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, 2021

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 November 3, 2021, the registrant had 91,847,137 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, manufacturing activities 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 and SER-287, 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. and NHSc Pharma Partners (collectively, 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, would 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 receives 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 caused by the novel strain of coronavirus 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, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 227,460	$ 116,049
Short term investments	119,927	137,567
Prepaid expenses and other current assets	10,174	5,774
Accounts receivable	1,250	9,387
Total current assets	358,811	268,777
Property and equipment, net	17,355	13,897
Operating lease assets	11,588	9,041
Restricted investments	2,150	1,400
Long term investments	5,788	49,825
Other non-current assets	601	—
Total assets	$ 396,293	$ 342,940
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,623	$ 4,018
Accrued expenses and other current liabilities (1)	48,900	14,226
Operating lease liabilities	6,099	5,115
Short term portion of note payable, net of discount	9,345	454
Deferred revenue - related party	21,624	22,602
Total current liabilities	94,591	46,415
Long term portion of note payable, net of discount	16,117	24,639
Operating lease liabilities, net of current portion	12,231	10,561
Deferred revenue, net of current portion - related party	89,413	85,572
Other long-term liabilities (2)	8,203	1,003
Total liabilities	220,555	168,190
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2021 and December 31, 2020; no shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at September 30, 2021 and December 31, 2020; 91,841,974 and 91,459,239 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	92	91
Additional paid-in capital	739,988	723,482
Accumulated other comprehensive income (loss)	11	(47)
Accumulated deficit	(564,353)	(548,776)
Total stockholders' equity	175,738	174,750
Total liabilities and stockholders' equity	$ 396,293	$ 342,940

[1] Includes related party amounts of $26,734 and $0 at September 30, 2021 and December 31, 2020, respectively (see Note 10)
[2] Includes related party amounts of $7,075 and $0 at September 30, 2021 and December 31, 2020, respectively (see Note 10)

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Collaboration revenue - related party	$ 126,725	$ 80	$ 136,636	$ 10,728
Grant revenue	—	1,337	1,070	2,907
Collaboration revenue	—	—	—	2,016
Total revenue	126,725	1,417	137,706	15,651
Operating expenses:				
Research and development expenses	39,882	23,861	105,139	65,703
General and administrative expenses	19,563	7,551	48,755	20,180
Collaboration (profit) loss sharing - related party	(1,127)	—	(1,127)	—
Total operating expenses	58,318	31,412	152,767	85,883
Income (Loss) from operations	68,407	(29,995)	(15,061)	(70,232)
Other (expense) income:				
Interest income	590	100	2,385	333
Interest expense	(744)	(730)	(2,172)	(2,165)
Other (expense) income	(35)	345	(729)	1,189
Total other (expense) income, net	(189)	(285)	(516)	(643)
Net income (loss)	$ 68,218	$ (30,280)	$ (15,577)	$ (70,875)
Net income (loss) per share attributable to common stockholders, basic	$ 0.74	$ (0.36)	$ (0.17)	$ (0.93)
Net income (loss) per share attributable to common stockholders, diluted	$ 0.72	$ (0.36)	$ (0.17)	$ (0.93)
Weighted average common shares outstanding, basic	91,757,614	83,531,617	91,649,035	75,914,361
Weighted average common shares outstanding, diluted	94,953,117	83,531,617	91,649,035	75,914,361
Net income (loss)	68,218	(30,280)	(15,577)	(70,875)
Other comprehensive income (loss):				
Unrealized gain (loss) on investments, net of tax of $0	(1)	1	58	2
Total other comprehensive income (loss)	(1)	1	58	2
Comprehensive income (loss)	$ 68,217	$ (30,279)	$ (15,519)	$ (70,873)

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

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

	Common Stock		Additional		Accumulated Other	Total Stockholders'
	Shares	Par Value	Paid-in Capital	Accumulated Deficit	Comprehensive Income (Loss)	Equity (Deficit)
Balance at December 31, 2019	70,143,252	$ 70	$ 411,255	$ (459,649)	$ —	$ (48,324)
Issuance of common stock from at the market equity offering	1,230,531	1	4,177		—	4,178
Issuance of common stock upon exercise of stock options	110,967	1	59	—	—	60
Issuance of common stock upon vesting of RSUs, net of tax withholdings	110,000	—	120	—	—	120
Issuance of common stock under ESPP	76,317	—	249	—	—	249
Stock-based compensation expense	—	—	1,959	—	—	1,959
Unrealized loss on investments	—	—	—	—	(10)	(10)
Net loss	—	—	—	(19,881)	—	(19,881)
Balance at March 31, 2020	71,671,067	72	417,819	(479,530)	(10)	(61,649)
Issuance of common stock from at the market equity offering	3,430,453	3	14,845	—	—	14,848
Issuance of common stock upon exercise of stock options	30,314	—	15	—		15
Stock-based compensation expense	—	—	1,914	—	—	1,914
Unrealized gain on investments	—	—	—	—	11	11
Net loss	—	—	—	(20,714)	—	(20,714)
Balance at June 30, 2020	75,131,834	75	434,593	(500,244)	1	(65,575)
Issuance of common stock from public offering, net of commissions, underwriting discounts and offering costs	12,075,000	12	243,736	—	—	243,748
Issuance of common stock from Securities Purchase Agreement, net of offering costs - related party	959,002	1	19,899	—	—	19,900
Issuance of common stock from at the market equity offering	1,126,697	1	5,745	—	—	5,746
Issuance of common stock upon exercise of stock options	1,828,027	2	12,048	—	—	12,050
Issuance of common stock upon vesting of RSUs, net of tax withholdings	15,000	—	—	—	—	—
Issuance of common stock under ESPP plan	78,976	—	213	—	—	213
Stock-based compensation expense	—	—	2,249	—	—	2,249
Unrealized gain on investments	—	—	—	—	1	1
Net loss	—	—	—	(30,280)	—	(30,280)
Balance at September 30, 2020	91,214,536	$ 91	$ 718,483	$ (530,524)	$ 2	$ 188,052

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	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
Unrealized gain on investments	—	—	—	—	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
Unrealized gain on investments	—	—	—	—	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 plan	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

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,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (15,577)	$ (70,875)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	14,548	6,122
Depreciation and amortization expense	4,395	5,069
Non-cash operating lease cost	2,292	1,693
Accretion of discount on investments	2,097	(105)
Non-cash interest expense	368	329
Collaboration (profit) loss sharing - related party	(1,127)	
Changes in operating assets and liabilities:		
Prepaid expenses and other current and long-term assets	(5,001)	(3,054)
Accounts receivable	8,137	(1,608)
Deferred revenue - related party	2,863	(11,917)
Accounts payable	4,781	1,032
Operating lease liabilities	(2,185)	(3,288)
Accrued expenses and other current and long-term liabilities (3)	42,960	919
Net cash provided by (used in) operating activities	58,551	(75,683)
Cash flows from investing activities:		
Purchases of property and equipment	(7,988)	(365)
Purchases of investments	(66,342)	(125,995)
Sales and maturities of investments	125,982	42,804
Purchase of restricted investments	(750)	—
Net cash provided by (used in) investing activities	50,902	(83,556)
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of commissions, underwriting discounts and offering costs	—	244,020
Proceeds from Securities Purchase Agreement, net of issuance costs - related party	—	20,000
Proceeds from exercise of stock options	1,131	12,065
Proceeds from issuance of common stock and restricted common stock	—	120
Proceeds from at the market equity offering, net of commissions	—	24,772
Issuance of common stock under ESPP	827	462
Net cash provided by financing activities	1,958	301,439
Net increase in cash and cash equivalents	111,411	142,200
Cash, cash equivalents and restricted cash at beginning of period	116,049	65,126
Cash, cash equivalents and restricted cash at end of period	$ 227,460	$ 207,326
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,836	$ 1,843
Supplemental disclosure of non-cash investing and financing activities:		
Issuance costs from public offering included in accounts payable and accrued expenses	$ —	$ 272
Securities Purchase Agreement issuance costs included in accounts payable and accrued expenses - related party	$ —	$ 100
Proceeds from exercise of stock options in prepaid expenses and other current assets	$ —	$ 61
Lease liability arising from obtaining right-of-use assets	$ 4,839	$ —
Property and equipment purchases included in accounts payable and accrued expenses	$ 316	$ —

[3]Includes related party amounts of $33,809 and $0 at September 30, 2021 and December 31, 2020, respectively (see Note 10)

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 company developing a novel class of live biotherapeutic drugs, which are consortia of microbes designed to treat disease by modulating the microbiome to treat or reduce disease by repairing the function of the microbiome to a non-disease state. The Company's lead product candidate, SER-109, is designed to reduce further recurrence of *Clostridioides difficile* infection ("CDI"), a debilitating infection of the colon, in patients who have received antibiotic therapy for recurrent CDI by treating the disruption of the colonic microbiome. In August 2020, the Company announced that SER-109 had achieved its primary endpoint of superiority to placebo in reducing CDI recurrence at week 8 in its Phase 3 ECOSPOR III clinical trial in patients with recurrent CDI. SER-109 was observed to be well tolerated, with no treatment-related serious adverse events observed in the active arm and an adverse event profile comparable to placebo. If approved by the U.S. Food and Drug Administration ("FDA"), we believe SER-109 will be a first-in-field oral microbiome drug. SER-287 and SER-301 are being developed by the Company to treat ulcerative colitis ("UC"). In addition, using its microbiome therapeutics platform, the Company is also developing product candidates to treat diseases where the microbiome is implicated, including SER-155, a consortium of cultivated bacteria, therapeutic candidate designed to reduce morbidity and mortality due to gastrointestinal infections, bacteremia and graft versus host disease ("GvHD") in immunocompromised patients, including in patients receiving allogeneic hematopoietic stem cell transplantation ("allo-HSCT") and solid organ transplants. The Company continues to evaluate microbiome pharmacokinetic and pharmacodynamic data from across its clinical and pre-clinical portfolios using its reverse translation microbiome therapeutics capabilities to conduct research on various indications, including pathogen infection and antibiotic resistant bacteria, inflammatory and immune diseases, cancer, and metabolic diseases.

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 pre-clinical 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.

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, 2021, the Company had an accumulated deficit of $564,353 and cash, cash equivalents and short and long-term investments of $353,175. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future. As of November 10, 2021, the issuance date of the condensed consolidated financial statements for the nine months ended September 30, 2021, the Company expects that its cash, cash equivalents and short and long-term investments will be sufficient to fund its operating expenses, debt service obligations and capital expenditure requirements for at least the next 12 months. 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 Pharma Partners (collectively, "Nestlé") if certain development, regulatory approval or sales target milestones are achieved. NHSc Pharma Partners is affiliated with Société des Produits Nestlé S.A. and Nestlé Health Science US Holdings, Inc. ("Nestlé Health Science"), both of which are significant stockholders of the Company. The milestone payments 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, 2021 and for the three and nine months ended September 30, 2021 and 2020 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, 2020 included in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2020, which was filed with the SEC on March 2, 2021 (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, 2020 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, 2021 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2021.

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, 2020, 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, 2021, with the exception of collaborative arrangements.

Collaborative Arrangements

The Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC Topic 808, Collaborative Arrangements ("Topic 808"). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of Topic 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of Topic 808 and which elements of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of Topic 606. For elements of collaboration arrangements that are accounted for pursuant to Topic 808, an appropriate recognition method is determined and applied consistently, either by analogy to authoritative accounting literature or by applying a reasonable and rational policy election. For those elements of the arrangement that are accounted for pursuant to Topic 606, the Company presents the arrangement as collaboration revenue – related party in the condensed consolidated statements of operations and comprehensive income (loss).

For collaboration arrangements that are within the scope of Topic 808, the Company evaluates the income statement classification for presentation of amounts due from or owed to other participants associated with multiple activities in a collaboration arrangement based on the nature of each separate activity. Amounts due from or owed to other participants that are the result of a collaborative relationship instead of a customer relationship are recorded as collaboration (profit) loss sharing in the condensed consolidated statements of operations and comprehensive income (loss).

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.

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including revenue, operating expenses, clinical trials and employee-related amounts, will depend on future developments that are highly uncertain, including new information that may emerge concerning COVID-19 and the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. We have made estimates of the impact of COVID-19 within our financial statements and there may be changes to those estimates in future periods. Actual results could differ from the Company's estimates.

Net Income (Loss) per Share

Basic net income (loss) per share is computed using the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is computed using the sum of the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options and unvested restricted stock.

The restricted stock units granted by the Company entitle the holder of such awards to ordinary cash dividends paid to substantially all holders of the Company's common stock, as if such shares were outstanding common shares at the time of the dividend. The dividends are paid in cash or shares of common stock when the applicable restricted stock unit vests. However, the unvested restricted stock units are not entitled to share in the residual net assets (deficit) of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Recently Issued 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. This standard will be effective for the Company on January 1, 2023. The Company is currently evaluating the potential impact that this standard may have on its condensed consolidated financial statements and related disclosures.

3. Fair Value Measurements

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

	Fair Value Measurements as of September 30, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 26,648	$ —	$ —	$ 26,648
Commercial paper	—	9,911	—	9,911
Investments:				
Commercial paper	—	13,347	—	13,347
Corporate bonds	—	46,748	—	46,748
Certificate of deposits	—	2,272		2,272
Government securities	—	63,348	—	63,348
	$ 26,648	$ 135,626	$ —	$ 162,274

	Fair Value Measurements as of December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 35,480	$ —	$ —	$ 35,480
Commercial paper	—	10,313	—	10,313
Corporate bonds	—	2,014	—	2,014
Investments:				
Commercial paper	$ —	$ 12,343	$ —	$ 12,343
Corporate bonds	—	68,289	—	68,289
Certificate of deposits	—	2,272	—	2,272
Government securities	—	104,488	—	104,488
	$ 35,480	$ 199,719	$ —	$ 235,199

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, certificate of deposits 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, 2021 and 2020.

As of September 30, 2021 and December 31, 2020, the Company held restricted investments of $2,150 and $1,400, respectively, which represent certificates of deposit that are classified as Level 2 in the fair value hierarchy.

4. Investments

Investments by security type consisted of the following at September 30, 2021 and December 31, 2020 (in thousands):

	September 30, 2021			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Investments:				
Commercial paper	13,347	$ —	$ —	$ 13,347
Corporate bonds	46,742	12	(6)	46,748
Certificate of deposit	2,272	—	—	2,272
Government securities	63,343	7	(2)	63,348
	$ 125,704	$ 19	$ (8)	$ 125,715

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Investments:				
Commercial paper	$ 12,343	$ —	$ —	$ 12,343
Corporate bonds	68,333	8	(52)	68,289
Certificate of deposits	2,272	-	-	2,272
Government securities	104,491	6	(9)	104,488
	$ 187,439	$ 14	$ (61)	$ 187,392

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 $2,150 and $1,400 as the cost approximates current fair value as of September 30, 2021 and December 31, 2020, respectively.

The amortized cost and fair value of investments in commercial paper, corporate bonds, certificate of deposits and government securities by contractual maturity, as of September 30, 2021 and December 31, 2020 were as follows (in thousands):

	Available-for-Sale as of September 30, 2021		Available-for-Sale as of December 31, 2020	
	Cost	Fair Value	Cost	Fair Value
Due in 1-year or less	$ 119,915	$ 119,927	$ 137,588	$ 137,567
Due after 1-year through 5-years	5,789	5,788	49,851	49,825
	$ 125,704	$ 125,715	$ 187,439	$ 187,392

5. Property and Equipment, Net

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

	September 30, 2021	December 31, 2020
Laboratory equipment	$ 18,261	$ 15,985
Computer equipment	3,139	2,874
Furniture and office equipment	1,096	1,033
Leasehold improvements	32,555	27,977
Construction in progress	1,020	348
	56,071	48,217
Less: Accumulated depreciation and amortization	(38,716)	(34,320)
	$ 17,355	$ 13,897

Depreciation and amortization expense was $1,493, $4,395, $1,576 and $5,069 for the three and nine months ended September 30, 2021 and 2020, respectively.

6. Accrued Expenses and Other Current Liabilities

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

	September 30, 2021	December 31, 2020
Development and clinical manufacturing costs	$ 13,530	$ 6,339
Payroll and payroll-related costs	7,006	6,734
Liability related to 2021 License Agreement (Note 10)	26,734	-
Facility and other	1,630	1,153
	$ 48,900	$ 14,226

7. 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 "Term Loan 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 Term Loan Facility, and as such, the additional amount up to $12,500 is 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.

Advances under the Term Loan 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 4.40%, and (ii) 9.65%. The Company will make interest only payments through December 1, 2021. Following the interest only period, the Company will repay the principal balance and interest of the advances in equal monthly installments through November 1, 2023.

The Company may prepay advances under the Loan Agreement, in whole or in part, at any time subject to a prepayment charge (the "Prepayment Premium") equal to: (a) 3.0% of amounts so prepaid, if such prepayment occurs during the first year following the Closing Date; (b) 2.0% of the amount so prepaid, if such prepayment occurs during the second year following the Closing Date, and (c) 1.0% of the amount so prepaid, if such prepayment occurs after the second year following the Closing Date.

Upon prepayment or repayment of all or any of the term loans under the Term Loan Facility, the Company will pay (in addition to any Prepayment Premium) an end of term charge of 4.85% of the aggregate funded amount under the Term Loan Facility. With respect to the first tranche, an end of term charge of $1,213 will be payable upon any prepayment or repayment. To the extent that the Company is provided additional advances under the Term Loan Facility, the 4.85% end of term charge will be applied to any such additional amounts.

The Term Loan 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.

Upon issuance, the first tranche was recorded as a liability with an initial carrying value of $24,575, 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 is 11.47%. As of September 30, 2021, the carrying value of the debt is $25,462, of which $9,345 is classified as a current liability and $16,117 is classified as a long-term liability on the condensed consolidated balance sheet. As of December 31, 2020, the carrying value of the debt was $25,093, of which $454 was classified as a current liability and $24,639 was classified as a long-term liability on the condensed consolidated balance sheet.

As of September 30, 2021 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
2021 (remaining 3 months)	$ 949
2022	11,970
2023	12,081
Total	$ 25,000

During the three and nine months ended September 30, 2021 and 2020, the Company recognized $744, $2,172, $730 and $2,165, respectively, of interest expense related to the Loan Agreement, which is reflected in interest expense on the condensed consolidated statement of operations and comprehensive income (loss).

8. Common Stock and Stock-Based Awards

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, 2021, 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, 2020:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2020	10,037,130	$ 9.54	7.87	$ 156,627
Granted	2,825,431	22.27		
Exercised	(281,668)	3.89		
Forfeited	(1,677,450)	12.11		
Outstanding as of September 30, 2021	10,903,443	$ 11.28	7.54	$ 19,879,702
Options exercisable as of September 30, 2021	5,197,692	$ 8.34	6.24	$ 10,950,342

The weighted average grant-date fair value of stock options granted during the three and nine months ended September 30, 2021 and 2020 was $10.08, $17.89, $18.12 and $3.03 per share, respectively.

During the three months ended March 31, 2019, the Company granted performance-based stock options to employees for the purchase of an aggregate of 1.1 million shares of common stock with a grant date fair value of $4.58 per share. These stock options are exercisable only upon achievement of specified performance targets. During the three months ended March 31, 2021, the Company modified the determination date to achieve the specified performance targets for 50% of the performance-based stock options. The determination date to achieve the specified performance targets was not modified for the remaining 50% of the performance-based stock options and these options expired on April 1, 2021. As of September 30, 2021, none of the 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, 2021, the Company did not record any expense for these performance-based stock options.

Additionally, during the three months ended March 31, 2021, the Company granted performance-based stock options to employees for the purchase of an aggregate 440 thousand shares of common stock with a grant date fair value of $14.93 per share. These stock options are exercisable only upon achievement of specified performance targets. As of September 30, 2021, 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, 2021, the Company did not record any expense for these stock options in the three and nine months ended September 30, 2021.

