of $1.1 million from the issuance of common stock associated with the exercise of stock options and $0.8 million in connection with the issuance of common stock under our ESPP.

Funding Requirements

Our expenses may increase substantially in connection with our ongoing clinical development activities and our 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 expenses will increase substantially if and as we:

- complete the clinical development, seek regulatory approval, and prepare for commercialization of SER-109 for patients with recurrent CDI;
- continue the clinical development of SER-155 to reduce incidences of gastrointestinal infections, bloodstream infections and GvHD in patients receiving allo-HSCT;
- continue evaluating preclinical stage programs to reduce incidence of infection, in indications such as cancer neutropenia, chronic liver disease, solid organ transplant, and antimicrobial resistant infections more broadly;
- continue translational research activities, informed by the SER-287 Phase 2b and SER-301 Phase 1b study data, to evaluate the potential to utilize biomarker-based patient selection and stratification in future clinical development efforts;
- make strategic investments in our research discovery and development platforms and capabilities to advance our priority programs;
- make strategic investments in manufacturing capabilities;
- maintain and augment our intellectual property portfolio and opportunistically acquire complementary intellectual property;
- potentially establish a sales and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products 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 impact of the COVID-19 pandemic;
- the impact of continued increase in inflation rates or interest rates;
- the progress and results of our clinical studies and preclinical development;
- the cost of manufacturing our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates and research activities;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales 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 and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products 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 the COVID-19 pandemic 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 loan and security agreement with Hercules currently 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 noted above, the magnitude and duration of the COVID-19 pandemic and its impact on our liquidity and future funding requirements is uncertain as of the filing date of this Quarterly Report as this continues to evolve globally. See "Risk Factors —Risks Related to Our Operations—The COVID-19 pandemic has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition" in Part II, Item 1A of this Quarterly Report for a further discussion of the possible impact of the COVID-19 pandemic on our business.

Contractual Obligations and Commitments

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Fluctuation Risk

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

As of September 30, 2022, our cash, cash equivalents and investments consisted of cash and money market accounts. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, an immediate 10% change in market interest rates would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

As of September 30, 2022, we had outstanding borrowings under the New Credit Facility. We accrue interest at a rate equal to the greater of either (i) the Prime Rate (as reported in The Wall Street Journal) plus 6.40%, and (ii) 9.65%. An immediate 10% change in the Prime 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 September 30, 2022, 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 September 30, 2022 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.

Opposition Proceeding

On October 19, 2016, the European Patent Office granted European Patent No. 2 575 835 B1 to The University of Tokyo. On April 25, 2017, we filed a notice of opposition to this patent in the European Patent Office, 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 has appealed certain aspects of the Opposition Division's decision, as have we and other opponents.

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 development-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 $65.6 million for the year ended December 31, 2021, and $181.4 million for the nine months ended September 30, 2022. As of September 30, 2022, we had an accumulated deficit of $795.7 million. 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 not completed development of any of our 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. We anticipate that our expenses may increase substantially as we:

- complete the clinical development, seek regulatory approval, and prepare for potential commercialization of SER-109 for patients with recurrent CDI;
- continue the clinical development of SER-155 to reduce incidences of gastrointestinal infections, bloodstream infections and GvHD in patients receiving allo-HSCT;
- continue evaluating preclinical stage programs to reduce incidence of infection, in indications such as cancer neutropenia, chronic liver disease, solid organ transplant, and antimicrobial resistant infections more broadly;
- continue translational research activities, informed by the SER-287 Phase 2b and SER-301 Phase 1b study data, to evaluate the potential to utilize biomarker-based patient selection and stratification in future clinical development efforts;
- make strategic investments in our research discovery and development platforms and capabilities to advance our priority programs;
- make strategic investments in manufacturing capabilities;
- maintain and augment our intellectual property portfolio and opportunistically acquire complementary intellectual property;
- potentially establish a sales and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products 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.

To become and remain profitable, we must succeed in developing and eventually 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 may 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 efforts, diversify our product offerings or even continue our operations.

We will need additional funding in order to complete development of our product candidates and commercialize our products, 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 as we continue the clinical development of SER-109 and prepare for its potential commercialization pending regulatory approval, continue the SER-155 Phase 1b study, continue research activities evaluating UC, and continue to research, develop and initiate clinical trials of our other product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution, including under the 2021 License Agreement. Furthermore, we have incurred and expect to continue to incur additional costs associated with operating as a public company, including as a result of no longer qualifying as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, or as a "smaller reporting 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 future commercialization efforts.

We expect that our cash, cash equivalents and investments as of September 30, 2022 will be sufficient to fund our operating expenses, debt service obligations and capital expenditure requirements for at least the next 12-months from the issuance of our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report. In addition, the specifics of existing and future clinical trial activities could impact capital requirements and cash projections. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the impact of the COVID-19 pandemic;
- the impact of a continued increase in inflation rates or interest rates;
- the progress and results of our clinical studies;
- the cost of manufacturing our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Additionally, market volatility resulting from the COVID-19 pandemic 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 any product candidates, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially 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. We have not yet demonstrated our ability to obtain regulatory approvals, 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, 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 SER-109, we are early in our development efforts and may not be successful in our efforts to use our microbiome therapeutics platform to build a pipeline of product candidates and develop marketable drugs.

We are using our microbiome therapeutics platform to develop microbiome therapeutic candidates. Other than SER-109, we are at an early stage of development and our platform has not yet, and may never, lead to approvable or marketable drugs. We are developing additional product candidates that we intend to be used 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 achieve market acceptance.

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

- completion of preclinical studies and clinical trials with positive results;
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing our own, commercial manufacturing capabilities;
- launching commercial sales of our 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, 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 product candidates we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

Our product candidates are based on microbiome therapeutics, which is an unproven approach to therapeutic intervention.

All of our product candidates are based on microbiome therapeutics, a novel potential 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. We have not, nor to our knowledge has any other company, received regulatory approval for, or manufactured on a commercial scale, a therapeutic based on this approach. We cannot be certain that our approach will lead to the development of approvable or marketable products or that we will be able to manufacture at commercial scale, if approved. In addition, our microbiome therapeutic candidates may have different effectiveness rates in various indications and in different geographical areas. Finally, the FDA or other regulatory authorities may lack experience in evaluating the safety and efficacy of products 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 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 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.

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 other product candidates. Prior to approving a new therapeutic product, the FDA (or other regulatory authorities) generally requires that safety and efficacy 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.

Additional clinical trials or changes in our development plans could cause us to incur significant development costs, delay or prevent the commercialization of SER-109 or otherwise adversely affect our business. In addition, prolonged disruptions caused by the COVID-19 pandemic could severely impact our preclinical studies and clinical trials, including by causing further difficulties or delays in initiating, enrolling, conducting, or completing our planned and ongoing clinical trials. See "—Risks Related to Our Operations—The COVID-19 pandemic has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition."

Our product development costs will increase if we continue to experience delays in clinical testing or marketing approvals. 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 Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, 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 to all member states concerned. 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. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors may still choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as clinical 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 MHR, launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closes on March 14, 2022 and aims 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 outcome of the consultation will be closely watched and will determine whether the UK chooses to align with the regulation or diverge from it to maintain regulatory flexibility. A decision by the UK not to closely align its regulations with the new approach that will be adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and/or make it harder to seek a marketing authorization in the EU for our product candidates on the basis of clinical trials conducted in the UK.

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, including the use of unapproved fecal microbiota transplant, or FMT;
- 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 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.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become 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. 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. 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. A proposal for revision of several legislative instruments related to medicinal products (potentially revising the duration of regulatory exclusivity, eligibility for expedited pathways, etc.) is currently expected to be adopted by the European Commission by the end of the first quarter or the beginning of the second quarter in 2023. The proposed revisions, once they are agreed and adopted by the European Parliament and European Council (currently not expected before the end of 2024 or early 2025) may have a significant impact on the biopharmaceutical industry in the long term.