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, 2020:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted stock units as of December 31, 2020	6,500	$ 25.36
Granted	565,798	$ 21.17
Vested	(650)	$ 25.36
Forfeited	(13,452)	$ 24.88
Unvested restricted stock units as of September 30, 2021	558,196	$ 21.12

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, 2021, the Company granted 565,798 RSUs. RSU's 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.

Stock-based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development expenses	$ 2,718	$ 1,368	$ 7,564	$ 3,358
General and administrative expenses	3,128	881	6,984	2,764
	$ 5,846	$ 2,249	$ 14,548	$ 6,122

9. Net Income (Loss) per Share

Basic and diluted net income (loss) per share attributable to common stockholders was calculated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Basic Earnings Per Share:				
Numerator:				
Net income (loss)	$ 68,218	$ (30,280)	$ (15,577)	$ (70,875)
Income (loss) attributable to common stockholders - basic	$ 68,218	$ (30,280)	$ (15,577)	$ (70,875)
Denominator:				
Weighted-average shares outstanding	91,757,614	83,531,617	91,649,035	75,914,361
Net income (loss) per share applicable to common stockholders - basic	$ 0.74	$ (0.36)	$ (0.17)	$ (0.93)
Diluted Earnings Per Share:				
Numerator:				
Net income (loss)	$ 68,218	$ (30,280)	$ (15,577)	$ (70,875)
Income (loss) attributable to common stockholders - diluted	$ 68,218	$ (30,280)	$ (15,577)	$ (70,875)
Denominator:				
Weighted-average shares outstanding	91,757,614	83,531,617	91,649,035	75,914,361
Dilutive impact from:				
Stock options to purchase common stock	3,186,762	—	—	—
Unvested restricted stock units	8,741	—	—	—
Weighted-average shares outstanding - diluted	94,953,117	83,531,617	91,649,035	75,914,361
Net income (loss) per share applicable to common stockholders - diluted	$ 0.72	$ (0.36)	$ (0.17)	$ (0.93)
Anti-dilutive potential common stock equivalents excluded from the calculation of net income (loss) per share:				
Stock options to purchase common stock	7,716,681	9,802,633	10,903,443	9,802,633
Unvested restricted stock units	549,455	—	558,196	—

The effect of dilutive securities was calculated using the treasury stock method.

The anti-dilutive potential common stock equivalents for the three months ended September 30, 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.

The anti-dilutive potential common stock equivalents for the nine months ended September 30, 2021 and the three and nine months ended September 30, 2020 were excluded from the computation of diluted net loss per share attributable to common

stockholders because those stock options to purchase common stock and restricted stock units had an anti-dilutive impact as the Company reported a net loss attributable to common stockholders for those periods.

10. Collaboration Revenue

License Agreement with NHSc Pharma Partners (Nestlé)

Summary of Agreement

In July 2021, the Company entered into a license agreement (the “2021 License Agreement”) with 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 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 recognizes 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 under the 2021 License Agreement. The amount allocated to the services performance obligation was not material.

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 will provide financial information about the pre-launch activities performed by both parties. The Company will reduce 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, 2021, there is $26,734 included in accrued expenses and other current liabilities and $7,075 included in other long-term liabilities.

The cost associated with pre-launch activities performed by the Company will be recorded within total operating expenses in the Company's condensed consolidated statements of operations and comprehensive income (loss). In the three and nine months ended September 30, 2021, the Company recognized $1,117 in research and development expenses and $1,701 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 income (loss). The Company recorded $1,127 of income in the collaboration (profit) loss sharing line for the three and nine months ended September 30, 2021.

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 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 ASC 606—*Revenue From Contracts with Customers* ("ASC 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,

2021, 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, 2021 and 2020, using the cost-to-cost method, which best depicts the transfer of control to the customer, the Company recognized ($5,883), $4,028, $80 and $10,728 of collaboration revenue – related party, respectively. During the three months ended September 30, 2021, the Company increased its estimate of the future costs that would be incurred from on-going research and development services to complete its performance obligation under the License Agreement that is recognized over time using an input method. The increase in the Company's estimate of the future costs was based on information received in the quarter regarding clinical trial design and resulted in a reduction in collaboration revenue – related party for the three months ended September 30, 2021 of $5,883.

As of September 30, 2021 and December 31, 2020, there was $104,146 and $108,174, respectively, of deferred revenue related to the unsatisfied portion of the performance obligation under the 2016 License Agreement. As of September 30, 2021, 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 income (loss).

AstraZeneca Research Collaboration and Option Agreement

Summary of the Agreement

In March 2019, the Company entered into a Research Collaboration and Option Agreement (the "Research Agreement") with MedImmune, LLC, a wholly owned subsidiary of AstraZeneca Inc. ("AstraZeneca"), to advance the mechanistic understanding of the microbiome in augmenting the efficacy of cancer immunotherapy. Under the Research Agreement, the Company and AstraZeneca conducted certain research and development activities as set forth on a research plan focused on the role of the microbiome in certain cancers and cancer immunotherapies, including the research program for SER-401, in combination with AstraZeneca compounds targeting various cancers.

Pursuant to the Research Agreement, the Company agreed not to conduct research or development on any microbiome products specifically designed by the Company during the term of the Research Agreement for the treatment of cancer ("Microbiome Oncology Products"), with or on behalf of any third party without the prior approval of the joint steering committee for the Research Agreement for at least three years after the effective date (the "Exclusivity Period"). Additionally, AstraZeneca paid the Company a total of $20,000 in three equal installments, the first of which the Company received in April 2019, the second of which the Company received in December 2019, and the third of which the Company received in January 2021. Such payments were payable even if the Research Agreement was terminated in accordance with its terms, unless the Research Agreement is terminated by AstraZeneca for the Company's uncured material breach. Additionally, AstraZeneca would bear its costs of conducting activities under the research plan and would reimburse the Company for all activities performed under the research plan based on actual full-time employee ("FTE") time and certain third-party costs incurred by the Company in connection therewith.

Under the Research Agreement, the Company granted to AstraZeneca an exclusive option to negotiate a worldwide, sublicensable exclusive license under relevant intellectual property rights controlled by the Company to exploit Microbiome Oncology Products for the treatment of cancer. Additionally, the Company granted to AstraZeneca an additional exclusive option to obtain a worldwide, sublicensable, license under certain intellectual property rights arising out of the Research Agreement or coming into the control of the Company during the term of the Research Agreement, to exploit AstraZeneca's oncology and other assets which are the subject of the research plan. AstraZeneca may exercise each option at any point prior to 90 days after the end of the Exclusivity Period (the "Option Exercise Period") by delivering an option exercise notice to the Company. If AstraZeneca exercised an option during the Option Exercise Period, the parties would enter into exclusive, good faith negotiations for a period of six months (the "Negotiation Period") regarding the terms of the definitive license agreement contemplated by such option. If no definitive agreement was reached during the Negotiation Period, subject to certain other terms and conditions applicable for a one (1) year period, the Company was free to license, further develop or otherwise exploit its assets that were the subject of the option without further obligation to AstraZeneca.

The term of the Research Agreement continued in effect until the Research Agreement was terminated by the parties in accordance with its terms by mutual written agreement. Either party may terminate the Research Agreement for the other party's uncured material breach or bankruptcy or insolvency-related events. AstraZeneca may terminate the Research Agreement for convenience. In December 2020, the Company received written notice from AstraZeneca that AstraZeneca elected to terminate the Research Agreement by and in accordance with its terms. The termination of the Research Agreement was effective on April 2, 2021, which was 120 days from the date of the termination notice.

Accounting Analysis

The Company assessed the Research Agreement in accordance with ASC 606 and concluded that AstraZeneca is a customer. The Company identified the following promises under the contract: (i) a research license, (ii) an obligation to perform research and development services, and (iii) participating on a joint steering committee. The Company assessed the promised goods and services to determine if they are distinct. Based on this assessment, the Company determined that AstraZeneca 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.

Each exclusive option granted to AstraZeneca provides AstraZeneca with the right to negotiate a license agreement in the future at fair value. Therefore, the Company concluded that each option does not constitute a performance obligation at inception and has been excluded from the initial allocation since each option represents a separate buying decision at market rates, rather than a material right in the contract.

At contract inception, the Company determined that the transaction price is comprised of: (i) the $20,000 fee, which represents fixed consideration, and (ii) the estimated reimbursement of research and development costs incurred, which represents variable consideration. The Company included the estimated reimbursement of research and development costs, approximately $13,900, in the transaction price at the inception of the arrangement because the Company is required to perform research and development services and the contract requires AstraZeneca to reimburse the Company for costs incurred. Also, since the related revenue would be recognized only as the costs are incurred, and the contract precludes the joint steering committee from changing the research plan without mutual agreement, the Company determined it is not probable that a significant reversal of cumulative revenue would occur.

The Company determined that revenue under the Research Agreement should be recognized over time as AstraZeneca simultaneously receives the benefit from the Company as the Company performs under the single performance obligation over time. The Company will recognize revenue for the single performance obligation using a cost-to-cost input method as the Company has concluded it best depicts the research and joint steering committee participation services performed prior to AstraZeneca's ability to negotiate a license. Under this method, the transaction price is recognized over the contract's entire performance period, using costs incurred relative to total estimated costs to determine the extent of progress towards completion.

In December 2020, the Company received written notice that AstraZeneca elected to terminate the Research Agreement. As a result of AstraZeneca's decision to terminate the Research Agreement, the Company's performance obligations under the Research Agreement ended as of December 31, 2020. The final transaction price of $23,377 is comprised of the $20,000 fixed consideration and $3,376 for the reimbursed research and development costs. The Company removed all costs associated with its remaining performance from the cost-to-cost model in the fourth quarter of 2020. This resulted in the Company recognizing the remaining deferred revenue of $15,145 to collaboration revenue in the year ended December 31, 2020.

For the three and nine months ended September 30, 2020, the Company recognized collaboration revenue of $0 and $2,016, respectively, under the Research Agreement. No collaboration revenue was recognized for three and nine months ended September 30, 2021, as the Company's performance obligations under the Research Agreement ended December 31, 2020.

Contract Balances from Contracts with Customers

The following table presents changes in the Company's contract liabilities during the nine months ended September 30, 2021 and 2020 (in thousands):

	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

	Balance as of December 31, 2019	Additions	Deductions	Balance as of September 30, 2020
Nine Months Ended September 30, 2020				
Contract liabilities:				
Deferred revenue - related party	$ 110,071	—	(10,728)	$ 99,343
Deferred revenue	$ 9,668	827	(2,016)	$ 8,479

During the three and nine months ended September 30, 2021 and 2020 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,	
	2021	2020	2021	2020
Revenue recognized in the period from:				
Amounts included in the contract liability at the beginning of the period	$ (4,618)	$ -	$ 4,028	$ 11,837

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.

11. Commitments and Contingencies

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, 2021 or December 31, 2020.

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, 2021 or December 31, 2020.

12. Income Taxes

The Company did not provide for any income taxes in its condensed consolidated statement of operations and comprehensive income (loss) for the three and nine month periods ended September 30, 2021 or 2020. While the Company has net income for the three months ended September 30, 2021, the Company is projecting book and tax losses for the twelve months ended December 31, 2021, for which it is more likely than not that the Company will not realize a benefit for as the Company has recorded a full valuation allowance against its deferred tax assets. Therefore, the Company has not recorded any income taxes for the three and nine months ended September 30, 2021 and 2020.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the 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, 2021 and December 31, 2020. Management reevaluates the positive and negative evidence at each reporting period.

As of September 30, 2021 and December 31, 2020, 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.

13. Related Party Transactions

As described in Note 10, in July 2021, the Company entered into the 2021 License Agreement with NHSc Pharma Partners (together with Société des Produits Nestlé S.A., "Nestlé"). NHSc Pharma Partners is an affiliate of two of the Company's significant stockholders, Société des Produits Nestlé S.A. and Nestlé Health Science U.S. Holdings, Inc. During the three and nine months ended September 30, 2021, the Company recognized $132,608 of related party revenue associated with the 2021 License Agreement. As of the three and nine months ended September 30, 2021 there was $6,891 of deferred revenue related to the 2021 License Agreement, which is classified as current or non-current in the condensed consolidated balance sheets. As of September 30, 2021 there was $26,734 included in accrued expenses and other liabilities and $7,075 included in other long term liabilities related to the 2021 License Agreement. The Company has made no payments to Nestlé during the three and nine months ended September 30, 2021. There is no amount due from Nestlé as of September 30, 2021.

As described in Note 10, in January 2016, the Company entered into the 2016 License Agreement with Société des Produits Nestlé S.A. (successor in interest to Nestec, Ltd.) 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. and its affiliate Nestlé Health Science U.S. Holdings, Inc. are two of the Company's significant stockholders. During the three and nine months ended September 30, 2021 and 2020, the Company recognized ($5,883), $4,028, $80 and $10,728 of related party revenue associated with the 2016 License Agreement, respectively. As of September 30, 2021 and December 31, 2020 there was $104,146 and $108,174 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, 2021 and 2020. There is no amount due from Nestlé as of September 30, 2021.

In August 2020, the Company entered into the Securities Purchase Agreement with Nestlé for the sale of 959,002 shares of its common stock at a purchase price of $20.855 per share (the "concurrent placement"). The Company received aggregate net proceeds from the concurrent placement of approximately $19,900 after deducting offering expenses payable by the Company.

In July 2019, the Company entered into a sublease agreement with Flagship Pioneering, one of the Company's significant stockholders, to sublease a portion of its office and laboratory space in Cambridge, Massachusetts. The term of the sublease agreement commenced in July 2019 and ends on the last day of the 24th calendar month following commencement. In the second quarter of 2021, the sublease agreement was extended to November 2021. Under this agreement, the Company recorded other income of $437, $1,361, $458 and $1,357 during the three and nine months ended September 30, 2021 and 2020 respectively. The Company received cash payments of $437, $1,361, $458 and $1,357 during the three and nine months ended September 30, 2021 and 2020, respectively.

14. Subsequent Events

Bacthera Long Term Manufacturing Agreement

On November 8, 2021, the Company entered into a Long Term Manufacturing Agreement (together with its exhibits, the "Bacthera Agreement") with BacThera AG ("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 the Company at Bacthera's Microbiome Center of Excellence in Visp, Switzerland, which is currently under construction; and (ii) provide manufacturing services to the Company for its SER-109 product and, if agreed by the parties, SER-287 product.

Under the terms of the Bacthera Agreement, the Company has agreed to pay Bacthera a total of at least 240,000 CHF (or approximately $262,000) for the initial term of the agreement, inclusive of the construction fees and annual operating fees (commencing with the completion of construction). The annual operating fee includes the cost of a baseline annual batch production volume. The Company has 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. The Company 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. The Company may also terminate the Bacthera Agreement for convenience after a defined period. In the event of a termination, the Company has 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 the Company, so that the Company could transfer the manufacturing operations to itself 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.

Letter Agreement with David S. Ege, Ph.D.

On November 4, 2021, the Company entered into a letter agreement with David Ege, Ph.D. pursuant to which the Company agreed to pay Dr. Ege a special, one-time cash bonus in a lump sum amount of $131, less applicable withholdings (the "Special Bonus"). The Special Bonus will be paid by December 4, 2021, subject to Dr. Ege's continued employment on the date of payment. Furthermore, if his employment is terminated by the Company for "Cause" or by his resignation without "Good Reason" (as such capitalized terms are defined in the employment agreement that he has entered into with the Company), in either case, within two years following the payment of the Special Bonus, Dr. Ege is required to repay the net amount of the Special Bonus to the Company within ten days following termination.

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 on Form 10-Q for the three and nine months ended September 30, 2021, or the 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 live biotherapeutic drugs, which are consortia of microbes designed to treat disease by modulating the microbiome to treat or reduce disease by repairing the function of a disease susceptible microbiome to a non-disease state. We have an advanced drug pipeline with late-stage clinical assets 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 a biologics license application, or BLA, for submission to the U.S. Food and Drug Administration, or FDA, and preparing for potential commercialization of SER-109, an investigational oral microbiome therapeutic for recurrent *Clostridioides difficile* infection, or CDI; we intend to seek agreement with the FDA to begin a rolling BLA submission for SER-109 in the first half of 2022 and to finalize the submission with data from the safety database in mid-2022.

Additionally, using our microbiome therapeutics platform, we are focusing our resources on obtaining clinical results from our clinical programs in ulcerative colitis, or UC, a form of inflammatory bowel disease, or IBD. Seres' SER-287 program has obtained Fast Track designation for the induction and maintenance of clinical remission in adult subjects with active mild-to-moderate UC, and Orphan Drug designation for the treatment of pediatric UC from the FDA. On July 22, 2021, we announced topline results from the Phase 2b study evaluating SER-287 in patients with mild-to-moderate UC. The study did not meet its primary endpoint of improving clinical remission rates compared to placebo. We anticipate obtaining additional microbiome biomarker data in the second half of 2021 and will re-evaluate our SER-287 development plans after analyzing the data.

Seres is also evaluating SER-301 in a Phase 1b study in patients with mild-to-moderate UC, and SER-155, which is in a Phase 1b study, to address gastrointestinal infections, bacteremia and graft-versus-host disease. In addition, we continue to build our portfolio and advance our technology with research programs in infectious disease more broadly and diseases where immunomodulation, such as cancer, may reduce or treat disease.

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 $15.6 million for the nine months ended September 30, 2021. As of September 30, 2021, we had an accumulated deficit of $564.4 million and cash, cash equivalents and short and long-term investments totaling $353.2 million. As of November 10, 2021, the issuance date of the condensed consolidated financial statements for the nine months ended September 30, 2021, 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.

Impact of Novel Coronavirus

We are monitoring the global outbreak and spread of the novel strain of coronavirus, or COVID-19, and have taken steps to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and actions taken by governmental and health authorities to address the COVID-19 pandemic. The spread of COVID-19 has caused us to modify our business practices, including implementing a work from home policy for all employees who are able to perform their duties remotely and restricting all nonessential travel, and we expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees, and other business partners in light of COVID-19. The impact of COVID-19 on our future results will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, impact of variants, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, the adoption and effectiveness of vaccines and vaccine distribution efforts and the effectiveness of other actions taken in the United States and other countries to contain and treat the disease. See "Risk Factors—Risks Related to Our Operations—The COVID-19 pandemic caused by the novel strain of coronavirus 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.

SER-109

SER-109 is an oral microbiome therapeutic candidate consisting of a consortium of purified Firmicutes spores. Our SER-109 manufacturing and quality systems for SER-109 are state-of-the-art and deliver the essential microbial components that facilitate potency while mitigating the risk of pathogen transmission. The SER-109 manufacturing purification process removes unwanted microbes reducing 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 approximately 170,000 cases per year in the United States. We completed enrollment with 182 patients with multiply recurrent CDI in ECOSPOR III. All patients who entered ECOSPOR III must have tested positive for *C. difficile* toxin, as currently recommended by the Infectious Diseases Society of America guidelines (McDonald Clin Infect Dis 2018). 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.

Analyses from the Phase 3 study Intent-to-Treat population show that 12.4% of subjects experienced a recurrence, versus 39.8% on placebo, which represents a relative risk of 0.32 (95% CI 0.18-0.58; $p<0.001$ for both steps of the testing procedure), with an absolute risk reduction of 27.4% and a relative risk reduction of 68%. The percent on SER-109 with a sustained clinical response was approximately 88%. 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 twenty-four weeks of follow-up. Results demonstrated that SER-109 significantly reduced recurrence rates compared to placebo over 24 weeks, 21.3% vs. 47.3%, respectively.