There may also be interruptions or delays in the operations of the FDA or other foreign regulatory authorities due to the COVID-19 pandemic, which may impact approval timelines. Regulatory authorities have substantial discretion in the approval process and may refuse to accept 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 is 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 filing 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 may 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. SER-287 received Fast Track designation from the FDA for the induction and maintenance of clinical remission in adults with mild-to-moderate UC. Fast Track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in addition to the potential for rolling review of a BLA for such product candidate. 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.

We have received Breakthrough Therapy designation for SER-109 for treatment of CDI, and we may seek a Breakthrough Therapy designation for our 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 are also eligible 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 the Breakthrough Therapy designation for SER-109 or 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 have 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 indication 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 or biologic for 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 Europe. 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 drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or other regulatory authorities determine that the request for designation was materially defective or if the manufacturer is unable to assure a sufficient quantity of the drug or biologic to meet the needs of patients with the rare disease or condition. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective.

Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity for a product may not effectively protect the product from competition because different drugs and biologics can be approved for the same 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 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, in March 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. According to the guidance, the FDA may request such remote interactive evaluations where the FDA determines that remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. More recently, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Regulatory authorities outside the United States, including the EMA, have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to 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, including SER-109, SER-287, and SER-301, could be 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 SER-109, 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 our SER-109 product and any improvements and modifications thereto developed pursuant to the terms of the 2021 License Agreement, or the 2021 Collaboration Products;
- by Nestlé if first commercial sale of the first 2021 Collaboration Product has not occurred by the fifth anniversary of the effective date of the 2021 License Agreement, with 180 days' prior written notice, which must be provided during a specified period set forth in the 2021 License Agreement;
- by Nestlé if regulatory approval for SER-109 is not granted after submission by us of a filing seeking first regulatory approval as set forth in the development and regulatory activity plan, and the parties fail to agree on further development

of SER-109 in accordance with the terms of the 2021 License Agreement, with 180 days' prior written notice, which must be provided within a specified period set forth in the 2021 License Agreement;

- 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 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 of any terminated products or discontinue any terminated products, 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. 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, 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 contract research organizations, or 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 healthcare 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 candidates for preclinical and clinical testing and for potential commercial manufacture, and we expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or that such quantities may not be available at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We rely, and expect to continue to rely, on third parties, including Recipharm and Bacthera, for certain aspects of materials supply for our product candidates in preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates on a timely basis or at all, or that such quantities will be available at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. For example, 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 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 our product candidates have never produced an FDA-approved therapeutic. One of the contract manufacturers on which we rely will be constructing a building in which to manufacture our product candidates, which may not be completed on time or at all or, upon completion, may not be approved by the FDA. 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. 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. Moreover, as a result of the COVID-19 pandemic, third-party manufacturers may be affected, which could disrupt their activities and as a result we could face difficulty sourcing key components necessary to produce supply of our product candidates, which may negatively affect our preclinical and clinical development activities.

We have no experience manufacturing our product candidates commercially, and we cannot assure you that we can manufacture our product candidates in compliance with regulations at a cost or in quantities necessary to make them commercially viable.

We have manufacturing facilities at our Cambridge, Massachusetts locations where we conduct process development, scale-up activities and a portion of the manufacture of microbiome therapeutics. The FDA and other comparable foreign regulatory authorities must, pursuant to inspections that are conducted after submitting a BLA or relevant foreign marketing submission, confirm that the manufacturing processes for the product meet cGMP or similar regulatory requirements outside the United States. We have not yet had any of our manufacturing facilities inspected.

We currently intend to rely in part on third-party manufacturers for the commercial manufacturing of SER-109 and may establish a manufacturing facility for SER-109 or any of our other product candidates for production at a commercial scale. We have no experience in manufacturing 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 Product Candidates and Other Legal Matters

Even if any of our product candidates receive marketing approval, it 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.

If any of our product candidates receives marketing approval, it 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 that are well established in the medical community or the use of FMT, and physicians may continue to rely on these treatments and our competitors and physicians may continue to seek to standardize and implement this procedure. If our product candidates receive approval but do not achieve an adequate level of acceptance, we or our collaborators may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our approved product candidates, if any, will depend on a number of factors, including:

- their efficacy, safety and other potential advantages compared to alternative treatments;
- the clinical indications for which our 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 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 no experience in the sale, marketing, or distribution of pharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish a sales and marketing organization or make arrangements with third parties to perform sales and marketing functions and we 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 in the United States and Canada. Under the 2021 License Agreement, Nestlé has the sole right to commercialize the 2021 Collaboration Products 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 the 2021 Collaboration Products in the 2021 Licensed Territory in accordance with the commercialization plan. Both parties will perform medical affairs activities for 2021 Collaboration Products in the 2021 Licensed Territory in accordance with a medical affairs plan. We will be responsible for commercialization and medical affairs activities costs incurred by the parties until first commercial sale of the first 2021 Collaboration Product in the 2021 Licensed Territory and in accordance with a pre-launch plan, up to a specified cap.

In the future, we expect to build a focused sales and marketing infrastructure, or certain components of such infrastructure, to market or co-promote our product candidates in the United States and potentially elsewhere, if and when they are approved. 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 rely and may increasingly rely on third parties, including Nestlé, to sell, market and distribute our product candidates. 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 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 our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. We are aware of a number of large pharmaceutical and biotechnology companies, as well as smaller, early-stage companies, that are pursuing the development 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 cure rates for recurrent CDI and our competitors and physicians may continue to seek to standardize and implement this procedure. 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 may develop. Our competitors also may obtain FDA or other regulatory approval for their products 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 any product candidates, the products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, any of which would harm our business.

Our ability to commercialize any 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 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 any products that we may develop.

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

- regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- decreased demand for any product candidates or products that we may develop;
- 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 may develop.

We currently hold $5.0 million in product liability insurance coverage in the aggregate, with a per occurrence limit of $5.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

Even if we and our collaborators are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, 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 12 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. This data exclusivity does not prevent another company from developing a product that is highly similar to the innovative product, generating its own data and seeking approval. Data exclusivity only assures that another company cannot rely upon the data within the innovator's application to support the biosimilar product's approval.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of 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 Europe, 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 European Union, or 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 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.

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

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

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

The FDA or other regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of our approved products. The FDA or other regulatory authorities closely regulates the post-approval marketing and promotion of drugs and biologics to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Violations of the FDA's and other regulatory authorities' restrictions relating to the promotion of prescription drugs by us or 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. It is difficult to predict whether or how any executive orders will be implemented, or whether they will be rescinded and replaced under the future administrations. The policies and priorities of the new administrations are unknown and could materially impact the regulations governing our product candidates.

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 any of our product candidates are approved and we or our collaborators are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory authorities strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory authorities as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it 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 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 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 any products for which we 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;
- 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 product candidates and affect the prices we may obtain.

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

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

Among the provisions of the ACA of importance to our 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;
- 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. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. It is unclear how healthcare reform measures enacted by Congress or implemented by the Biden administration or other challenges to the ACA, if any, will impact the ACA or our business. 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 of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2030, 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. Under current law enacted as part of the ACA, drug manufacturers' Medicaid Drug Rebate Program rebate liability is 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 generate revenue, attain profitability, or commercialize our product candidates, if approved.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Individual states in the United States have become increasingly active in implementing regulations designed to contain pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Most significantly, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated, and while the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

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

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

In some countries, particularly the EU member states, the pricing of certain pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various EU member states and parallel distribution or arbitrage between low-priced and high-priced member states, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. Even if a pharmaceutical product obtains a marketing authorization in the EU, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all. If coverage and reimbursement of our products are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, 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 a very early stage. For some 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 24 active patent application families (which includes an option to license certain IP from MD Anderson and exclusive licenses to certain IP from Memorial Sloan Kettering Cancer Center). Of these, 22 applications have been nationalized and two are pending at the PCT stage. While we have obtained 24 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, such claims would not prevent a third party from

commercializing alternative compositions that do not include both of the bacterial populations claimed in pending applications, potential applications or patents that have or may issue. There can be no assurance that any such alternative composition will not be equally effective. Further, given that our SER-109 product candidate 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 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. In addition, given the early stage of prosecution of our portfolio, it may be some time before we understand 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 has appealed certain aspects of the Opposition Division's decision, as have we and other opponents. 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 our product candidates or any other products or product candidates;
- any of our pending patent applications will issue as patents at all;