We believe the SER-109 safety results across completed studies have been favorable, with an adverse event profile comparable to subjects who received placebo. In September 2021, we achieved enrollment of 300 subjects with the ECOSPOR IV open-label study. The target enrollment of a minimum of 300 subjects for the SER-109 safety database was reached in conjunction with a prior completed Phase 3 study, ECOSPOR III. Seres is required by the FDA to demonstrate safety of SER-109 in at least 300 subjects who have received the dose to be commercialized, consistent with standard FDA guidance, with a 24-week follow-up period, to support a BLA submission. The ECOSPOR IV open-label study includes patients with recurrent CDI, including individuals with a first recurrence of CDI. We intend to seek agreement with the FDA to begin a rolling BLA submission for SER-109 in the first half of 2022 and finalize the submission with data from the safety database in mid-2022.

In November 2021, we initiated a SER-109 expanded access program at various sites 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.

SER-287

SER-287, a donor-derived oral microbiome therapeutic candidate consisting of a consortium of highly purified Firmicutes spores, is designed to restore a healthy gastrointestinal microbiome in individuals with UC. There are over 700,000 UC patients in the United States and fewer than one-third of patients on current therapies achieve remission. Approved treatments are often inadequate to control disease activity and are often associated with significant side effects, including immunosuppression.

On July 22, 2021, we announced topline results from the Phase 2b study evaluating SER-287 in patients with mild-to-moderate UC. The study did not meet its primary endpoint of improving clinical remission rates compared to placebo. The primary objective of the induction portion of the Phase 2b study was to evaluate the safety and efficacy of SER-287, after 10 weeks of induction dosing (following vancomycin pre-conditioning) in achieving clinical remission in participants with mild-to-moderate UC. The trial was a

randomized, placebo controlled, double blind, parallel group multicenter study which enrolled 203 UC patients at approximately 100 sites throughout the U.S. and Canada. Dosing was explored in two SER-287 cohorts (full induction dose and step-down induction dose) versus placebo and patients were randomized according to a 1:1:1 ratio. Clinical remission was analyzed and defined by a 3-component modified Mayo Score. No statistically significant differences were observed in absolute clinical remission rates between the three treatment arms (10.3% for the full induction dose, n=68 and 10.6% for the step-down induction dose, n=66 versus 11.6% for placebo, n=69). There were also no statistically significant differences observed across the three treatment groups for endoscopic improvement, endoscopic remission or symptomatic remission.

Both dosing regimens of SER-287 were generally well tolerated. Treatment emergent adverse events, or AEs, were observed in 67.6%, 46.2% and 50.7% of subjects in the induction dose, step-down dose (both of which included six days of oral vancomycin preconditioning) and placebo treatment arms, respectively. The majority of observed AEs were mild or moderate in severity. The most commonly observed AEs were UC, diarrhea, nausea and abdominal distension. Four participants on active treatment reported serious treatment emergent adverse events (worsening ulcerative colitis, colonic dysplasia, congestive heart failure with decreased hemoglobin, and appendicitis), as did one on placebo (worsening ulcerative colitis).

Given the lack of a clinical efficacy signal identified in the Phase 2b study, we have closed the open label and maintenance portions of the study. We anticipate obtaining additional microbiome biomarker data in the second half of 2021 and will re-evaluate our SER-287 development plans after analyzing the totality of the data. These results, including detailed microbiome and drug activity data, will provide us with valuable information that will help us better understand study conclusions and determine next steps for the SER-287 program, as well as our future microbiome therapeutics approach more generally.

SER-301

We are also advancing our next generation, rationally-designed, cultivated microbiome drug discovery and development capabilities, focusing on advancing SER-301, a therapeutic candidate for UC. SER-301 is a consortia 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. SER-301 is formulated for oral delivery. 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 order to enhance desired pharmacological properties.

SER-301 is designed to reduce induction of pro-inflammatory activity, improve epithelial barrier integrity and TNF-α driven inflammation 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.

In November 2020 we enrolled our first patient in the SER-301 Phase 1b study. This initial clinical study of SER-301 is being conducted in Australia and New Zealand. As a result of enrolling the first patient in the clinical study, we received a $10.0 million milestone payment under our collaboration and license agreement, or the 2016 License Agreement, with Société des Produits Nestlé S.A., (or, together with NHSc Pharma Partners, Nestlé, successor in interest to Nestec, Ltd.).

SER-155

SER-155 is a consortium of cultivated bacteria is a microbiome therapeutic candidate designed to decrease infection and translocation of antibiotic resistant bacteria in the gastrointestinal tract and modulate host immune responses to decrease GvHD. SER-155 is formulated for oral delivery. 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 morbidity and mortality due to gastrointestinal infections, bacteremia and GvHD in immunocompromised patients, including in patients receiving allo-HSCT or solid organ transplants. In 2017 and 2019, respectively, we were awarded a highly competitive grant and additional funding from CARB-X to support continued preclinical research and early development work for SER-155. In May 2021, the FDA indicated studies for SER-155 may proceed under an Investigational New Drug, or IND, application and we graduated from the CARB-X program and will receive no additional funding. 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.

SER-401

In March 2021, we announced that we, in collaboration with study partners, The Parker Institute for Cancer Immunotherapy and The University of Texas MD Anderson Cancer Center, voluntarily discontinued further enrollment of our study evaluating the safety and drug activity of SER-401 or fecal microbiota transplant, or FMT, in combination with nivolumab in patients with metastatic melanoma.

A preliminary analysis of results from 10 subjects who received either SER-401 or placebo in combination with nivolumab indicated that SER-401 was safe and well-tolerated. There were no patients enrolled in the FMT portion of the study. Subjects currently enrolled in the study will complete the study protocol. Given challenges in enrollment due to the COVID-19 pandemic, subsequent anticipated time to study completion, and progress in our preclinical oncology pipeline, we have decided to deprioritize further development of SER-401. The Company will continue to advance its research and development efforts in cancer, applying learnings from the SER-401 trial.

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;
- re-evaluate the clinical development of SER-287 for the treatment of UC in light of the Phase 2b clinical study results and in conjunction with the additional microbiome biomarker data, which we expect in the second half of 2021;
- continue the clinical development of SER-301 for the treatment of UC;
- continue the clinical development of SER-155 to address gastrointestinal infections, bacteremia and graft-versus-host disease;
- make strategic investments in our research discovery and development platforms and capabilities, including identifying candidates for additional disease indications;
- 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 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. See "Risk Factors—Risks Related to Our Operations—The COVID-19 pandemic caused by the novel strain of coronavirus 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. 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.

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 (*C. difficile*) and SER-287 (ulcerative colitis) extend through 2034. We plan on continuing to broaden our patent portfolio. Currently, we have 23 active patent application families, which includes 20 nationalized applications, one pending at the PCT stage, and two pending U.S. provisional applications. To date, we have obtained 16 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, pre-clinical activities and clinical trials on our behalf as well as contract manufacturing organizations that manufacture drug products for use in our pre-clinical 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 pre-clinical 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. All costs associated with the 2016 License Agreement with Nestlé are recorded in research and development expense in the condensed consolidated statements of operations and comprehensive income (loss).

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 pre-clinical 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 and, as such, are classified as costs of our microbiome therapeutics platform research, along with external costs directly related to our microbiome therapeutics platform.

The table below summarizes our research and development expenses incurred on our platform and by product development program for those that have begun clinical development.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(in thousands)			
Microbiome therapeutics platforms	$ 23,559	$ 12,456	$ 61,735	$ 36,744
SER-109	13,309	5,668	31,709	12,199
SER-287	1,568	3,870	7,976	13,109
Early stage programs	1,446	1,867	3,719	3,651
Total research and development expenses	$ 39,882	$ 23,861	$ 105,139	$ 65,703

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, seek regulatory approval, and prepare for commercialization of SER-109, re-evaluate the clinical development of SER-287, continue to discover and develop additional product candidates, including SER-301 and 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, corporate and business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our headcount 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, or the SEC, 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 license agreement that we entered into with NHSc Pharma Partners (Nestle) in July 2021 as discussed in Note 10 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 premium 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. While we have net income for the three months ended September 30, 2021, we are projecting book and tax losses for the twelve months ended December 31, 2021, for which it is more likely than not that we will not realize a benefit for as we have recorded a full valuation allowance against our deferred tax assets. Thus, we did not provide for any income taxes in the three and nine months ended September 30, 2021 or 2020.

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, 2020, filed with the SEC on March 2, 2021, 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. Except as discussed in Note 2 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report with respect to collaborative arrangements, there have been no material changes to that information disclosed in our Annual Report during the three and nine months ended September 30, 2021.

Results of Operations

Comparison of Three Months Ended September 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Revenue:			
Collaboration revenue - related party	$ 126,725	$ 80	$ 126,645
Grant revenue	—	1,337	(1,337)
Collaboration revenue	—	—	—
Total revenue	126,725	1,417	125,308
Operating expenses:			
Research and development	39,882	23,861	16,021
General and administrative	19,563	7,551	12,012
Collaboration (profit) loss sharing - related party	(1,127)	—	(1,127)
Total operating expenses	58,318	31,412	26,906
Income (loss) from operations	68,407	(29,995)	98,402
Other (expense) income:			
Interest income	590	100	490
Interest expense	(744)	(730)	(14)
Other (expense) income	(35)	345	(380)
Total other (expense) income, net	(189)	(285)	96
Net income (loss)	$ 68,218	$ (30,280)	$ 98,498

Revenue

Total revenue was $126.7 million and $1.4 million for the three months ended September 30, 2021 and 2020, respectively. The total increase of $125.3 million was primarily due to collaboration revenue recognized from the co-commercialization license agreement entered into with Nestlé Health Science during the third quarter of 2021.

Research and Development Expenses

	Three Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Microbiome therapeutics platforms	$ 23,559	$ 12,456	$ 11,103
SER-109	13,309	5,668	7,641
SER-287	1,568	3,870	(2,302)
Early stage programs	1,446	1,867	(421)
Total research and development expenses	$ 39,882	$ 23,861	$ 16,021

Research and development expenses were $39.9 million for the three months ended September 30, 2021, compared to $23.9 million for the three months ended September 30, 2020. The increase of $16.0 million was due primarily to the following:

- an increase of $11.1 million in research expenses related to our microbiome therapeutics platforms due primarily to increases in employee related costs of $9.1 million and facility-related costs of $2.0 million;
- an increase of $7.6 million in expenses related to our SER-109 program due primarily to increases in facility-related costs of $3.7 million, clinical trial consulting expense of $2.1 million, R&D consultant related costs of $1.6 million, contract manufacturing costs of $1.0 million, and partially offset by a decrease in sequencing work costs of $0.7 million;

- a decrease of $2.3 million in expenses for our SER-287 program due primarily to a decrease in clinical trial consulting expense of $1.8 million and R&D consultant related costs of $0.4 million; and
- a decrease of $0.4 million in expenses for our early stage programs due primarily to a decrease in facility-related costs of $0.2 million and sequencing works costs of $0.2 million.

General and Administrative Expenses

	Three Months Ended September 30,		
	2021	2020	Change
		(in thousands)	
Personnel related (including stock-based compensation)	$ 6,792	$ 2,659	$ 4,133
Professional fees	10,586	3,354	7,232
Facility-related and other	2,185	1,538	647
Total general and administrative expenses	$ 19,563	$ 7,551	$ 12,012

General and administrative expenses were $19.6 million for the three months ended September 30, 2021, compared to $7.6 million for the three months ended September 30, 2020. The increase of $12.0 million was due primarily to the following:

- an increase in personnel related costs of $4.1 million primarily related to increases in employee stock-based compensation expense of $2.2 million, salaries and related payroll taxes of $1.3 million, and employee bonus expense of $0.5 million;
- an increase in professional fees of $7.2 million primarily due to increases in professional service and consulting fees of $6.7 million and recruiting fees of $0.5 million; and
- an increase in facility-related and other costs of $0.6 million primarily due to an increase in IT-related expenses of $0.8 million and lab and office supplies of $0.2 million.

Collaboration (Profit) Loss Sharing - related party

Collaboration (profit) loss sharing – related party was $1.1 million of income to us for the three months ended September 30, 2021. There was no collaboration (profit) loss sharing for the three months ended September 30, 2020. For the three months ended September 30, 2021 we incurred $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 $0.6 million of pre-launch expenses for the three months ended September 30, 2021. Therefore, the $1.1 million of income recorded represents the sharing of 50% of the pre-launch expenses and represents income to us because we performed more of the pre-launch activities than our collaborative partner.

Other (Expense) Income, Net

Other (expense) income, net for the three months ended September 30, 2021 and 2020 was $0.2 million of expense and $0.3 million of expense, respectively. The $0.1 million reduction in other (expense) income, net was primarily due to an increase in interest income of $0.5 million, offset by an increase in other expense of $0.4 million, primarily related to the amortization of investments.

Comparison of Nine Months Ended September 30, 2021 and 2020

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		
	2021	2020	Change
		(in thousands)	
Revenue:			
Collaboration revenue - related party	$ 136,636	$ 10,728	$ 125,908
Grant revenue	1,070	2,907	(1,837)
Collaboration revenue	-	2,016	(2,016)
Total revenue	137,706	15,651	122,055
Operating expenses:			
Research and development	105,139	65,703	39,436
General and administrative	48,755	20,180	28,575
Collaboration (profit) loss sharing - related party	(1,127)	-	(1,127)
Total operating expenses	152,767	85,883	66,884
Loss from operations	(15,061)	(70,232)	55,171
Other (expense) income:			
Interest income	2,385	333	2,052
Interest expense	(2,172)	(2,165)	(7)
Other (expense) income	(729)	1,189	(1,918)
Total other income (expense), net	(516)	(643)	127
Net loss	$ (15,577)	$ (70,875)	$ 55,298

Revenue

Total revenue was $137.7 million and $15.7 million for the nine months ended September 30, 2021 and 2020, respectively. The total increase of $122.1 million was primarily due to collaboration revenue recognized from the co-commercialization license agreement entered into with Nestlé Health Science during the third quarter of 2021.

Research and Development Expenses

	Nine Months Ended September 30,		
	2021	2020	Change
		(in thousands)	
Microbiome therapeutics platforms	$ 61,735	$ 36,744	$ 24,991
SER-109	31,709	12,199	19,510
SER-287	7,976	13,109	(5,133)
Early stage programs	3,719	3,651	68
Total research and development expenses	$ 105,139	$ 65,703	$ 39,436

Research and development expenses were $105.1 million for the nine months ended September 30, 2021 and $65.7 million for the nine months ended September 30, 2020. The increase of $39.4 million was due primarily to the following:

- an increase of $25.0 million in research expenses related to our microbiome therapeutics platforms, due primarily to increases in employee related costs of $21.4 million and facility-related costs of $4.1 million, and partially offset by a decrease in depreciation expense of $0.6 million;
- an increase of $19.5 million in expenses related to our SER-109 program due primarily to increases in facility-related costs of $6.4 million, clinical trial consulting expense of $5.4 million, R&D consultant related costs of $5.1 million, and contract manufacturing costs of $2.6 million;
- a decrease of $5.1 million in expenses for our SER-287 program due primarily to decreases in clinical trial consulting expenses of $3.2 million, facility-related costs of $1.4 million, R&D consultant related costs of $0.7 million, and contract manufacturing costs of $0.3 million, and partially offset by an increase of $0.5 million in sequencing work costs; and
- an increase of $0.1 million in expenses for our early stage programs due primarily to an increase in clinical trial consulting expense of $1.2 million, and partially offset by decreases in sequencing work costs of $0.5 million, R&D consultant related costs of $0.3 million and facility-related costs of $0.2 million.

General and Administrative Expenses

	Nine Months Ended September 30,		
	2021	2020	Change
		(in thousands)	
Personnel related (including stock-based compensation)	$ 16,520	$ 7,304	$ 9,216
Professional fees	25,533	8,676	16,857
Facility-related and other	6,702	4,200	2,502
Total general and administrative expenses	$ 48,755	$ 20,180	$ 28,575

General and administrative expenses were $48.8 million for the nine months ended September 30, 2021 compared to $20.2 million for the nine months ended September 30, 2020. The increase of $28.6 million was due primarily to the following:

- an increase in personnel related costs of $9.2 million due primarily to increases in employee stock-based compensation expense of $4.2 million, salaries and related payroll taxes of $3.8 million, and employee bonus expense of $1.2 million;
- an increase in professional fees of $16.9 million due primarily to increases in professional service and consulting fees of $13.5 million, recruiting fees of $2.1 million and legal, accounting and bank fees of $1.2 million; and
- an increase in facility-related and other costs of $2.5 million due primarily to increases in IT-related expenses of $1.3 million and lab and office supplies of $1.2 million.

Collaboration (Profit) Loss Sharing - related party

Collaboration (profit) loss sharing – related party was $1.1 million of income to us for the nine months ended September 30, 2021. There was no collaboration (profit) loss sharing for the nine months ended September 30, 2020. For the nine months ended September 30, 2021 we incurred $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 $0.6 million of pre-launch expenses for the nine months ended September 30, 2021. Therefore, the $1.1 million of income recorded represents the sharing of 50% of the pre-launch expenses and represents income to us because we performed more of the pre-launch activities than our collaborative partner.

Other (Expense) Income, Net

Other (expense) income, net for the nine months ended September 30, 2021 and 2020 was $0.5 million of expense and $0.6 million of expense, respectively. The $0.1 million reduction in other (expense) income, net was primarily due to an increase in interest income of $2.1 million, offset by an increase in other expense of $1.9 million, primarily related to the amortization of investments.

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.

In August 2020, we completed an underwritten public offering in which we sold 10,500,000 shares of the Company's common stock at a public offering price of $21.50 per share. In addition, we granted the underwriters a 30-day option to purchase up to an additional 1,575,000 shares of its common stock at the public offering price, less underwriting discounts and commissions, which the underwriters exercised in full. We received aggregate net proceeds from the offering of approximately $243.7 million after deducting underwriting discounts and commissions and offering expenses payable by us.

In August 2020, we entered into a Securities Purchase Agreement with Nestlé for the sale of 959,002 shares of our common stock at a purchase price of $20.855 per share, which we refer to as the concurrent placement. We received aggregate net proceeds from the concurrent placement of approximately $19.9 million after deducting offering expenses payable by us.

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 $150,000, from time to time, through an "at the market" equity offering program under which Cowen acts as sales agent. As of September 30, 2021, we have not sold any shares of common stock under the Sales Agreement.

As of September 30, 2021, we had cash, cash equivalents and short- and long-term investments totaling $353.2 million and an accumulated deficit of $564.4 million. As of November 10, 2021, the issuance date of the interim condensed consolidated financial statements for the nine months ended September 30, 2021, we expect our cash, cash equivalents and investments 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 such 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 Société des Produits Nestlé S.A., or, together with NHSc Pharma Partners, 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 recorded revenue of $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. 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 Pharma Partners (Nestlé)

On July 1, 2021, we entered into a License Agreement, or the 2021 License Agreement, with NHSc Pharma Partners, or, together with Société des Produits Nestlé S.A, 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 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. 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 on July 21, 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.

Agreement with AstraZeneca

In March 2019, we entered into a Research Collaboration and Option Agreement, or the Research Agreement, with MedImmune, a wholly owned subsidiary of AstraZeneca. In December 2020, we received written notice from AstraZeneca that they elected to terminate the Research Agreement by and in accordance with its terms. The termination of the Research Agreement became effective on April 2, 2021, which was 120 days from the date of the notice.

Long Term Manufacturing Agreement with Bacthera

In November 2021, we entered into a Long Term Manufacturing Agreement, or, together with its exhibits, 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 the Company at Bacthera's Microbiome Center of Excellence in Visp, Switzerland, which is currently under construction; and (ii) provide manufacturing services to us for SER-109 and, if agreed by the parties, SER-287. For a further description of the Bacthera Agreement, see Part II, Item 5. "Other Information" in this Quarterly Report.

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 Term Loan 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 Term Loan 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.