- we will be able to successfully commercialize 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, only 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 issued 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 our product candidates 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, products or use of 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 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. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, 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, our products or the use of our products. We are aware of several pending patent applications containing one or more claims that could be construed to cover some of our product candidates or technology, should those claims issue in their original form or in the form presently being pursued. In addition, we are aware of third-party patent families that include issued and allowed patents, including in the United States, including claims that, if valid and enforceable, could be construed to cover some of our product candidates or their methods of use. On April 25, 2017, we filed a notice of opposition in the European Patent Office challenging the validity of a patent issued to The University of Tokyo and requesting that it be revoked in its entirety for the reasons set forth in our opposition. The oral proceedings were held at the European Patent Office on February 18, 2019 and the Opposition Division required The University of Tokyo to narrow the scope of the claims of the patent. The University of Tokyo has appealed certain aspects of the Oppositions Division's decision, as have we and other opponents.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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 COVID-19 pandemic has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition.

The COVID-19 pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, and facilities and production have been suspended. In response to the spread of COVID-19 we have limited the number of staff in any given research and development laboratory. We are continuing to monitor the impact of the COVID-19 pandemic on our operations and ongoing clinical development activity. Our mitigation activities to minimize COVID-19-related operation disruptions are ongoing, however, given the severity and evolving nature of the situation, the timing of clinical readouts is uncertain. As a result of the COVID-19 pandemic, we or our collaborators may experience further disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns, global shipping delays or stoppages and disruptions in delivery systems;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.
- refusal of the FDA or other regulatory authorities to accept data from clinical trials in affected geographies;
- impacts from prolonged remote work arrangements, such as increased cybersecurity risks and strains on our business continuity plans; and
- delays or difficulties with equity offerings due to disruptions and uncertainties in the securities market.

In addition, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic further impacts our business, including our preclinical studies and clinical trials, results of operations and financial condition will depend on future developments which are highly uncertain and cannot be predicted with confidence. Such factors include but are not limited to the duration and severity of the pandemic, the impact of variants, travel restrictions, quarantines, shelter-in-place orders and social distancing recommendations and regulations in the U.S. and other countries, business closures or business disruptions, the adoption and effectiveness of vaccines and vaccine distribution efforts, and the effectiveness of other actions taken in the U.S. and other countries to contain and treat the disease.

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. 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. 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.

We may expand our operational capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We may experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of lead discovery and product development, regulatory affairs, clinical affairs and manufacturing and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage potential future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such potential growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

We currently have limited international operations, but our business strategy incorporates potentially expanding internationally if any of our product candidates receive regulatory approval. We have conducted clinical studies in Australia and New Zealand in the past, and may in the future conduct clinical studies in other countries as well. We currently plan to rely on collaborators, including Nestlé, to commercialize certain approved products outside of North America. 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, 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;
- political unrest and wars, such as the current situation with Ukraine and Russia, 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, political and economic instability, including terrorism and political unrest, outbreak of disease or epidemics such as the COVID-19 pandemic, 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.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

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 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. 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 use or disclosure, unauthorized access, inappropriate modification and the risk of our being unable to adequately monitor and audit and modify our controls over our critical 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 and infrastructure may still be vulnerable to, and we have in the past experienced, attacks by hackers or viruses or breaches due to employee error, malfeasance or other malicious or inadvertent disruptions. Further, attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working 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. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, breach, or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, and regulatory penalties. Notice of breaches may be required to affected individuals or other state, federal or foreign regulators, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could 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 we can protect our data from breach. Unauthorized access, loss or dissemination could also disrupt our operations and damage our reputation, any of which could adversely affect our business.

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 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 directly subject to its requirements or penalties. 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, some of which may be more stringent than HIPAA. 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. In addition, the CCPA went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the CPRA recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia and Colorado, and have been proposed in other states and at the 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, the CPRA 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.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. For example, in Europe, the GDPR went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals 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 company, whichever is greater. 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; in July 2020, the Court of Justice of the EU, or CJEU, limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses, or SCCs. The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer of personal data outside of the EEA and not the UK; the UK's Information Commissioner's Office launched a public consultation on its draft revised data transfers mechanisms in August 2021 and laid its proposal before Parliament, with the UK SCCs expected to come into force in March 2022, with a two-year grace period. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. 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.