Advances under the Term Loan 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 4.40%, and (ii) 9.65%. We will make interest only payments through December 1, 2021, and will then repay the principal balance and interest of the advances in equal monthly installments after the interest only period and continuing through November 1, 2023. We paid Hercules a commitment fee of $0.4 million at the closing. We may prepay advances under the loan and security agreement with Hercules, in whole or in part, at any time subject to a prepayment charge equal to: (a) 3.0% of amounts so prepaid, if such prepayment occurs during the first year; (b) 2.0% of the amount so prepaid, if such prepayment occurs during the second year, and (c) 1.0% of the amount so prepaid, if such prepayment occurs after the second year. Upon prepayment or repayment of all or any of the term loans, we will pay (in addition to the prepayment premium) an end of term charge of 4.85% of the aggregate funded amount under the Term Loan Facility.

The Term Loan 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.

The Term Loan Facility includes affirmative and negative covenants 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, creating liens and selling assets, in each case subject to certain exceptions, including, among others, the ability for us to issue up to $150.0 million in convertible notes and entering into exclusive outbound licenses for our intellectual property. The Term Loan Facility also includes a liquidity covenant that does not apply when our market capitalization exceeds $350.0 million.

The Term Loan 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.

As of September 30, 2021 and December 31, 2020, the outstanding principal under the Term Loan Facility was $25.0 million and $25.0 million, respectively. For a further description of the Term Loan Facility, see Note 7 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,	
	2021	2020
	(in thousands)	
Cash provided by (used in) operating activities	$ 58,551	$ (75,683)
Cash provided by (used in) investing activities	50,902	(83,556)
Cash provided by financing activities	1,958	301,439
Net increase in cash, cash equivalents and restricted cash	$ 111,411	$ 142,200

Operating Activities

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 Nestle Health Science for pre-launch activities in conjunction with the co-commercialization license agreement entered into with Nestlé Health Science during the third quarter of 2021. The increase in accounts payable was due to the timing of payments. The increase in deferred revenue was primarily due to the co-commercialization license agreement entered into with Nestlé Health Sciences during the third quarter of 2021. 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.

During the nine months ended September 30, 2020, operating activities used $75.7 million of cash, primarily due to a net loss of $70.9 million and cash used from changes in our operating assets and liabilities of $17.9 million, partially offset by non-cash charges of $13.1 million. Net cash used for changes in our operating assets and liabilities during the nine months ended September 30, 2020 consisted of an increase in prepaid expenses and other current assets of $3.1 million, an increase in accounts receivable of $1.6 million, a decrease in deferred revenue of $11.9 million, an increase in accounts payable of $1.0 million, a decrease in operating lease liabilities of $3.3 million and an increase in accrued expenses and other current liabilities of $0.9 million. The increase in prepaid expenses was due to timing of payments to vendors. The increase in accounts receivable was due to our reimbursable costs per our agreements. The decrease in deferred revenue was primarily due to the recognition of collaboration revenue. The increase in accounts payable was due to the timing of payments. The decrease in operating lease liabilities was due to the cash payment of lease obligations.

Investing Activities

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.

During the nine months ended September 30, 2020, net cash used in investing activities was $83.6 million, consisting maturities of investments of $42.8 million, partially offset by purchases of investments of $126.0 million and purchases of property and equipment of $0.4 million, partially offset by sales and maturities of investments of $42.8 million.

Financing Activities

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 2015 Employee Stock Purchase Plan, or ESPP.

During the nine months ended September 30, 2020, net cash provided by financing activities was $301.4 million, consisting of $244.0 million in proceeds from our follow-on public offering of common stock, net of commissions, underwriting discounts and offering costs, $20.0 million in proceeds from the concurrent placement, net of issuance costs, $12.1 million from the issuance of common stock and exercise of stock options, $24.8 million from the issuance of common stock under the 2019 and 2020 Sales Agreements, and $0.5 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;
- re-evaluate the clinical development of SER-287 for the treatment of UC in light of the Phase 2b clinical study results and in conjunction with the additional microbiome biomarker data, which we expect in the second half of 2021;
- continue the clinical development of SER-301 for the treatment of UC;
- continue the clinical development of SER-155 to address gastrointestinal infections, bacteremia and graft-versus-host diseases;
- make strategic investments in our research discovery and development platforms and capabilities, including identifying candidates for additional disease indications;
- 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 progress and results of our clinical studies and pre-clinical development;
- the cost of manufacturing clinical supplies of 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 pre-clinical 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 "Impact of Novel Coronavirus" above and "Risk Factors—Risks Related to Our Operations—The COVID-19 pandemic caused by the novel strain of coronavirus 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. Except as disclosed under the caption "Bacthera Long Term Manufacturing Agreement" in Part II, Item 5. "Other Information" in this Quarterly Report, there have been no material changes from the contractual commitments and obligations previously disclosed in our Annual Report.

Off-Balance Sheet Arrangements

As of September 30, 2021, we did not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

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, 2021, 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, 2021, we had outstanding borrowings under the Term Loan 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 4.40%, 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 Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Quarterly Report, 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, or the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2021.

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, 2021 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 $70.3 million for the year ended December 31, 2020, and $15.6 million for the nine months ended September 30, 2021. As of September 30, 2021, we had an accumulated deficit of $564.4 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;
- re-evaluate the clinical development of SER-287 for the treatment of UC in light of the Phase 2b clinical study results and in conjunction with the additional microbiome biomarker data, which we expect in the second half of 2021;
- continue the clinical development of SER-301 for treatment of UC;
- continue the clinical development of SER-155 to address gastrointestinal infections, bacteremia and graft-versus-host disease;
- make strategic investments in our research discovery and development platforms and capabilities, including identifying candidates for additional disease indications;
- 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, prepare for the potential commercialization of SER-109, re-evaluate the clinical development of SER-287, continue clinical studies of SER-301 and SER-155 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. 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, 2021 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 progress and results of our clinical studies;
- the cost of manufacturing clinical supplies for our product candidates;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for our other 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 and SER-287, 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. 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 live biotherapeutic drug candidates, which are consortia of microbes designed to treat or reduce disease by modulating the microbiome through key compositional and functional changes relevant to disease outcomes. 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.

For example, in March 2020, as a result of the COVID-19 pandemic, we halted further enrollment of the completed ECOSPOR III trial with 182 patients enrolled. Following receipt of the Phase 3 top-line data from ECOSPOR III, the FDA reaffirmed its prior position that at least 300 patients at 24 weeks will be required for the safety database for SER-109. In September 2021, we achieved enrollment of 300 subjects with the ECOSPOR IV open-label study. The target enrollment of a minimum of 300 subjects for the SER-109 safety database was reached in conjunction with ECOSPOR III. We may also be required to treat more patients with SER-109 than we currently expect before we are able to generate a safety database sufficient to allow us to seek approval of SER-109. 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 caused by the novel strain of coronavirus 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.

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, for CDI;
- 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. 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 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 ulcerative colitis 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 EMA or the FDA 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 EMA determines 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 can subsequently approve the same drug or biologic for the same condition if the FDA concludes 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 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 ability to hire and retain key personnel and accept the

payment of user fees, and other events that may otherwise affect the FDA's 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, including for 35 days beginning on December 22, 2018, 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.

The FDA intends to use a risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. In addition, on April 15, 2021, the FDA issued a guidance document in which the FDA outlined plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical or is otherwise limited by travel restrictions, but where the FDA determines that a remote evaluation would still be appropriate. Regulatory authorities outside the United States may adopt 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 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, would 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. 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 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 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 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. 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 receives 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 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. 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. For example, the results of the 2020 U.S. Presidential Election may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these orders will be implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of the new administration are unknown and could materially impact the regulations governing our product candidates.

In addition, the EU has adopted the Clinical Trials Regulation, or CTR, in April 2014, which is expected to become applicable by early 2022. The CTR will be directly applicable in all EU member states, repealing the current Clinical Trials Directive. Conduct of all clinical trials performed in the European Union will continue to be bound by currently applicable provisions until the new CTR becomes applicable. The extent to which ongoing clinical trials will be governed by the CTR will depend on when the CTR becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the CTR becomes applicable the CTR will at that time begin to apply to the clinical trial. The CTR harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which will notably contain a centralized EU portal and database.

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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and regulations implemented thereunder, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- 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 other healthcare professionals beginning 2022 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;
- 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; and

- state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. By way of example, the CCPA, effective January 1, 2020, creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. 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 California Privacy Rights Act, or CPRA, was also recently voted into law by California residents. The CPRA significantly amends the CCPA and imposes additional data protection obligations on covered companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. It also creates a new California data protection agency specifically tasked to enforce the law, which would likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. The substantive requirements for businesses subject to the CPRA will go into effect on January 1, 2023 and become enforceable on July 1, 2023. In Europe, the GDPR, which went into effect in May 2018, introduces strict requirements for processing the personal data of European Union data subjects. 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. Further, from January 1, 2021, companies have to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g. fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term. These changes may lead to additional costs and increase our overall risk exposure. On June 28, 2021, the European Commission adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the United Kingdom adequacy decision will automatically expire in June 2025 unless the European Commission renews or extends that decision.

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, 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, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional Congressional action is taken. 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. 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 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 member states of the EU, 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 as our grant from CARB-X to support certain work for SER-155. 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. In addition, under our CARB-X grant, we may be required in the future to grant a private sector charitable organization a license to certain of our intellectual property related to the subject matter of the CARB-X grant if, after a certain period of time, we are not developing and have not licensed a third party to develop the applicable technology for certain indications in a given country, and the organization wishes to do so. 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 23 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, 20 applications have been nationalized, one is pending at the PCT stage, and two are pending at the provisional stage. While we have obtained 16 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 full impact of these decisions is not yet known. For example, in view of these and subsequent court decisions, the USPTO has issued various materials to patent examiners providing guidance for determining the patent eligibility of claims reciting laws of nature, natural phenomena or natural products. Our current product candidates include natural products, therefore, this decision and its interpretation by the courts and the USPTO may impact prosecution, defense and enforcement of our patent portfolio. On March 4, 2014, the USPTO issued a memorandum reflecting the USPTO's interpretation of the cases related to patent eligibility of natural products. The March 4, 2014 memorandum was superseded by interim guidance published on December 15, 2014. Additional guidance was published in July 2015 (July 2015 Update: Subject Matter Eligibility) and May 2016 (May 2016 Subject Matter Eligibility Update). 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 caused by the novel strain of coronavirus 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 2020, a strain of novel coronavirus disease, COVID-19, was declared a pandemic and spread across the world, including throughout the United States, Europe, and Asia. The 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 closed our executive offices with our administrative employees continuing their work outside of our offices, restricted on-site staff to only those required on-site to execute their job responsibilities and limited the number of staff in any given research and development laboratory. On March 30, 2020, as a result of the COVID-19 pandemic, we halted further enrollment of the completed ECOSPOR III trial. In September 2021, we achieved enrollment of 300 subjects with the ECOSPOR IV open-label study. The target enrollment of a minimum of 300 subjects for the SER-109 safety database was reached in conjunction with ECOSPOR III. Additionally, SER-287 development activity was impacted by the COVID-19 pandemic and by multiple clinical sites halting non-essential procedures, including endoscopies, and while enrollment is now complete, site staff must still remain available to finalize study participant data. We are continuing to monitor the impact of the COVID-19 pandemic on our operations and ongoing clinical development activity, including on the SER-301 Phase 1b study in ulcerative colitis. 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 outbreak, 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 outbreak continues to rapidly evolve. The extent to which the outbreak 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 of the outbreak, the impact of variants, travel restrictions, quarantines, shelter-in-place orders and social distancing in the United States 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 United States 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 currently conduct clinical studies in Australia and New Zealand. We may 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;
- 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;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, 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.

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 liability may be subject to certain limitations.

As of December 31, 2020, we had net operating loss carryforwards, or NOLs, of $390.0 million for federal income tax purposes and $386.9 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, 2020, we also had federal and state research and development and other tax credit carryforwards of approximately $36.4 million and $7.5 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 $20.7 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, 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 Sec.382 study performed in Q1 2021 and may experience ownership changes in the future because of future transactions in our stock, some of which may be outside our control. 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. 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 change may require us to pay federal income taxes in future years despite federal income 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 Term Loan Facility, is 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 Term Loan 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 Term Loan 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.

The Term Loan 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 Term Loan Facility also includes a liquidity covenant. 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 81% 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 an "emerging growth company" and, as a result are subject to certain enhanced disclosure requirements.

The last day of the fiscal year following the fifth anniversary of our IPO was December 31, 2020. As a result, commencing January 1, 2021, we are subject to certain requirements that apply to other public companies but did not previously apply to us due to our status as an emerging growth company. Compliance with these enhanced disclosure requirements will increase our costs and could negatively affect our results of operations and financial condition. Moreover, once we become a large accelerated filer on December 31, 2021, we will be required to comply with the auditor attestation requirements under Section 404 of the Sarbanes Oxley Act of 2002, as amended, or Section 404.

We are a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors. Once we are no longer a smaller reporting company, we will be subject to certain enhanced disclosure requirements.

We are a "smaller reporting company" as defined under the rules promulgated under the Exchange Act. We will remain a smaller reporting company until December 31, 2021. Smaller reporting companies are able to provide simplified executive compensation disclosure and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, or supplemental financial information.

We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile.

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

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.

Bacthera Long Term Manufacturing Agreement

On November 8, 2021, we entered into a Long Term Manufacturing Agreement, or, together with its exhibits, 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 SER-109 and, if agreed by the parties, SER-287.

Under the terms of the Bacthera Agreement, we have agreed to pay Bacthera a total of at least 240,000,000CHF for the initial term of the agreement, inclusive of the construction fees and annual operating fees (commencing with the completion of construction). 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 us technical assistance, 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.

Letter Agreement with David S. Ege, Ph.D.

On November 4, 2021, we entered into a letter agreement with David Ege, Ph.D. pursuant to which we agreed to pay Dr. Ege a special, one-time cash bonus in a lump sum amount of $131,000, less applicable withholdings (the "Special Bonus"). The Special Bonus will be paid by December 4, 2021, subject to Dr. Ege's continued employment on the date of payment. Furthermore, if his employment is terminated by us for "Cause" or by his resignation without "Good Reason" (as such capitalized terms are defined in the employment agreement that he has entered into with us), in either case, within two years following the payment of the Special Bonus, Dr. Ege is required to repay the net amount of the Special Bonus to us within ten days following termination.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Restated Certificate of Incorporation, filed on July 1, 2015	8-K	001-37465	3.1	7/1/15	
3.2	Amended and Restated Bylaws	8-K	001-37465	3.2	12/7/20	
10.1^	License Agreement, dated July 1, 2021, by and between the Registrant and NHSc Pharma Partners					*
10.2#	Letter Agreement, dated November 4, 2021, by and between the Registrant and David S. Ege, Ph.D.					*
10.3#	Non-Employee Director Compensation Program					*
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.

# Indicates management contract or compensatory plan.

^ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Regulation S-K, Item 601(b)(10). Such omitted information is both (i) not material and (ii) the type that the Registrant treats as private or confidential. Additionally, certain schedules and attachments to this exhibit have been omitted pursuant to Regulation S-K, Items 601(a)(5).

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 10, 2021

By: /s/ David Arkowitz

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

EXHIBIT 10.1

[***] 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.

Execution Version

LICENSE AGREEMENT

THIS LICENSE AGREEMENT ("**Agreement**"), dated as of July 1, 2021 (the "**Effective Date**") is entered into between Seres Therapeutics, Inc., a corporation organized and existing under the laws of Delaware, having an office located at 200 Sidney Street, Cambridge, MA 02139, USA ("**Seres**") and NHSc Pharma Partners, a simple partnership within the meaning of article 530 *et seq*. of the Swiss Code of Obligations, having an office located at Avenue Nestlé 55, 1800 Vevey, Switzerland ("**Licensee**").

BACKGROUND

A. Seres owns or controls certain patents, know-how and other intellectual property relating to the product known as SER-109;

B. Licensee has experience in marketing and distributing pharmaceutical products;

C. Under the Existing Agreement (defined below), Seres has granted to Licensee certain exclusive rights and licenses for the exploitation of SER-109 outside of the United States and Canada; and

D. Seres is now willing to grant to Licensee, and Licensee desires to obtain, certain co-exclusive rights and licenses with respect to the commercialization of SER-109 in the United States and Canada.

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

ARTICLE I
DEFINITIONS

I.1 "**Additional Clinical Study**" shall have the meaning set forth in Section 4.4.

I.2 "**Affiliate**" shall mean, with respect to a Party or other Person, any corporation or other business entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with that Party or other Person for so long as such Party or other Person controls, is controlled by or is under common control with such corporation or other business entity, regardless of whether such Affiliate is or becomes an Affiliate on or after the Effective Date. For the purpose of this definition only, "control" (including, with correlative meaning, the terms "controlled by" and "under common control") of a Person means (a) ownership, directly or indirectly, beneficially or legally, of fifty percent (50%) or more of the outstanding voting securities or capital stock of the Person, or comparable ownership interests with respect to a Person other than a corporation or (b) the actual power, either directly or indirectly

through one or more intermediaries, to direct or cause the direction of the management and policies of such Person, whether by the ownership of voting equity of such Person, by contract or otherwise.

I.3 "**Allowable Expenses**" shall mean, with respect to a Collaboration Product for any period, subject to the provisions of this Agreement, the following expenses that are incurred by a Party or any of its Affiliates and are directly attributable or reasonably allocable to [***] or other relevant activities indicated below, for such Collaboration Product in the Licensed Territory during such period:

(a) [***] in respect of [***] used in [***];

(b) [***], or any other costs incurred for [***] that the Parties mutually agree in writing to include as Allowable Expenses, and [***] incurred in accordance with the applicable [***];

(c) an amount equal to the [***] incurred by [***] *plus* an additional amount equal to the [***] included in such [***];

(d) [***], excluding the [***] and [***] and subject to [***];

(e) [***], excluding the [***] and subject to [***];

(a) payments to [***] for access to [***], excluding [***], in amounts not exceeding the [***];

(b) costs associated with [***], or [***], except to the extent such costs constitute [***] for which a Party or its Affiliate is required [***];

(c) costs associated with [***] (including [***]);

(d) [***];

(e) [***] arising out of [***], except to the extent such [***] constitute [***] for which a Party or its Affiliate is required [***];

(f) [***]; and

(g) costs of [***] in respect of [***], in each case, to the extent such costs are not taken into account in the calculation of [***].

If any cost or expense is directly attributable or reasonably allocable to more than one activity, such cost or expense shall only be counted as an Allowable Expense with respect to one of such activities.

I.2 "**Biological Product**" shall mean (a) a biological product as defined in 42 U.S.C. § 262(i); or (b) any product substantially equivalent to the preceding clause under any applicable Laws in any other jurisdiction.

I.3 "**BLA**" shall mean, in the United States, a Biologics License Application, as defined in the United States Public Health Service Act (42 U.S.C. § 262), and applicable regulations promulgated thereunder by the FDA, or any equivalent application that replaces such application, or any corresponding foreign application in the Licensed Territory.

I.1 "**Business Days**" shall mean any day other than Saturday, Sunday or any other day on which commercial banks in Boston, Massachusetts or Geneva, Switzerland are authorized or required by applicable Law to remain closed.

I.2 "**Calendar Quarter**" shall mean each successive period of three calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

I.3 "**Calendar Year**" shall mean each successive period of 12 calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

I.1 "**Canada**" shall mean Canada and its territories and possessions.

I.2 "**Change of Control**" shall mean, with respect to a Party: (a) the acquisition by any Third Party of beneficial ownership of fifty percent (50%) or more of the then outstanding common shares or voting power of such Party, other than acquisitions by employee benefit plans sponsored or maintained by such Party; (b) the consummation of a business combination involving such Party, unless, following such business combination, the stockholders of such Party immediately prior to such business combination beneficially own directly or indirectly more than fifty percent (50%) of the then outstanding common shares or voting power of the entity resulting from such business combination; or (c) the sale of all or substantially all of such Party's assets or business relating to the subject matter of the Agreement; provided, however, that notwithstanding (a) through (c) above, a sale or issuance of a Party's securities in a financing for capital raising purposes, including a public offering of securities, shall not constitute a Change of Control.

I.3 "**Change of Control Group**" shall mean, with respect to a Party, the Person or group of Persons that is the acquirer of, or a successor to, such Party in connection with a Change of Control, together with Affiliates of such Person or group of Persons that are not Affiliates of such Party immediately prior to the completion of such Change of Control of such Party.

I.4 "**Clinical Studies**" shall mean any human clinical study of Collaboration Products, including without limitation Phase III Clinical Studies, Phase IV Clinical Studies, and Post-Approval Studies.

I.5 "**CMC**" means chemistry, manufacturing and controls.

I.6 "**Co-Exclusive**" shall mean, as between Seres (and its Affiliates) and Licensee (and its Affiliates), a license that is exclusive to Licensee and its Affiliates, provided that Seres also

reserves full rights for itself and its Affiliates and Third Party subcontractors in accordance with Section 18.10, to Exploit the Licensed Intellectual Property and Product Trademarks for the licensed purposes, subject to the terms of this Agreement and the Existing Agreement, including Section 2.6.

I.7 "**Collaboration Products**" shall mean SER-109 and any improvements and modifications thereto Developed pursuant to Section 4.4.

I.8 "**Combination Product**" shall mean a therapeutic preparation containing a Collaboration Product and one or more active ingredients that are not Collaboration Products sold for a single invoiced price.

I.9 "**Commercialization**" shall mean any and all activities directed to the preparation for sale of, offering for sale of, or sale of a product, including activities related to registering, launching, marketing, promoting, distributing, Detailing, booking of sales, importing, pricing, reimbursement, Market Access, HEOR Activities, and advertising such product, and interacting with Regulatory Authorities regarding any of the foregoing, but excluding any activities relating to Development, Manufacturing and Medical Affairs Activities. When used as a verb, "**to Commercialize**" and "**Commercializing**" means to engage in Commercialization, and "**Commercialized**" has a corresponding meaning.

I.10 "**Commercialization Costs**" shall mean with respect to a Collaboration Product, the [***] that are incurred by a Party or any of its Affiliates during the Term that are directly attributable or reasonably allocable to the Commercialization of such Collaboration Product in the Licensed Territory, including [***] in accordance with [***] and other costs incurred by [***] in performing the activities contemplated by [***]; but in each case only to the extent consistent with the [***]. For the avoidance of doubt, [***].

I.11 "**Commercialization Plan and Budget**" shall mean a written plan governing the Commercialization activities to be conducted by the Parties for a Collaboration Product in the Field in the United States and, solely upon mutual written agreement of the Parties to Commercialize such Collaboration Product in Canada, also in Canada.

I.12 "**Commercially Reasonable Efforts**" shall mean with respect to a Party's applicable obligations hereunder in respect of a Collaboration Product, that level of efforts and resources that a similarly situated biopharmaceutical company would reasonably be expected to commit to the corresponding activity in respect of a product of similar commercial potential at a similar stage in its lifecycle, taking into account issues of safety and efficacy, product profile, difficulty in manufacturing such product, expected or actual competitiveness of alternative products, the actual or expected patent or other proprietary position of such product (including patent coverage and regulatory exclusivity), the then current competitive environment for such product and the likely timing of such product's entry into the market, the regulatory environment and status of such product, the expected and actual reimbursability and pricing, the expected and actual amounts of marketing and promotional expenditures required and the potential profitability of the product, and other relevant scientific, technical and commercial factors. Without limiting the foregoing, in relation to Development and Commercialization activities, Commercially Reasonable Efforts shall be determined on a country-by-country basis.

I.13 "**Committee**" shall mean any of the JSC, JDC, JCC, JMAC or any Working Group established pursuant to Section 3.3(a).

I.14 "**Confidential Information**" shall mean any and all technical, business or other Information or data of a Party or its Affiliates provided orally, visually, in writing, graphically, electronically, or in another form by or on behalf of one (1) Party (or an Affiliate or representative of such Party) to the other Party (or to an Affiliate or representative of such Party) in connection with this Agreement, whether prior to, on, or after the Effective Date, including Information relating to the terms of this Agreement, and any such Information relating to any Collaboration Product (including the Regulatory Documentation), any Exploitation of any Collaboration Product, any Know-How with respect thereto, or the scientific, regulatory, financial or business affairs or other activities of either Party.

I.15 "**Control**" (including any variations such as "**Controlled**" and "**Controlling**"), shall mean with respect to any Intellectual Property Rights, material or document, the legal authority or right (whether by ownership, license or otherwise) of a Party to grant a license or a sublicense of or under such Intellectual Property Rights, or to provide or provide access to such material or document, to the other Party without breaching the terms of any agreement with a Third Party existing at the time such Party would be required hereunder to grant the other Party such license, sublicense, or access.

I.16 "**Corporate Names**" means (a) in the case of Seres, the trademark "Seres" and the corresponding corporate logo or such other names and logos referring to Seres (or its Affiliates) as Seres may designate in writing from time to time, and (b) in the case of Licensee, the trademarks "**Nestlé**", "**Aimmune**" and "**Nestlé Health Science**" and any foreign language versions thereof and the corresponding corporate logos, and such other names and logos referring to Licensee (or its Affiliates) as Licensee may designate in writing from time to time, in each case (a) and (b) together with any variations and derivatives thereof.

I.17 "**Cost of Goods Sold**" shall mean, with respect to a Collaboration Product, the consolidated cost incurred by a Party or any of its Affiliates in Manufacturing the relevant Collaboration Product (including [***]) in accordance with this Agreement and calculated in accordance with GAAP, in bulk, vialed or finished product form as the case may be, including: (a) to the extent that such Collaboration Product is Manufactured by one or more Third Party contractors, [***]; and (b) to the extent that such Collaboration Product is Manufactured by a Party or its Affiliate, [***]; provided that, Cost of Goods Sold shall, [***].

I.18 "**Cover**" shall mean with respect to any Patent and activity, that such Patent would be infringed by such activity in the absence of the licenses granted pursuant to this Agreement.

I.19 "**Data**" shall mean any and all research data, pharmacology data, preclinical data, clinical data, including raw data, as well as marketing, Market Access, pharmacovigilance, and other data directly related to Collaboration Products, in each case to the extent Controlled by a Party or its Affiliates as of the Effective Date or during the Term.

I.20 "**Data Protection Law**" shall mean all applicable Laws governing the collection, use, storage, transmission, transfer, processing, security, safeguarding, and disclosure of Personal

Information, including, to the extent applicable, the Health Insurance Portability and Accountability Act, the California Consumer Privacy Act of 2018, state data security laws, state data breach notification laws, and any other legislation relating to privacy, data protection, and data security, direct marketing or the interception or communication of electronic messages, in each case as amended, consolidated, re-enacted or replaced from time to time.

I.21 "**Deficit Party**" shall have the meaning set forth in Section 7.4(b)(ii)(A).

I.22 "**Defending Party**" shall have the meaning set forth in Section 11.3(g).

I.23 "**Detail**" shall mean, with respect to a Collaboration Product, the face-to-face (whether in person or via videoconference) communication, in a health care setting, of Collaboration Product information by a Sales Representative to one or more physicians, hospitals, laboratories, and other health care professionals and health care organizations licensed or authorized to prescribe drugs and who are on a target list for such Collaboration Product mutually agreed by the Parties for such Collaboration Product ("**Target Audience**"), during which information regarding a Collaboration Product is communicated in a manner consistent with applicable Law and industry standards as either the leading product (i.e., "first position") or second product (i.e., "second position"). "Details" for purposes of this Agreement include only Exclusive Details, Primary Position Details and Secondary Position Details with respect to a Collaboration Product. For the avoidance of doubt, discussions at conventions, exhibit booths, or other scientific meetings or a reminder or sample drop shall not constitute "Details". "**Detail**" when used as a verb and "**Detailing**" shall have correlative meanings.

I.24 "**Development**" or "**Develop**" shall mean non-clinical and clinical drug development activities reasonably related to the development and submission of information to a Regulatory Authority or otherwise related to the research, identification, testing and validation of a therapeutic agent, including, without limitation, toxicology, pharmacology and other discovery and pre-clinical efforts, test method development and stability testing, manufacturing process and CMC development and scale-up, life cycle management, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical trials (including, without limitation, pre- and post-approval studies, but excluding Phase IV Clinical Studies and other investigator-initiated studies for an approved Collaboration Product (the conduct of which shall constitute Medical Affairs Activities)), and all other activities necessary or reasonably useful for or otherwise requested or required by a Regulatory Authority as a condition to or in support of obtaining or maintaining a Regulatory Approval.

I.25 "**Development and Regulatory Activity Plan**" shall mean the development plan for the Development activities undertaken by Seres for Collaboration Products in the Field for the United States, including the Ongoing Clinical Studies, and upon mutual written agreement of the Parties to make Regulatory Filings for or conduct Clinical Studies of Collaboration Products in Canada, for Canada, as updated from time to time pursuant to and in accordance with Section 4.3.

I.26 "**Disclosing Party**" shall have the meaning set forth in Section 10.1(a).

I.27 "**Dispute**" shall have the meaning set forth in Section 17.1.

I.28 "**Drug**" shall mean (a) a "drug," as defined in 21 U.S.C. § 321; (b) a "medicinal product," as defined in Directive 2001/83/EC of the European Parliament and of the Council; or (c) any product substantially equivalent to the preceding clause (a) or clause (b) under any applicable Laws in any other jurisdiction.

I.29 "**Enforcing Party**" shall have the meaning set forth in Section 11.3(d).

I.30 "**Exclusive Detail**" shall mean, with respect to a Collaboration Product, a Detail, (a) in which key attributes of the Collaboration Product are orally presented consistent with the terms of this Agreement and (b) where the Collaboration Product is given the sole and exclusive emphasis (*i.e.*, no other product presented).

I.31 "**Exercise Notice**" shall have the meaning set forth in Section 2.2.

I.1 "**Existing Agreement**" shall mean the Collaboration and License Agreement between Seres and Licensee (as successor in interest to Nestec Ltd.), dated January 9, 2016, as amended from time to time in accordance with its terms.

I.2 "**Exploit**" shall mean to make, have made, import, export, use, sell or offer for sale, including to Develop, Commercialize, Manufacture and have Manufactured.

I.3 "**FD&C Act**" shall mean the United States Food, Drug and Cosmetic Act (21 U.S.C. § 301 *et seq*.), as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

I.4 "**FDA**" shall mean the US Food and Drug Administration, or any successor entity thereto.

I.5 "**Field**" shall mean the treatment of CDI and rCDI and associated complications, as well as any other indications for which a given Collaboration Product may be Developed pursuant to Section 4.4 by mutual agreement of the Parties.

I.6 "**First Commercial Sale**" shall mean the first sale for use or consumption by an end user of a Collaboration Product in the Licensed Territory following receipt of the first Regulatory Approval of such Collaboration Product in for the Licensed Territory.

I.7 "**FTE**" shall mean a commitment of time and effort to constitute a full-time equivalent person, consisting of [***] (i.e., one fully committed person or multiple partially committed persons aggregating to one (1) full time person), with appropriate Development, regulatory or other relevant capabilities and seniority employed by a Party or its Affiliates assigned to directly perform specified activities with respect to an Additional Clinical Study, Shared Clinical Study, Post-Approval Study, the Manufacture of Collaboration Products, Life Cycle Management, other regulatory activities, implementing risk evaluation and mitigation strategies, enforcement of Third Party Infringement actions, Commercialization or Medical Affairs Activities of Collaboration Products, or any other activities specified under this Agreement, as applicable, pursuant to this Agreement.

I.8 "**FTE Costs**" shall mean the product of: (a) that number of FTEs (proportionately, on a per-FTE basis) used by a Party or its Affiliates in directly performing activities with respect to any Additional Clinical Study, Shared Clinical Study, Post-Approval Study, the Manufacture of Collaboration Products, Life Cycle Management, other regulatory activities, implementing risk evaluation and mitigation strategies, enforcement of Third Party Infringement actions, Commercialization or Medical Affairs Activities of Collaboration Products, or any other activities specified under this Agreement, as applicable, *multiplied* by (b) the applicable FTE Rate.

I.9 "**FTE Rate**" shall mean, unless otherwise agreed between the Parties, an annual rate per FTE as set forth on Exhibit A, which may be prorated on a daily or hourly basis as necessary and as may be adjusted from time to time by mutual agreement of the Parties.

I.10 "**GAAP**" shall mean, with respect to a Person, the generally accepted accounting principles in the United States as consistently applied to such Person.

I.11 "**Global Safety Database**" shall have the meaning set forth in Section 4.7(b).

I.12 "**Good Clinical Practices**" or "**GCP**" shall mean the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA, as such standards, practices and procedures may be updated from time to time, including applicable quality guidelines promulgated under the ICH, or any other equivalent Laws in the Licensed Territory.

I.13 "**Good Laboratory Practices**" or "**GLP**" shall mean the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, as such standards may be updated from time to time, including applicable quality guidelines promulgated under the ICH, or any other equivalent Laws in the Licensed Territory.

I.14 "**Good Manufacturing Practices**" or "**GMP**" shall mean the standards relating to current Good Manufacturing Practices for fine chemicals, API, intermediates, bulk products or finished pharmaceutical products set forth in (a) 21 U.S.C. 351(a)(2)(B), in FDA regulations at 21 C.F.R. Parts 210 and 211, or (b) the ICH Guidelines relating to the manufacture of active ingredients and finished pharmaceuticals, as such standards may be updated from time to time, including applicable quality guidelines promulgated under the ICH, or any other equivalent Laws in the Licensed Territory.

I.15 "**Governmental Authority**" shall mean any domestic or foreign entity exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to government, including any governmental authority, agency, department, board, commission, court, tribunal, judicial body or instrumentality of any union of nations, federation, nation, state, municipality, county, locality or other political subdivision thereof.

I.16 "**HEOR**" shall have the meaning set forth in Section 1.56.

I.17 "**HEOR Activities**" shall mean evidence generation and dissemination in support of pricing and reimbursement or establishment of the value proposition of a Collaboration Product or other activities applying the results of health economics and outcomes research ("**HEOR**") (e.g.,

clinical outcome assessment development and validation or use of HEOR-related endpoints in Clinical Studies or real world evidence generation).

I.18 "**ICH**" shall mean the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

I.19 "**Improvements**" shall have the meaning set forth in Section 11.1(c).

I.20 "**IND**" shall mean an Investigational New Drug Application (as such term is defined in the FD&C Act and the regulations promulgated thereunder), clinical trial exemption, or similar application or submission for approval to conduct human clinical investigations that is filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

I.21 "**Indemnitee**" shall have the meaning set forth in Section 16.4.

I.22 "**Indemnitor**" shall have the meaning set forth in Section 16.4.

I.23 "**Indirect Taxes**" shall mean customs, duties, value added taxes, excise taxes, use taxes and sales taxes, consumption taxes and other similar taxes.

I.24 "**Information**" shall mean all information and materials of a technical, scientific, business and other nature, including Know-How, inventions, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other materials, and other biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, reagents (e.g., plasmids, proteins, cell lines, assays and compounds) and biological methodology; in each case (whether or not confidential, proprietary, patented or patentable, of commercial advantage or not) in written, electronic or any other form now known or hereafter developed.

I.25 "**Inventions**" shall mean any and all inventions (whether or not patentable), that are conceived during the Term and in the course of activities conducted pursuant to this Agreement by one or more employees, Affiliates, sublicensees (including Sublicensees) or independent contractors of Seres and/or Licensee.

I.26 "**Intellectual Property Rights**" shall mean all Patents, trade secrets, copyrights, Trademarks, moral rights, Know-How and any and all other intellectual property or proprietary rights now known or hereafter recognized in any jurisdiction.

I.27 "**Joint Commercialization Committee**" or "**JCC**" shall have the meaning set forth in Section 3.2(a).

I.28 "**Joint Development Committee**" or "**JDC**" shall have the meaning set forth in Section 3.2(a).

I.29 "**Joint Intellectual Property**" shall mean Joint Inventions and Joint Patents.

I.30 "**Joint Inventions**" shall have the meaning set forth in Section 11.1(f).

I.31 "**Joint Medical Affairs Committee**" or "**JMAC**" shall have the meaning set forth in Section 3.2(a).

I.32 "**Joint Patents**" shall have the meaning set forth in Section 11.1(f).

I.33 "**Joint Steering Committee**" or "**JSC**" shall have the meaning set forth in Section 3.1(a).

I.34 "**Know-How**" shall mean any invention, discovery, Data, information, process, method, technique, material (including any chemical or biological material), technology, result, cell line, compound, probe, sequence or other know-how, whether or not patentable.

I.35 "**Law**" shall mean any applicable national, supranational, federal, state, local or foreign law, statute, ordinance, principle of common law, or any rule, regulation, standard, judgment, order, writ, injunction, decree, arbitration award, agency requirement, license or permit of any Governmental Authority, including any rules, regulations, guidelines, directives or other requirements of Regulatory Authorities, including all GMP, GLP and GCP, and including all laws pertaining to the pharmaceutical industry or the healthcare industry, anti-trust or competition laws and all anti-bribery or anti-corruption laws, as applicable.

I.36 "**LCIA**" shall have the meaning set forth in Section 17.2.

I.37 "**Liabilities**" shall have the meaning set forth in Section 16.1.

I.38 "**Licensed Intellectual Property**" shall mean the Licensed Patents and the Licensed Know-How.

I.39 "**Licensed Know-How**" shall mean all Know-How that is Controlled by Seres or its Affiliates as of the Effective Date or at any time during the Term, including [***], and Seres' interest in any Joint Invention, that is necessary or reasonably useful for the Commercialization of the Licensed Products in the Field in accordance with this Agreement, or Licensee's or its Affiliates' or Sublicensees' Development of Licensed Products in the Field in accordance with Section 4.4.

I.40 "**Licensed Patents**" shall mean any and all Patents that (a) are Controlled by Seres or its Affiliates as of the Effective Date of this Agreement or at any time during the Term, including any Patents [***], and Seres' interest in any Joint Patents, and (b) either (i) Cover any Licensed Product or the Commercialization thereof in the Field, or (ii) Cover inventions, the practice of which are otherwise necessary or reasonably useful for the Commercialization of Licensed Products in the Field in accordance with this Agreement, or Licensee's or its Affiliates' or Sublicensees' Development of Licensed Products in the Field in accordance with Section 4.4. Licensed Patents existing as of the Effective Date are listed in Exhibit B hereto. For clarity, Licensed Patents include the [***] Patents.

I.41 "**Licensed Products**" shall mean any and all therapeutic products or therapeutic product candidates that are clinically Developed, approved or Commercialized for the Field by or

on behalf of Seres, the Exploitation of which utilizes or utilized, or is or was covered by, the Microbiome Technology. For the sake of clarity, the Licensed Products include the Collaboration Products.

I.42 "**Licensed Territory**" shall mean the United States and Canada.

I.43 "**Licensee Indemnitees**" shall have the meaning set forth in Section 16.2.

I.44 "**Licensee Sole Inventions**" shall have the meaning set forth in Section 11.1(e).

I.45 "**Licensee Sole IP**" shall have the meaning set forth in Section 11.3(a).

I.46 "**Licensee Sole Patents**" shall have the meaning set forth in Section 11.1(e).

I.47 "**Life Cycle Management**" shall mean those additional Development activities for any Collaboration Product, including the preparation and filing of Regulatory Filings therefor, after the first Regulatory Approval for a Collaboration Product has been obtained, but excluding Post-Approval Studies.

I.48 "**Life Cycle Management Costs**" shall mean, with respect to a Collaboration Product, the FTE Costs and Out-of-Pocket Costs incurred by a Party or any of its Affiliates during the Term that are directly attributable or reasonably allocable to Life Cycle Management activities for such Collaboration Product in the Licensed Territory that are approved by the JSC under Sections 4.4 and 4.6.