The EU has also proposed a Regulation on Privacy and Electronic Communications, or ePrivacy Regulation, which, if adopted, would impose new obligations on the use of personal data in the context of electronic communications, particularly with respect to online tracking technologies and direct marketing. Additionally, the EU adopted the EU Clinical Trials Regulation, which came into effect on January 31, 2022. This regulation imposes new obligations on the use of data generated from clinical trials and enables European patients to have the opportunity to access information about clinical trials.

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 data protection regime, 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 company's global annual revenue for the preceding financial year, whichever is greater. 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 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, 2021, we had net operating loss carryforwards, or NOLs, of $402.5 million for federal income tax purposes and $394.1 million for state income tax purposes, which may be available to offset our future taxable income, if any. Our federal and state NOLs begin to expire in various amounts in 2035, provided that federal NOLs generated in taxable years after December 31, 2017 will not be subject to expiration. As of December 31, 2021, we also had federal and state research and development and other tax credit carryforwards of approximately $43.7 million and $11.9 million, respectively, available to reduce future income tax liabilities. 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 $23.7 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 three-year period. We have experienced ownership changes in the past, per the Section 382 study performed through December 31, 2020, and may experience ownership changes in the future because of future transactions in our stock, some of which may be outside our control. We believe that none of the existing tax attributes will expire unused as a result of the calculated limitations. If we undergo future ownership changes, 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. Federal NOLs arising in periods beginning after December 31, 2017 may generally only be used to offset 80% of taxable income in years beginning after December 31, 2020, which may require us to pay federal income taxes in future years despite generating federal NOLs in prior years.

The terms of our credit facility 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.

In October 2019, we entered into a loan and security agreement with Hercules pursuant to which a term loan facility in aggregate principal amount 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. We did not meet the milestone requirements for the second tranche under the Original Credit Facility, and as such, the additional second tranche amount of up to $12.5 million is not available for us to borrow. We elected not to borrow the third tranche of $12.5 million, which was available upon Hercules' approval until June 30, 2021. The Original Credit Facility is secured by a lien on substantially all of our assets, other than intellectual property. We also agreed not to pledge or secure our intellectual property to others.

In April 2020, we entered into an amendment to the loan and security agreement with Hercules, 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.

In February 2022, we entered into a second amendment to the loan and security agreement with Hercules, or the Second Amendment, which amended the Original Credit Facility. Pursuant to the Second Amendment, term loans in an aggregate principal amount of up to $100.0 million, or the New Credit Facility, have become available to us in five tranches, subject to certain terms and conditions: (i) the first tranche in an aggregate principal amount of $25.0 million that was outstanding as of the February 24, 2022 effective date, or the Effective Date, (ii) the second tranche in an aggregate principal amount of $12.5 million that has been advanced to us and was outstanding as of the Effective Date, (iii) the third tranche in an aggregate principal amount of $12.5 million that has been advanced to us and was outstanding as of the Effective Date, (iv) the fourth tranche in an aggregate principal amount of $25.0 million available upon satisfaction of certain conditions, including the approval by the FDA of a biologics license application in respect of SER-109 by no later than December 15, 2023, and (v) the fifth tranche in an aggregate principal amount of up to $25.0 million that is available through the amortization date upon satisfaction of certain conditions, including the lenders' investment committee approval.

The New Credit Facility includes affirmative and negative covenants and events of default applicable to us. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on our transferring collateral, making changes to the nature of our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, engaging in transactions with affiliates. The New Credit Facility also includes a conditional liquidity covenant commencing on June 15, 2023, which ceases to apply if certain conditions including the Regulatory Approval Milestone are satisfied.

Events of default include, among other things and subject to customary exceptions: (i) insolvency, liquidation, bankruptcy or similar events; (ii) failure to pay any debts due under the loan and security agreement with Hercules or other loan documents on a timely basis; (iii) failure to observe certain covenants under the loan and security agreement with Hercules; (v) occurrence of a material adverse effect; (vi) material misrepresentation by us; (vii) occurrence of any default under any other agreement involving material indebtedness; and (viii) certain material money judgments. If we default under the loan and security agreement, Hercules may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Any declaration by Hercules 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.