I.49 "**Manufacture**" shall mean all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, and shipping of a product or any intermediate thereof, including process qualification and validation; pre-clinical, clinical and commercial manufacture; product characterization; stability testing; and quality assurance and quality control.

I.50 "**Manufacturing Budget**" shall have the meaning set forth in Section 9.1.

I.51 "**Manufacturing Costs**" shall mean, [***].

I.52 "**Manufacturing Know-How**" shall mean all Licensed Know-How that is solely directed to the Manufacture of Collaboration Products in the Field.

I.53 "**Manufacturing Markup**" shall have the meaning set forth in Section 9.2.

I.54 "**Manufacturing Standards**" shall mean all applicable specifications, GMP and any requirements of any Regulatory Authority.

I.55 "**Market Access**" shall mean any and all processes and activities conducted to establish, seek and maintain pricing and reimbursement for a Collaboration Product, as well as country level, state, regional and local payor processes and activities to obtain and maintain local and regional patient access for such Collaboration Product, including price setting; national mandatory rebate negotiations with applicable Governmental Authorities; preparing

reimbursement and economic dossiers; and policy-related activities associated with any of the foregoing.

I.56 "**Medical Affairs Activities**" shall mean design, strategies, oversight and implementation of activities designed to ensure or improve appropriate medical use of, conduct medical education in respect of a Collaboration Product, including activities of Medical Liaisons, grants to support continuing independent medical education (including independent symposia, and congresses), and development, publication and dissemination of scientific and clinical information in support of an approved indication for such Collaboration Product, as well as medical information services (and the content thereof) provided in response to inquiries communicated via sales representatives or other external-facing representatives or received by letter, phone call or email or other means of communication, and the design and conduct of Phase IV Clinical Studies and other investigator-initiated studies for an approved Collaboration Product, but excluding any activities relating to Development or Commercialization.

I.57 "**Medical Affairs Activities Costs**" shall mean, with respect to a Collaboration Product, the FTE Costs and Out-of-Pocket Costs incurred by a Party or any of its Affiliates during the Term that are directly attributable or reasonably allocable to Medical Affairs Activities for such Collaboration Product in the Licensed Territory; but in each case, only to the extent consistent with the then-current Medical Affairs Plan and Budget (as updated and amended in accordance with this Agreement).

I.58 "**Medical Affairs Plan and Budget**" shall mean a written plan governing the Medical Affairs Activities to be conducted by the Parties for a Collaboration Product in the Licensed Territory.

I.59 "**Medical Liaisons**" shall mean those health care professionals employed or engaged by a Party or any of its Affiliates with appropriate health care experience to engage in in-depth dialogues with physicians regarding medical issues associated with a Collaboration Product, and are not Sales Representatives or otherwise engaged in direct selling or promotion of a Collaboration Product.

I.60 "**Microbiome Product**" means any product for which the active ingredient is [***], in any formulation or composition, [***], as well as methods for, and compositions for use in, manufacturing any of the foregoing compositions, in each case, that is intended to be used as a drug product and is the subject of a Regulatory Approval for use in the Field. For clarity, Microbiome Products exclude [***], in each case that are not and are not intended to be the subject of a Regulatory Approval for use in the Field.

I.61 "**Microbiome Technology**" shall mean all Information, whether or not patented or patentable, Controlled by Seres and its Affiliates as of the Effective Date or during the Term, comprising or relating to the use of [***], in any formulation or composition, for (a) [***], (b) [***], and/or (c) [***], as well as methods for, and compositions for use in, manufacturing any of the foregoing compositions, but excluding [***].

I.62 "[***]" shall mean [***].

I.63 "[***] **Agreement**" shall mean [***].

I.64 "[***] **Costs**" shall mean [***].

I.65 "[***] **Patents**" shall mean [***].

I.66 "**Nestlé Health Science Unit**" means collectively, those personnel and resources of Licensee and its applicable Affiliates that are assigned to and comprise "Nestlé Health Science" for purposes of Nestlé S.A.'s internal reporting purposes.

I.67 "**Net Sales**" shall mean the gross amount invoiced by or on behalf of Licensee, its Affiliates and their respective Sublicensees for sales of Collaboration Products in the Licensed Territory (other than sales among Licensee, its Affiliates or Sublicensees for subsequent resale in which case the first sale to a Third Party that is not a Sublicensee shall be used for calculation of Net Sales), *less* the following deductions if and to the extent they are (a) included in the gross invoiced sales price of Collaboration Products or otherwise directly incurred by Licensee, its Affiliates and their respective Sublicensees with respect to the sale of Collaboration Products, (b) normal and customary for Licensee, its Affiliates or their respective Sublicensees, as applicable, (c) not otherwise deducted in computing other amounts hereunder:

(i) trade discounts, including trade, cash and quantity discounts or rebates, credits or refunds (including inventory management fees, discounts or credits),

(ii) allowances or credits for claims, returns or rejections of Collaboration Products, including recalls,

(iii) actual freight and insurance costs, including without limitation the costs of export licenses, shipping, postage and handling charges, incurred in transporting Collaboration Products to customers,

(iv) rebates and chargebacks or retroactive price reductions made to federal, state or local governments (or their agencies), or any Third Party payor, administrator or contractor, including managed health organizations,

(v) customs duties, sales, excise and use taxes and any other governmental charges (including value added tax) actually paid in connection with the transportation, distribution, use or sale of Collaboration Products (but excluding what are commonly known as income taxes), and

(vi) [***] in connection with the Collaboration Products, provided that any recovered [***] will be included in Net Sales in the Calendar Quarter in which they are recovered.

In the case of sale or other disposal of Collaboration Products for non-cash consideration, the gross revenue attributable to such Collaboration Product for purposes of calculating Net Sales in respect thereof shall include the fair market price of such non-cash consideration. Notwithstanding the foregoing, provision of Collaboration Products for the purpose of [***] shall not be deemed to be a sale. For clarity, any consideration received for Collaboration Products [***] shall not be included in the calculation of Net Sales.

Net Sales shall be determined in accordance with GAAP.

I.2 "**Non-Defending Party**" shall have the meaning set forth in Section 11.3(g).

I.3 "**Non-Enforcing Party**" shall have the meaning set forth in Section 11.3(d).

I.4 "**Notice**" shall have the meaning set forth in Section 2.2.

I.5 "**Notice of Termination**" shall have the meaning set forth in Section 13.2.

I.6 "**Ongoing Clinical Study**" shall have the meaning in Section 4.1(a).

I.7 "**Other Income**" shall mean any payment or income (other than Net Sales) received by a Party or its Affiliate from a Third Party that is attributable to a Collaboration Product or is received in connection with the grant of a sublicense or other right or activity with respect to the Collaboration Products, in each case, in the Licensed Territory, excluding recoveries in connection with any Third Party Infringement or Third Party Challenge (which are addressed in Section 11.3(f)).

I.8 "**Other Mark**" shall have the meaning in Section 12.3.

I.9 "**Out-of-Pocket Costs**" shall mean reasonable amounts actually paid to Third Party vendors, consultants, suppliers or contractors, for services or materials, as applicable, provided by each such Third Party and other reasonable amounts actually paid to Third Parties (including travel and entertainment expenses) that are, in each case, directly related to an Additional Clinical Study, a Shared Clinical Study, a Post-Approval Study, the Manufacture of Collaboration Products, performing the activities contemplated by Section 5.4, Life Cycle Management, other regulatory activities, implementing risk evaluation and mitigation strategies, enforcement of Third Party Infringement actions, clearance of Product Trademarks, establishment and maintenance of rights of Product Trademarks, Commercialization or Medical Affairs Activities of or in respect to Collaboration Products, or any other activities specified under this Agreement, as applicable, to the extent such services or materials apply to the activities in or in respect of the Licensed Territory contemplated in this Agreement. For clarity, Out-of-Pocket Costs do not include (a) payments for a Party's internal salaries or benefits for its employees, general office or facility supplies, insurance, general information technology, utilities, or capital expenditures, or (b) items included in the determination of the FTE Rate.

I.10 "**Party**" shall mean Seres or Licensee, individually; and "**Parties**" shall mean Seres and Licensee, collectively.

I.11 "**Party Allowable Expenses**" shall have the meaning set forth in Section 7.4(b)(ii)(A).

I.12 "**Party Net Amount**" shall have the meaning set forth in Section 7.4(b)(ii)(A).

I.13 "**Party Tactical Matters**" shall mean, with respect to a Party, such Party's operational or tactical-level matters and functions allocated or delegated to such Party pursuant to a Commercialization Plan and Budget, Medical Affairs Plan and Budget, or otherwise pursuant to

this Agreement with respect to a Collaboration Product, including Life Cycle Management, Commercialization activities, Manufacturing activities and Medical Affairs Activities with respect to such Collaboration Product. For clarity, Party Tactical Matters exclude any specific responsibilities or determinations that are expressly delegated to a Committee under this Agreement, or expressly require the consent of the other Party or any Committee.

I.14 "**Patent(s)**" shall mean any and all national, regional and international (a) issued patents and pending patent applications (including provisional patent applications), (b) patent applications filed either from the foregoing or from an application claiming priority to the foregoing, including all provisional applications, converted provisionals, substitutions, continuations, continuations-in-part, divisions, renewals and continued prosecution applications, and all patents granted thereon, (c) patents-of-addition, revalidations, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, pediatric exclusivity, patent term extensions, supplementary protection certificates or the equivalent thereof, (d) inventor's certificates, utility models, petty patents, innovation patents and design patents, (e) other forms of government-issued rights substantially similar to any of the foregoing, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing and (f) United States and foreign counterparts of any of the foregoing.

I.15 "**Payee Party**" shall have the meaning set forth in Section 8.3(b).

I.16 "**Paying Party**" shall have the meaning set forth in Section 8.3(b).

I.17 "**Person**" shall mean an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

I.18 "**Personal Information**" shall mean "personally identifiable information," "personal data," or equivalent terms as defined by applicable Data Protection Laws.

I.19 "**Pharmacovigilance Agreement**" shall have the meaning set forth in Section 4.7(c).

I.20 "**Phase II Clinical Study**" shall mean a Clinical Study, the principal purpose of which is to make a preliminary determination as to whether a product is safe for its intended use and to obtain sufficient information about such product's efficacy, in a manner that is generally consistent with 21 C.F.R. § 312.21(b), as amended (or its successor regulation), to permit the design of Phase III Clinical Studies.

I.21 "**Phase III Clinical Study**" shall mean a pivotal Clinical Study with a defined dose or a set of defined doses of a therapeutic product designed to ascertain efficacy and safety of such product, in a manner that is generally consistent with 21 C.F.R. § 312.21(c), as amended (or its successor regulation), for the purpose of enabling the preparation and submission of a BLA or a foreign equivalent thereof.

I.22 "**Phase IV Clinical Study**" shall mean a post-marketing Clinical Study with respect to any Collaboration Product with respect to any indication that is commenced after the receipt of Regulatory Approval for such indication, including the trials referred to in 21 C.F.R. § 312.85, but excluding Post-Approval Studies.

I.23 "**Post-Approval Study**" shall mean any non-clinical study or Clinical Study that is conducted as a commitment made to a Regulatory Authority as a condition of, or mandated by a Regulatory Authority in connection with, obtaining or maintaining, a Regulatory Approval.

I.24 "**Post-Approval Study Costs**" shall mean FTE Costs and Out-of-Pocket Costs directly related or reasonably allocable to Post-Approval Studies conducted in accordance with Section 4.1(b).

I.25 "**Pre-Launch Costs and Expenses**" means the Commercialization Costs, the Medical Affairs Activities Costs and any other costs and expenses (but excluding any Development costs and expenses) incurred by the Parties and their Affiliates in the performance of their obligations hereunder during the Pre-Launch Period in connection with the activities set forth in the Pre-Launch Plan described in Section 5.1(a), in an aggregate amount up to the Pre-Launch Cap.

I.26 "**Pre-Launch Cap**" shall have the meaning set forth in Section 7.4(a).

I.27 "**Pre-Launch Period**" shall mean the period of time commencing on the Effective Date until the date of First Commercial Sale of the first Collaboration Product in the Licensed Territory.

I.28 "**Pre-Launch Plan**" shall have the meaning set forth in Section 5.1(a).

I.29 "**Pre-Launch Supply Costs**" shall have the meaning set forth in Section 9.2.

I.30 "**Primary Position Detail**" shall mean, with respect to a Collaboration Product, a Detail, other than an Exclusive Detail, (a) in which key attributes of the Collaboration Product are orally presented consistent with the terms of this Agreement and (b) where the Collaboration Product is given primary emphasis (*i.e.*, an emphasis that is more important than the emphasis given to any other product presented, as a first position detail).

I.31 "**Product Information**" shall have the meaning set forth in Section 10.5.

I.32 "**Product Liability Losses**" shall mean any and all Liabilities that relate to Third Party Claims in respect of personal injury or death (or risk of personal injury or death) arising from, relating to or otherwise in respect of, the use or ingestion of, or exposure to, a Collaboration Product, whether based on negligence, strict product liability or any other product liability theory, including any such liability predicated on any alleged or actual Manufacturing, design or formulation defect or failure to warn or any breach of any express or implied warranties, in each case relating to Collaboration Product sold or alleged to have been sold, or Commercialization or Medical Affairs Activities conducted or alleged to have been conducted, in the Licensed Territory.

I.33 "**Product Trademark**" shall have the meaning set forth in Section 12.1(a).

I.34 "**Proposed Sublicense**" shall have the meaning set forth in Section 2.2.

I.35 "**Prosecuting Party**" shall have the meaning set forth in Section 11.2(c).

I.36 "**Protocol**" shall have the meaning set forth in Section 4.4(a).

I.37 "**Quality Agreement**" shall have the meaning set forth in Section 9.3.

I.38 "**Quarterly Royalty Report**" shall have the meaning set forth in Section 7.4(a).

I.39 "**Receipts**" shall have the meaning set forth in Section 7.4(b)(ii)(A).

I.40 "**Receiving Party**" shall have the meaning set forth in Section 10.1(a).

I.41 "**Recurrent *C. difficile* Infection**" or "**rCDI**" shall mean an episode of a *C. difficile* infection ("**CDI**") in a patient who has [***] within [***].

I.42 "**Regulatory Approval**" shall mean, with respect to any Collaboration Product in any country or regulatory jurisdiction, any and all approvals and licensures from the applicable Regulatory Authority sufficient for the import, distribution, marketing, use, offering for sale, and sale of the Collaboration Product for use in the Field in such country or jurisdiction in accordance with applicable Laws, but excluding any applicable pricing and reimbursement approvals.

I.43 "**Regulatory Authority**" shall mean any national or supranational Governmental Authority (including, without limitation, the FDA) which has regulatory responsibility and authority in one or more countries for review and approval of Development and Commercialization of therapeutic products.

I.44 "**Regulatory Documentation**" shall mean all (a) Regulatory Filings and other registrations, licenses, authorizations, and approvals of or with Regulatory Authorities (including Regulatory Approvals); (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files; and (c) Data contained or relied upon in any of the foregoing, in each case ((a), (b), and (c)) relating to the Development, Manufacture, or Commercialization of a Collaboration Product in a particular country or jurisdiction.

I.45 "**Regulatory Expenses**" shall mean, with respect to a Collaboration Product, the FTE Costs and Out-of-Pocket Costs incurred by a Party or any of its Affiliates during the Term that are directly attributable or reasonably allocable to obtaining or maintaining Regulatory Approvals for such Collaboration Product.

I.46 "**Regulatory Filing**" shall mean any and all regulatory applications and/or related documentation submitted on or before the date hereof, or any time during the Term, to a Regulatory Authority with respect to a Collaboration Product in connection with the initiation or conduct of Clinical Studies, and/or to seek Regulatory Approval for such Collaboration Product in the Field,

including, without limitation, any INDs, drug master files, manufacturing master files, BLAs, or any supplements thereto.

I.47 "**Relevant Third Party Right**" shall have the meaning set forth in Section 7.5.

I.48 "**REMS Costs**" shall mean FTE Costs and Out-of-Pocket Costs directly related or reasonably allocable to any risk evaluation and mitigation strategy that is implemented as a commitment to a Regulatory Authority as a condition of, or in connection with obtaining or maintaining, a Regulatory Approval.

I.49 "**ROW Territory**" shall mean all countries of the world other than the Licensed Territory.

I.50 "**Royalty Base Amount**" shall mean, with respect to any Collaboration Product in the Licensed Territory during any applicable period, the amount, if any, by which the sum of (a) the Net Sales *plus* (b) Other Income attributable to such Collaboration Product during such period exceeds (c) the Allowable Expenses attributable to such Collaboration Product during such period. For the avoidance of doubt, (i) income and withholding taxes imposed on either of the Parties or their Affiliates, (ii) any payments made by Licensee to Seres pursuant to Section 7.1 or 7.2 and (iii) indemnification payments by a Party to the other Party or to an Indemnitee hereunder or under the Supply Agreement, will not be included in the calculation of the Royalty Base Amount.

I.51 "**Royalty Payment Amount**" shall have the meaning set out in Section 7.4(a).

I.52 "**Rules**" shall have the meaning set forth in Section 17.2.

I.53 "**Sales Representative**" of a Party means (a) an employee of such Party or an Affiliate of such Party engaged by such Party or an Affiliate of such Party to promote a Collaboration Product on behalf of such Party or such Affiliate, or (b) a subcontractor engaged by such Party or Affiliate in accordance with Section 18.10 to promote a Collaboration Product on behalf of such Party or such Affiliate, which shall include any contract sales organization engaged by either Party in accordance with Section 5.5(g) with the approval of the JCC (if such approval is required under Section 5.5(g)); excluding, in each case ((a) and (b)), (i) those employees or independent contractors of either Party or such Affiliate that are solely engaged in telemarketing, professional education or other indirect activities in support of direct selling, and (ii) Medical Liaisons of a Party or such Affiliate.

I.54 "**Secondary Position Detail**" shall mean, with respect to a Collaboration Product, a Detail (a) in which key attributes of the Collaboration Product are orally presented consistent with the terms of this Agreement and (b) where the Collaboration Product is given significant but not primary emphasis (*i.e.*, an emphasis that is at least or more important than the emphasis given to any other product presented other than the product that is presented as a Primary Position Detail), as a second position detail.

I.55 "**Senior Executives**" shall mean, (in the case of Seres) Seres' and (in the case of Licensee) the Nestlé Health Science Unit's respective [***] senior officers, depending on the subject matter of the dispute.

I.56 "**SER-109**" shall mean [***].

I.57 "**Seres Indemnitees**" shall have the meaning set forth in Section 16.1.

I.58 "**Shared Clinical Study**" shall have the meaning set forth in Section 4.4(c).

I.59 "**Shared Clinical Study Budget**" shall have the meaning set forth in Section 4.4(c).

I.60 "**Shared Clinical Study Costs**" shall mean FTE Costs and Out-of-Pocket Costs directly attributable or reasonably allocable to Shared Clinical Studies, including Manufacturing Collaboration Products and maintaining the safety database therefor, conducted in accordance with this Agreement.

I.61 "**Subcommittee**" shall have the meaning set forth in Section 3.2(a).

I.62 "**Sublicensee**" shall mean a Third Party that has been granted a right to sell, market, distribute and/or promote any Collaboration Product in the Field and in the Licensed Territory pursuant to Section 2.2. As used in this Agreement, "**Sublicensee**" shall not include a wholesaler, distributor or reseller of such Collaboration Product, to the extent that Licensee or its Affiliate sells to such Person such Collaboration Product and receives only supply price payments.

I.63 "**Supply Agreement**" shall have the meaning set forth in Section 9.2.

I.64 "**Supply Costs**" shall have the meaning set forth in Section 9.2.

I.65 "**Surplus Party**" shall have the meaning set forth in Section 7.4(b)(ii)(A).

I.66 "**Target Audience**" shall have the meaning set forth in Section 1.31.

I.67 "**Tax**" or "**Taxes**" shall mean any present or future taxes, levies, imposts, charges, withholdings, assessments or fees in the nature of a tax (including penalties and additions to tax and interest thereon).

I.68 "**Tax Action**" shall have the meaning set forth in Section 8.3(b).

I.69 "**Third Party**" shall mean any Person, corporation, joint venture or other entity, other than Seres, Licensee and their respective Affiliates.

I.70 "**Third Party Challenge**" shall have the meaning set forth in Section 11.3(a).

I.71 "**Third Party Claim**" shall have the meaning set forth in Section 16.1.

I.72 "**Third Party Infringement**" shall have the meaning set forth in Section 11.3(a).

I.73 "**Third Party License Payments Threshold**" shall have the meaning set forth in Section 7.5(c).

I.74 "**Term**" shall have the meaning set forth in Section 13.1.

I.75 "**Trademark**" shall mean any registered or unregistered trademark, service mark, trade dress, trade name, logo, insignia, domain name, symbol, design, or combinations thereof.

I.76 "**Trademark Costs**" shall mean the direct Out-of-Pocket Costs, including the reasonable fees and expenses incurred to outside counsel and other Third Parties, including Trademark searching, filing, prosecution and maintenance fees recorded as an expense by a Party or any of its Affiliates in accordance with its customary accounting practices during the Term, in connection with the clearance of Product Trademarks and the establishment and maintenance of rights of Product Trademarks in the Licensed Territory.

I.77 "**Transition Period**" shall have the meaning set forth in Section 14.2(a)(i).

I.78 "**True-Up Amount**" shall have the meaning set forth in Section 7.4(b)(ii)(B).

I.79 "**True-Up Delta**" shall have the meaning set forth in Section 7.4(b)(ii)(B).

I.80 "**Transition Working Group**" and "**TWG**" shall have the meaning set forth in Section 14.3(f).

I.81 "**United States**" or "**U.S.**" shall mean the United States of America, its territories and possessions.

I.1 "**Working Group**" shall have the meaning set forth in Section 3.3(a).

ARTICLE II
GRANT OF LICENSE

I.1 **License Grant to Licensee**. Subject to the terms and conditions of this Agreement, including Section 5.5 with respect to promotion activities, Seres hereby grants to Licensee a Co-Exclusive (with Seres and its Affiliates), perpetual license under the Licensed Intellectual Property, with the right to sublicense (subject to Section 2.2) through multiple tiers, to (a) Develop, Commercialize, and conduct Medical Affairs Activities in respect of Licensed Products in the Licensed Territory in the Field and to use Licensed Products in connection therewith, and (b) Develop, Commercialize, and conduct Medical Affairs Activities in respect of Collaboration Products in the Licensed Territory in any field or indication and to use Collaboration Products in connection therewith. For the sake of clarity, Seres shall not, and shall ensure that its Affiliates do not, grant any licenses or sublicenses to a Third Party under any of the Licensed Intellectual Property to (i) Develop, Commercialize, or conduct Medical Affairs Activities in respect of, Licensed Products in the Licensed Territory in the Field, or to use Licensed Products in connection therewith, except with respect to Third Party subcontractors in accordance with Section 18.10, or (ii) Develop, Commercialize, or conduct Medical Affairs Activities in respect of, Collaboration Products in the Licensed Territory in any field or indication, or to use Collaboration Products in connection therewith, except with respect to Third Party subcontractors in accordance with Section 18.10. Notwithstanding anything to the contrary in this Section 2.1, the license granted to Licensee hereunder is not intended to restrict Licensee from conducting Development and Commercialization activities and Medical Affairs Activities outside of the Licensed Territory so long as such activities are in support of the sale of Collaboration Products or Licensed Products within the Licensed Territory.

I.2 **Sublicense**. Licensee shall have the right to grant sublicenses of the rights granted to it by Seres under Section 2.1 (a) to [***] and (b) to [***]. The terms of any sublicense granted pursuant to this Section 2.2 shall be consistent with the terms and conditions of this Agreement. Notwithstanding the foregoing, [***] pursuant to this Section 2.2 shall be required for the grant of rights to independent contractors performing activities under this Agreement on Licensee's or [***] behalf. Licensee shall at all times remain responsible for, and shall be liable under this Agreement with respect to, any breach of this Agreement resulting directly or indirectly from the performance by its Sublicensees under any such sublicenses (determined *mutatis mutandis* as if such Sublicensees were Licensee hereunder). Licensee shall furnish to Seres a true and complete copy of each sublicense agreement entered into with a Third Party and each amendment thereto, which sublicense agreement may be redacted to omit information not directly relevant to compliance with this Agreement or as may otherwise be required by Law, within [***] after the sublicense or amendment has been executed.

I.3 Retained Rights. Licensee acknowledges and agrees that Seres retains all rights in and to the Licensed Intellectual Property not expressly granted to Licensee pursuant to Section 2.1. Licensee acknowledges and agrees that the license granted to it in Section 2.1 under the [***] Patents are subject to [***] reserved rights as provided under Section 2.2 of the [***] Agreement, and the rights of the United States government as provided under Section 2.3 of the [***] Agreement.

I.4 License to Seres. During the Term, Licensee shall and hereby does grant to Seres a [***], license, [***], under [***], solely to Exploit the Collaboration Products in the ROW Territory, and to Develop and Manufacture Collaboration Products in the Licensed Territory both for Commercialization of the Collaboration Products by or on behalf of Seres, its Affiliates or sublicensees in the ROW Territory and for Commercialization by or on behalf of Licensee and Seres in the Licensed Territory, in each case, solely to the extent that such activities are not precluded by any exclusive or co-exclusive license granted to Licensee or its Affiliates pursuant to this Agreement or the Existing Agreement. This license shall be superseded by the license granted under Section 14.2(c) upon the termination of this Agreement pursuant to Section 13.2, 13.3, 13.4 or 13.5. The terms of any sublicense granted pursuant to this Section 2.4 shall be consistent with the terms and conditions of this Agreement. Seres shall at all times remain responsible for, and shall be liable under this Agreement with respect to, any breach of this Agreement resulting directly or indirectly from the performance by its Affiliates and Third Parties under any sublicenses granted pursuant to this Section 2.4 (determined *mutatis mutandis* as if such sublicensees were Seres hereunder).

I.5 Transfer of Licensed Know-How.

(a) Initial Transfer. [***], Seres shall provide Licensee with copies of and/or reasonable access to all existing material Licensed Know-How, except for Manufacturing Know-How, as Licensee may reasonably request that exists as of the Effective Date and that have not previously been transferred to Licensee. Such Licensed Know-How may be provided and/or made accessible to Licensee in the form of copies of written documents or other tangible form, and/or as electronic files in a mutually acceptable format and medium, as agreed upon by the JSC.

(b) Subsequent Transfers. During the Term, Seres shall provide Licensee with copies of and reasonable access to all existing material Licensed Know-How, except for Manufacturing Know-How, necessary to enable Licensee to exercise its rights and perform its obligations under this Agreement, together with supporting documentation, and provide reasonable assistance to Licensee as may be necessary for Licensee to Develop Collaboration Products in accordance with this Agreement and to Commercialize Collaboration Products in the Field in the Licensed Territory.

I.1 **Certain Limitations; Exclusivity**.

(a) Notwithstanding anything to the contrary in this Agreement, but without limiting Licensee's rights under the Existing Agreement, [***].

(b) During the Term, neither Seres nor Licensee will, subject to Section 18.9, [***].

I.2 No Other Rights; Existing Agreement. Except for the rights and licenses expressly granted in this Agreement, each Party retains all rights under its Intellectual Property Rights, and no additional rights shall be deemed granted to the other Party by implication, estoppel or otherwise. For clarity, this Agreement shall not modify the Parties' rights and obligations under the Existing Agreement, and Licensee's Exploitation of Collaboration Products in and in respect of the ROW Territory shall be governed by the terms and conditions of the Existing Agreement.

I.3 [***] **Agreement**. Licensee acknowledges that it has received an unredacted copy of the [***] Agreement from Seres. Licensee acknowledges that the license granted by Seres to Licensee under Section 2.1 with respect to the [***] Patents are, in addition to being subject to the terms and conditions of this Agreement, subject to the applicable terms and conditions of the [***] Agreement. Licensee acknowledges that, pursuant to Section 3.1 of the [***] Agreement, Seres will furnish to [***] a true and complete copy of this Agreement and any current and future amendments thereto. To the extent reasonably requested by Seres, Licensee will cooperate with Seres to support Seres' compliance with the [***] Agreement in accordance with the terms therein and [***].

ARTICLE III
GOVERNANCE

III.1 Joint Steering Committee.

(a) Formation. [***], Seres and Licensee shall establish a joint steering committee ("**Joint Steering Committee**" or "**JSC**"), which shall have overall responsibility for overseeing the activities conducted pursuant to this Agreement, which oversight shall be conducted through the Subcommittees as set forth in Section 3.2. The JSC shall be composed of an equal number of representatives from each of Licensee and Seres, selected by such Party. Unless the Parties otherwise agree, the exact number of representatives for each of Licensee and Seres shall be three (3) representatives, each of whom shall be at a level which allows such representative to make decisions on behalf of the Party he/she represents with respect to the relevant matters. Either Party may replace its respective JSC representatives at any time with prior written notice to the other Party; provided that the criteria for composition of the JSC set forth in the preceding sentence

continues to be satisfied following any such replacement of a Party's representative on the JSC. The Joint Steering Committee shall perform the functions and assume the responsibilities and have such authority only as set forth in this Agreement.

(b) Specific Duties. The Joint Steering Committee shall have the following duties, all of which, for clarity, are specific to the Licensed Territory unless otherwise expressly stated:

(i) Provide general direction and oversight over the JDC with respect to the activities set forth in this Agreement related to the Development and regulatory strategy and submissions for Collaboration Products in the Field in the Licensed Territory;

(ii) Approve Additional Clinical Studies as Shared Clinical Studies and the Shared Clinical Study Budgets therefor, including any updates thereto;

(iii) Approve Life Cycle Management plans for Collaboration Products in the Licensed Territory, including the budget therefor and updates thereto;

(iv) Discuss Patent filing strategies in the Licensed Territory;

(v) Discuss and approve Manufacturing Budgets and other material decisions relating to strategies and plans for Manufacturing the Collaboration Products in the Licensed Territory to support Commercialization, including timeline and plan for production of commercial supplies of Collaboration Products, back-up suppliers, inventory control, commercial scale-up plans, and labeling and packaging plans and artwork therefor;

(vi) Direct and oversee the JCC on the commercial issues that fall within the purview of the JCC;

(vii) Approve the Commercialization Plan and Budget for a Collaboration Product and all substantive amendments and updates with respect thereto;

(viii) Approve the Development or Commercialization of a Combination Product for a particular country in the Licensed Territory and evaluate appropriate adjustments to the definition of Net Sales, if any, needed in light of such Combination Product;

(ix) Direct and oversee the JMAC on the Medical Affairs Activities issues that fall within the purview of the JMAC;

(x) Approve the Medical Affairs Plan and Budget for each Collaboration Product and all substantive amendments and updates with respect thereto;

(xi) Approve pricing, discounting and rebating strategies for Collaboration Products in the Licensed Territory pursuant to Section 5.8, in compliance with applicable Laws;

(xii) Review such matters as are referred to it by a Subcommittee or Alliance Managers and approve or resolve any such matters that are required by this Agreement to be approved by the applicable Subcommittee or Working Group;

(xiii) Determine any modifications to the scope of matters delegated to the Subcommittees and Working Groups, which, notwithstanding anything to the contrary herein, shall not be subject to a Party's final decision-making authority under Section 3.4(b)(iv)(A) and Section 3.4(b)(iv)(B); and

(xiv) Perform such other duties as are specifically assigned to the JSC in accordance with this Agreement.

III.2 Subcommittees.

(a) Formation. [***], Seres and Licensee shall establish a joint commercialization committee ("**Joint Commercialization Committee**" or "**JCC**"), a joint development committee ("**Joint Development Committee**" or "**JDC**"), and a joint medical affairs committee ("**Joint Medical Affairs Committee**" or "**JMAC**") (each of the JCC, the JDC, and the JMAC, a "**Subcommittee**"). Each Subcommittee shall be subject to the oversight of the JSC. The JCC shall be principally responsible for overseeing the Commercialization of Collaboration Products in the Licensed Territory. The JDC shall be principally responsible for overseeing the Development of Collaboration Products in the Licensed Territory. The JMAC shall be principally responsible for overseeing the Medical Affairs Activities with respect to Collaboration Products in the Licensed Territory. Each Subcommittee shall be composed of an equal number of representatives from each of Licensee and Seres, selected by such Party. Unless the Parties otherwise agree, the exact number of representatives in each Subcommittee for each of Licensee and Seres shall be three (3) representatives, each of whom shall be at a level which allows such representative to make decisions on behalf of the Party he/she represents with respect to the relevant matters. Either Party may replace its respective Subcommittee representatives at any time with prior written notice to the other Party; provided that the criteria for composition of each Subcommittee set forth in the preceding sentence continues to be satisfied following any such replacement of a Party's representative on the applicable Subcommittee. Each Subcommittee shall perform the functions and assume the responsibilities, and have such authority only, as set forth in this Agreement and as modified by the JSC from time to time in accordance with Section 3.1(b)(xiii).

(b) Specific Duties of the Joint Development Committee. The Joint Development Committee shall have the following duties, all of which, for clarity, are specific to the Licensed Territory unless otherwise expressly stated:

(i) Discuss the Development of Collaboration Products in the Field in the Licensed Territory, including with respect to the conduct of and data analysis for the Ongoing Clinical Studies and any Post-Approval Studies in the Licensed Territory;

(ii) Confer regarding the status and progress of activities under the Development and Regulatory Activity Plan;

(iii) Review and approve Protocols for Additional Clinical Studies, recommend to the JSC to be approved as Shared Clinical Studies, and all substantive amendments and updates with respect thereto, and discuss and determine a Shared Clinical Study Budget for each Shared Clinical Study, including updates thereto, for approval by the JSC;

(iv) Amend the Development and Regulatory Activity Plan to include any approved Shared Clinical Studies and Shared Clinical Study Budgets, and monitor progress and oversee execution of such studies;

(v) Discuss regulatory strategies in the Licensed Territory, review Regulatory Filings and coordinate the exchange of information between the Parties with respect to Regulatory Filings in the Licensed Territory;

(vi) Discuss and develop Life Cycle Management plans for Collaboration Products in the Licensed Territory, including the budget therefor and updates thereto, and, jointly with the JCC, recommend to the JSC for approval Life Cycle Management plans;

(vii) Amend the Development and Regulatory Activity Plan to include any approved Life Cycle Management plans, and monitor progress and oversee execution of approved Life Cycle Management plans, including with respect to SER-109 Life Cycle Management; and

(viii) Perform such other duties as are specifically assigned to the JDC in accordance with this Agreement.

(c) Specific Duties of the Joint Commercialization Committee. The Joint Commercialization Committee shall have the following duties, all of which, for clarity, are specific to the Licensed Territory unless otherwise expressly stated:

(i) Establish Life Cycle Management strategies for Collaboration Products in the Licensed Territory, including whether to seek new indications, formulations or uses for the Collaboration Products in the Licensed Territory, and, jointly with the JDC, recommend to the JSC for approval Life Cycle Management plans;

(ii) Review and recommend to the JSC for approval Commercialization Plans and Budgets and all substantive amendments and updates with respect thereto;

(iii) Facilitate the flow of information with respect to the Commercialization of the Collaboration Products in the Licensed Territory;

(iv) Monitor progress under, and oversee implementation of, approved Commercialization Plans and Budgets, monitor the Parties' compliance with the job descriptions and time periods for hiring Sales Representatives and other personnel in the Licensed Territory as set forth in the Commercialization Plans and

Budgets, and monitor Commercialization Costs incurred by or on behalf of the Parties;

(v) If Seres elects to provide Details pursuant to Section 5.5(b), coordinate sales force activities and strategies in accordance with Commercialization Plans and Budgets;

(vi) Approve the use of any contract sales organizations requested by a Party, subject to and in accordance with Section 5.5(g);

(vii) Recommend to the JSC pricing, discounting and rebating strategies for Collaboration Products in the Licensed Territory, in compliance with applicable Laws; monitor Collaboration Product pricing and reimbursement in the Licensed Territory;

(viii) Oversee publications and communications for the Collaboration Products in the Licensed Territory, including with respect to health and economic outcomes research publications;

(ix) Review each Party's financial reports pertaining to Allowable Expenses for each Collaboration Product in the Licensed Territory, provided pursuant to this Agreement; and

(x) Perform such other duties as are specifically assigned to the JCC in accordance with this Agreement.

(d) Specific Duties of the Joint Medical Affairs Committee. The Joint Medical Affairs Committee shall have the following duties, all of which, for clarity, are specific to the Licensed Territory unless otherwise expressly stated:

(i) Review and recommend to the JSC for approval Medical Affairs Plans and Budgets, and all substantive amendments and updates with respect thereto, and oversee the implementation of Medical Affairs Activities to be conducted by Seres under such Medical Affairs Plans and Budgets, in each case for the Licensed Territory;

(ii) Monitor progress under, and oversee implementation of, approved Medical Affairs Plans and Budgets, monitor Seres' compliance with the job descriptions and time periods for hiring Medical Liaisons in the Licensed Territory as set forth in the Medical Affairs Plans and Budgets, and monitor Medical Affairs Activities Costs incurred by or on behalf of Seres;

(iii) Facilitate the flow of information with respect to the Medical Affairs Activities in the Licensed Territory and coordinate the flow of such information with other Committees, as appropriate;

(iv) Provide updates on Medical Affairs Activities in the Licensed Territory to the JSC; and

(v) Perform such other duties as are specifically assigned to the JMAC in accordance with this Agreement.

III.3 Working Groups.

(a) Establishment. From time to time, the JSC or a Subcommittee may establish and delegate duties to working groups (each, a "**Working Group**") to oversee particular projects or activities within their respective authority. Each Working Group and its activities shall be subject to the oversight, review and approval of, and shall report to the JSC or Subcommittee, as applicable. A Working Group shall be composed of an equal number of representatives from each of Seres and Licensee, selected by such Party, and the total number of members of each Working Group will be determined by the JSC or Subcommittee, as applicable. Each Working Group shall meet at such times and in such places as directed by the JSC or Subcommittee, as applicable. In no event shall the authority of any Working Group exceed that specified for it by the JSC or Subcommittee, as applicable, as set forth in this Article III.

(b) Specific Working Groups. [***], the Parties shall form the following Working Groups:

(i) a Patent Working Group to monitor and coordinate Patent strategies and prosecution and other proceedings with respect to the Licensed Patents in the Licensed Territory as set out in Article XI, which will report to the JSC;

(ii) a Publications Working Group to monitor and coordinate the publication and communications strategy for the Collaboration Products in accordance with Section 10.4 and which will establish an annual medical and scientific communications plan, which will report to the JCC;

(iii) a Manufacturing Working Group to monitor and coordinate the Manufacture, supply and quality of Collaboration Products in or for the Licensed Territory in accordance with the Supply Agreement and Quality Agreement, which will report to the JSC; and

(iv) a Finance Working Group to monitor and coordinate accounting and financial matters relating to the activities conducted pursuant to this Agreement, which will report to the JSC.

III.4 Committee Meetings and Procedures.