Risks Related to Our Common Stock

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control or 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 72.8% of our outstanding voting stock. As a result, if these stockholders were to choose to act together, they would be able to control or 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 control or 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 no longer a "smaller reporting company" and, as a result we are subject to certain enhanced disclosure requirements.

As of December 31, 2021, we are no longer a “smaller reporting company” as defined under the rules promulgated under the Exchange Act. Since we are no longer a smaller reporting company, we are unable to provide simplified executive compensation disclosure or take advantage of certain other reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. Moreover, as a large accelerated filer, we are required to comply with the auditor attestation requirements under Section 404 of the Sarbanes Oxley Act of 2002, as amended, or Section 404.

We expect that the loss of smaller reporting company status and compliance with the related additional disclosure requirements will increase our legal and financial compliance costs and cause management and other personnel to divert attention from operational and other business matters to these additional public company reporting requirements.

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, our loan and security agreement with Hercules Capital 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:

- 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;
- developments related to any future collaborations;
- regulatory or legal developments in the United States and other countries;
- development of new product candidates that may address our markets and may make our product candidates less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;
- announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;

- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

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

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

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

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

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

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

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

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. Additionally, we are no longer a non-accelerated filer, so we are 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.

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.

None.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference			Filing Date	Filed/ Furnished Herewith
		Form	File No.	Exhibit		
3.1	Restated Certificate of Incorporation, filed on July 1, 2015	8-K	001-37465	3.1	7/1/15	
3.2	Amended and Restated Bylaws	8-K	001-37465	3.2	12/7/20	
10.1#	Supply Agreement, dated September 15, 2015, by and between Seres Therapeutics, Inc. and GenIbet BioPharmaceuticals, SA, as amended					*
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					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

* Filed herewith.
** Furnished herewith.
# Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Regulation S-K, Item 601(b)(10)(iv). Such omitted information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

SIGNATURES

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

SERES THERAPEUTICS, INC.

Date: November 2, 2022

By: /s/ David Arkowitz

David Arkowitz
Executive Vice President, Chief Financial Officer and Head of Business Development
(Principal Financial and Accounting Officer)

[***] 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.

10.5.2 Export/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.

10.5.3 Other 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. [***].

1.1.1 EU 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, [***].

1.1.1 Cooperation. 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.

10.6 Audits. 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 [***].

10.7 Foreign 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

11.1 Confidentiality 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).

11.2 Public 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

12.1 By 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.

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

12.3 Disclaimer 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

13.1 Indemnification 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.

13.2 Indemnification 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) [***].

13.3 Notification 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

15.1 **Term**. 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.

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

15.3 **Early 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 [***].

15.4 **Termination 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.

15.5 Termination 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.

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

15.7 Effect 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

3.2 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.

3.3 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:

3.3.1 a 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;

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

3.3.3 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.

3.4 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.

3.5 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) [***].

3.6 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.

3.7 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.

3.8 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.

3.9 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

3.10 No Consequential Damages.

3.10.1 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 [***].

3.11 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.

3.12 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.

3.13 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

[***]

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Exhibit 4

Charges

[***]

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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 Genlbet BioPharmaceuticals SA ("Genlbet").

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/[***]
[***]

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

Exhibit 31.1

CERTIFICATIONS

I, Eric D. Shaff, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Seres Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2022

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

Exhibit 31.2

CERTIFICATIONS

I, David Arkowitz, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Seres Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2022

By: /s/ David Arkowitz
David Arkowitz
Executive Vice President, Chief Financial Officer and Head of Business Development
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

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

(1) The Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 2, 2022

/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, David Arkowitz, Executive Vice President, Chief Financial Officer and Head of Business Development of Seres Therapeutics, Inc. (the "Company"), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 2, 2022

/s/ David Arkowitz
David Arkowitz
Executive Vice President, Chief Financial Officer and Head of Business Development
(Principal Financial and Accounting Officer)