(a) Committee Meetings. Each Committee shall meet at least [***], or more or less often as otherwise agreed to by the Parties, provided that it shall meet within [***] after the formation thereof in accordance with this Article III. Committee meetings may be conducted by telephone, video-conference or in person as determined by its members. Unless otherwise agreed by the Parties, all in-person meetings of a Committee shall be held on an alternating basis between Seres' facilities and Licensee's facilities. One Party shall be responsible for appointing an individual to record the minutes of each Committee meeting, which minutes shall clearly document any decisions made by the Committee at such meeting. Unless otherwise agreed by the Parties, this responsibility shall alternate between the Parties every twelve (12) months, with Seres being

responsible for the initial twelve (12) months following the Effective Date. Committee meeting minutes shall be circulated to the Parties within [***] following the meeting for review, comment and ratification by the Parties. No action taken at any meeting of a Committee shall be effective unless at least one (1) representative of each Party is participating. With the consent of the other Party (not to be withheld unreasonably), other employee representatives of a Party may attend any Committee meeting as non-voting observers at such Party's sole cost and expense; provided that such employees must be bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

(b) Decision-Making.

(i) All decisions required by this Agreement to be made by any Committee (including for clarity each Subcommittee and Working Group) shall be decided by unanimous vote, with each Party's representatives [***].

(ii) In the event that a Subcommittee or a Working Group fails to reach [***], then such disagreement shall be referred to the JSC for resolution. For clarity, each Party shall have the right to make determinations in its discretion with respect to such Party's Party Tactical Matters, provided that such determinations are consistent with the Development and Regulatory Activity Plan, the Commercialization Plan and Budget, the Manufacturing Budget, or Medical Affairs Plan and Budget, as applicable, the terms of this Agreement, and applicable Law, except that disputes as to whether or not a matter is a Party Tactical Matter may be escalated in accordance with this Section 3.4(b)(ii) and, if applicable, Section 3.4(b)(iv).

(iii) In the event that the JSC fails to reach [***] and such matter is not subject to a Party's final decision-making authority under Section 3.4(b)(iv)(A) and Section 3.4(b)(iv)(B), then either Party may, by written notice to the other Party, have such matter referred to the Senior Executives, who shall meet promptly and negotiate in good faith pursuant to Section 17.1. If despite such good faith efforts, the Senior Executives are unable to resolve such disagreement, then either Party may submit such dispute for resolution via arbitration in accordance with Section 17.2.

(iv) Except with respect to any matters that this Agreement provides must be consented or agreed to, or approved by, the other Party, anything to the contrary contained in this Agreement:

(A) Seres shall be entitled to make the final determination with respect to any disagreement regarding a matter for which approval or resolution of the JSC is expressly required herein, or that is submitted to the JSC for resolution in accordance with Section 3.4(b)(ii), that is primarily related to [***]; provided, in each case of [***], and [***], that [***]; and

(B) Licensee shall be entitled to make the final determination with respect to any disagreement regarding a matter for which approval or

resolution of the JSC is expressly required herein, or that is submitted to the JSC for resolution in accordance with Section 3.4(b)(ii), that is primarily related to [***]; provided that in each case of [***] and [***].

(ii) Any matter that is resolved in accordance with this Section 3.4 shall be deemed to have been approved by the JSC in the manner of such resolution.

I.2 Alliance Managers. [***], each Party shall appoint a representative ("**Alliance Manager**") to facilitate communications between the Parties and to act as a liaison between the Parties with respect to activities to be conducted pursuant to this Agreement. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party. Each Party's Alliance Managers shall be entitled to attend all Committee meetings as non-voting members. Each Alliance Manager may bring any matter to the attention of a Committee where such Alliance Manager reasonably believes that such matter requires attention of such Committee.

I.3 Scope of Governance. Notwithstanding the creation of the JSC, JCC, JDC, JMAC and/or any Working Group, each Party shall retain the rights, powers and discretion granted to it under this Agreement, and neither the JSC, JCC, JDC, JMAC nor any Working Group shall have any rights, powers or discretion unless expressly provided herein or delegated by the JSC, or the Parties expressly otherwise agree in writing. The Alliance Managers shall not have any rights, powers or discretion except as expressly granted to the Alliance Managers hereunder. The decisions of the JSC, JCC, JDC, JMAC, any Working Group and Alliance Managers shall be consistent with the terms and conditions of this Agreement. In no event shall the JSC, JCC, JDC, JMAC, any Working Group or the Alliance Managers have any power to modify, amend or waive compliance with this Agreement. For clarity, other than matters for which approval or resolution of the JSC or a Subcommittee is expressly required herein: (a) Seres shall be responsible for and shall have discretion with respect to (i) all Development activities for Collaboration Products in the Field in the Licensed Territory in accordance with, and subject to, Sections 4.1, 4.3, 4.4 and 4.5, (ii) all Regulatory Filings for Collaboration Products in the Field in the Licensed Territory in accordance with, and subject to, Section 4.6, and (iii) the Manufacturing of Collaboration Products for Development in the Field in the Licensed Territory in accordance with, and subject to, Article IX and the Supply Agreement and (b) Licensee shall be responsible for and shall have discretion with respect to all other activities in respect of the Collaboration Products pursuant to this Agreement, including all Commercialization activities with respect to the Collaboration Products in the Licensed Territory in accordance with, and subject to, Article V.

I.4 Cost of Governance. The Parties agree that the costs incurred by each Party in connection with its participation at any meetings under this Article III shall be borne solely by such Party and shall not be Allowable Expenses.

I.5 Senior Executive Meetings. From time to time, but in any event at least [***] per Calendar Year, the [***] of Seres and the Nestlé Health Science Unit shall meet (by telephone, video-conference or in person as determined by [***]) to discuss the status of activities conducted pursuant to this Agreement, including any issues relating to the Development or Commercialization of Collaboration Products in the Field in the Licensed Territory, and provide feedback on any issues raised during such discussions.

I.6 **Dissolution of Committees**. Upon the [***] of the Effective Date, or such earlier date that the Parties mutually agree in writing, all Committees shall automatically disband. Upon the disbanding of a Committee, such Committee shall have no further obligations under this Agreement and, thereafter, the Alliance Managers shall be the contact persons for the exchange of information under this Agreement, and decisions of such Committee shall be made by (a) Seres with respect to (i) all Development activities for Collaboration Products in the Field in the Licensed Territory in accordance with, and subject to, Sections 4.1, 4.3, 4.4 and 4.5, (ii) all Regulatory Filings for Collaboration Products in the Field in the Licensed Territory in accordance with, and subject to, Section 4.6, and (iii) the Manufacturing of Collaboration Products for Development in the Field in the Licensed Territory in accordance with, and subject to, Article IX and the Supply Agreement or (b) Licensee with respect to all other activities in respect of the Collaboration Products pursuant to this Agreement, including all Commercialization activities with respect to the Collaboration Products in the Licensed Territory in accordance with, and subject to, Article V and the other terms and conditions of this Agreement.

ARTICLE IV
DEVELOPMENT AND REGULATORY ACTIVITIES

IV.1 Current Development.

(a) Ongoing Clinical Studies. Seres shall remain responsible for and shall complete at its sole cost all ongoing Clinical Studies as of the Effective Date in the Licensed Territory, as listed in the initial Development and Regulatory Activity Plan attached to this Agreement as Exhibit C (each, an "**Ongoing Clinical Study**"), including preparing all analysis and reports therefor, to support Regulatory Approval of SER-109 in the Licensed Territory for the treatment of rCDI, and shall remain responsible for contracting with and managing any Third Party independent contractor performing activities in connection with such Clinical Studies. For the sake of clarity, no costs incurred by Seres in performing its obligations under this Section 4.1(a) shall constitute Allowable Expenses.

(b) Post-Approval Studies for First Regulatory Approval. Seres shall be responsible for and shall complete any Post-Approval Study for the first Regulatory Approval of SER-109 in the Field in the United States, and shall pay and be solely responsible for the Post-Approval Study Costs therefor. For clarity, no costs incurred by Seres in performing its obligations under this Section 4.1(b) shall constitute Allowable Expenses.

IV.2 Rights of Reference and Data Access. Subject to any applicable reimbursement of costs in Section 4.4(e) below, Licensee shall have the right to cross-reference the Regulatory Filings Controlled by Seres during the Term for Collaboration Products, and to access such Regulatory Filings and any Data to the extent such cross-reference and access is required by applicable Law or reasonably useful for the performance of its obligations and exercise of its rights under this Agreement. Subject to any applicable reimbursement of costs in Section 4.4(e) below, Seres hereby grants to Licensee, its Affiliates and sublicensees, a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) in the United States, or an equivalent right of access/reference in any other country or region, to any Data, including Seres' or its Affiliate's clinical dossiers, Controlled by Seres or such Affiliate for Collaboration Products for the sole purpose of the performance of its obligations and exercise of its rights under this Agreement,

subject to the limitations set forth in this Section 4.2. Upon written request by Licensee, Seres or its Affiliate shall provide a signed statement to this effect, in accordance with 21 C.F.R. § 314.50(g)(3) or the equivalent as required in any country or region or otherwise provide appropriate notification of such right of reference of Licensee to the applicable Regulatory Authority. Seres will cooperate, and cause its Affiliates to cooperate, with Licensee to effect the foregoing. For clarity, nothing contained in this Section 4.2 shall limit any right of reference in respect of, or right to use or access, any Regulatory Filings or Data Licensee and its Affiliates have pursuant to the Existing Agreement.

IV.3 Seres Development Obligations.

(a) Without limiting Section 4.2, Seres shall use Commercially Reasonable Efforts to complete all Development activities in respect of SER-109 as set forth in the initial Development and Regulatory Activity Plan attached to this Agreement as Exhibit C, as may be required to obtain the first Regulatory Approval of SER-109 in the Field in the United States, and any Post-Approval Studies for which Seres is responsible pursuant to Section 4.1(b); provided that the foregoing shall not require Seres to conduct any pre-approval Phase III Clinical Studies not contemplated by the initial Development and Regulatory Activity Plan. If the FDA (x) requires the conduct of such a pre-approval Phase III Clinical Study prior to the grant of such first Regulatory Approval or (y) does not grant Regulatory Approval for SER-109 within the period of [***] following the initial submission by Seres of a Regulatory Filing seeking such first Regulatory Approval as set forth in the initial Development and Regulatory Activity Plan, then: (i) Seres shall notify Licensee thereof, and for [***] thereafter, which period may be extended by mutual agreement of the Parties, the Parties shall discuss and attempt in good faith to agree on each Party's responsibilities for the conduct of additional Clinical Study(ies) for SER-109 and any other modifications to the initial Development and Regulatory Activity Plan, provided that the funding for any such additional Clinical Study(ies) shall be borne [***] by Seres and [***] by Licensee, and (ii) [***]. For clarity, (1) Seres shall not have any obligations to use Commercially Reasonable Efforts to make Regulatory Filings for Collaboration Products in Canada, unless and until the Parties mutually agree in writing to conduct specified regulatory activities for Collaboration Products in Canada, and (2) Seres shall not have any obligations to conduct Clinical Studies of Collaboration Products in Canada unless and until the Parties mutually agree in writing to conduct specified Clinical Study(ies) for Collaboration Products in Canada. Subject to the foregoing and the remaining provisions of this Article IV, Seres shall be responsible for all Development activities for Collaboration Products in the Field in the United States [***], subject to Section 4.4 with respect to Life Cycle Management Costs, in accordance with the Development and Regulatory Activity Plan.

(b) The initial Development and Regulatory Activity Plan sets forth the Development activities to be conducted for SER-109 in the Field in the United States until the first Regulatory Approval for SER-109 is obtained in the Field in the United States. In addition to any Clinical Studies governed by Section 4.1(b) or Section 4.3(a), either Party may propose for review by the JDC an amendment to the Development and Regulatory Activity Plan to include any additional Development activities to be conducted by Seres in the Field in the Licensed Territory. Each Party shall reasonably consider and comment on any such proposal, [***]. The Development and Regulatory Activity Plan, as amended from time to time, will clearly identify the Collaboration Products covered thereby (including any required or anticipated label elements) and shall include,

to the extent available, details of: [***]. If the terms of the Development and Regulatory Activity Plan contradict, or create inconsistencies or ambiguities with, the terms of this Agreement or the Existing Agreement, then the terms of this Agreement or the Existing Agreement, as applicable, shall govern.

IV.4 Life Cycle Management. The Parties acknowledge and agree that, as of the Effective Date, the Parties intend to Develop SER-109 in the United States under this Agreement for the treatment of patients with rCDI and associated complications as the first indication. In accordance with Sections 3.2(b)(vi) and 3.2(c)(i), the JDC and JCC shall develop Life Cycle Management strategies and a Life Cycle Management plan for Collaboration Products under this Agreement addressing [***] and, if the Parties mutually agree in writing to conduct Clinical Study(ies) or make Regulatory Filings for Collaboration Products in Canada, for Canada, for a Collaboration Product. If the JSC approves a given Life Cycle Management plan recommended by the JDC and JCC, then the Development and Regulatory Activity Plan shall be amended by the JDC to include such activity, and the agreed upon Life Cycle Management Costs thereof shall be specified therein. If any such approved Life Cycle Management activities are to be conducted by Licensee, then Licensee shall use Commercially Reasonable Efforts to complete all such activities as set forth in the Development and Regulatory Activity Plan. Notwithstanding the foregoing, if the JSC does not approve the conduct of Life Cycle Management activities proposed by a Party (the "**Proposing Party**") pertaining to Development of Collaboration Products to include [***], then (i) with respect to pre-clinical Development, the Proposing Party shall have the right to conduct any such pre-clinical Development at its sole cost and at its discretion (and for clarity an amendment to the Development and Regulatory Activity Plan shall not be needed), and (ii) with respect to clinical Development, the process set forth in Sections 4.4(a)-(e) for Additional Clinical Studies shall apply. If any Regulatory Filings for Collaboration Product in the Licensed Territory contain Data from pre-clinical Development activities conducted solely by a Proposing Party at the Proposing Party's expense pursuant to clause (i) of the immediately preceding sentence as the basis for the grant of a new or expanded Regulatory Approval for Collaboration Products in the Licensed Territory, then the other Party shall reimburse the Proposing Party for [***]. Notwithstanding anything to the contrary in the foregoing, with respect to any Clinical Study, other than a Post-Approval Study, of Collaboration Products for use in the treatment of a primary CDI or rCDI or associated complications in the Licensed Territory that either Party proposes for Seres to perform as a sponsor (any such Clinical Study, an "**Additional Clinical Study**"):

(a) The Proposing Party shall provide the JDC an opportunity to review and approve a proposed study protocol and related budget to such protocol (together, the "**Protocol**"). The JDC shall, as soon as reasonably practicable, recommend to the JSC whether to approve the Additional Clinical Study that is the subject of such Protocol.

(b) [***] after receipt by the JDC of the Protocol, the JSC shall determine whether to approve such Additional Clinical Study and the budget therefor. For clarity, the JSC may approve such Additional Clinical Study sooner than [***].

(c) In the event the JSC approves the Additional Clinical Study, and the budget therefor, then such Additional Clinical Study will be designated as a shared Clinical Study (the "**Shared Clinical Study**" and such budget therefor, the "**Shared Clinical Study Budget**"), and the Shared Clinical Study Costs incurred in accordance with the Shared Clinical Study Budget

shall be included in [***]. The initial Shared Clinical Study Budget shall be updated by the JDC from time to time for approval by the JSC to incorporate changes thereto as a result of [***] negotiations with Third Party vendors, consultants, suppliers and contractors for services and materials relating to the Shared Clinical Study. [***] shall select such Third Party vendors, consultants, suppliers and contractors [***], and as between the Parties, [***].

(d) If the JSC does not approve the Additional Clinical Study as a Shared Clinical Study, either expressly or by failing to provide written notice of approval to the Parties within the [***] period set forth in Section 4.4(b), the Proposing Party shall be free to conduct such Additional Clinical Study at its sole discretion, cost and expense (and for clarity an amendment to the Development and Regulatory Activity Plan shall not be needed), by itself or with or through a Third Party contractor within the Licensed Territory. If [***] elects to conduct an Additional Clinical Study pursuant to this Section 4.4(d), [***]. The Proposing Party shall select such Third Party vendors, consultants, suppliers and contractors at its sole discretion, and as between the Parties, [***]. For clarity, any proposed Additional Clinical Study shall be performed by [***] unless the JSC does not approve such Additional Clinical Study as a Shared Clinical Study, in which case [***] shall have the right to perform such Additional Clinical Study in accordance with this Section 4.4(d) if [***] is the Proposing Party therefor.

(e) If a Proposing Party conducts an Additional Clinical Study at its expense pursuant to Section 4.4(d), above, then if any Regulatory Filings for Collaboration Product in the Licensed Territory contain Data from such Additional Clinical Study as the basis for the grant of a new or expanded Regulatory Approval for Collaboration Products in the Licensed Territory, the other Party shall reimburse the Proposing Party for [***].

IV.5 Development Efforts; Manner of Performance; Reports.

(a) Development Efforts; Development Records. The Party conducting, or whose Affiliate or Third Party subcontractor is conducting, any Development activities for Collaboration Products in the Field in the Licensed Territory shall ensure that such Development activities are conducted in good scientific manner and in compliance with applicable Laws, including Good Manufacturing Practices, Good Laboratory Practices and Good Clinical Practices, current standards for pharmacovigilance practice, and all applicable requirements relating to the protection of human subjects. Such Party shall maintain, and require its Affiliates and Third Party subcontractors to maintain, records of its Development activities of Collaboration Products in the Field in the Licensed Territory conducted pursuant to this Agreement in sufficient detail and in good scientific manner as will properly reflect all work done and results achieved by or on behalf of Seres in the performance of the Development activities.

(b) Development Reports. At each meeting of the JDC, each Party will report on Development activities conducted with respect to the Collaboration Products in the Field in the Licensed Territory performed or caused to be performed by or on behalf of such Party or its Affiliates since the last meeting of the JDC, and provide such other information as may be reasonably requested by the JDC with respect to such Development activities. Without limiting the foregoing, each Party, to the extent it is conducting Development activities hereunder, shall provide a written report to the JDC every [***] commencing with the [***], which reports shall include, to the extent available, a summary of such Party’s progress in performing its obligations

under the Development and Regulatory Activity Plan and activities accomplished by such Party in relation thereto since the prior report, including, to the extent applicable, a summary of significant results, adverse event reports, information and Data generated, Manufacturing developments, significant challenges anticipated and updates regarding significant intellectual property and supply chain matters, with respect to each Collaboration Product in the Field. The Parties will agree on an appropriate format for such written reports, which may consist of a compilation of separate subject matter reports (or excerpts therefrom) that are generated in the ordinary course by or on behalf of the Party responsible for the relevant Development activities.

IV.6 Regulatory Matters.

(a) Ownership of and Responsibility for Regulatory Filings. Unless otherwise agreed by the Parties in writing and except for Regulatory Filings contemplated by Section 5.6(a), Seres or its Affiliates shall at all times during the Term own and maintain all Regulatory Filings for Collaboration Products in the Field in the Licensed Territory. Subject to Sections 4.6(b) and 5.6(a), Seres or its Affiliates shall have the responsibility for all regulatory affairs related to Collaboration Products in the Field in the Licensed Territory, including the preparation and filing of Regulatory Filings and maintenance of Regulatory Approvals in the Field in the Licensed Territory and the payment of fees payable to Regulatory Authorities, at its sole cost, subject to the rest of this Section 4.6(a) with respect to Regulatory Expenses for Life Cycle Management activities. With respect to regulatory activities for Collaboration Products in the Field in the Licensed Territory, including the preparation and submission of Regulatory Filings and maintenance of Regulatory Approvals, (i) that are approved by the JSC pursuant to the Life Cycle Management plan for Collaboration Products under Section 4.4, the Regulatory Expenses incurred therefor are Life Cycle Management Costs and included in Allowable Expenses, or (ii) that are not approved by the JSC as Life Cycle Management activities but are related to an Additional Clinical Study conducted independently by the Proposing Party under Section 4.4(d), if any Regulatory Filings for Collaboration Product in the Licensed Territory contain Data from an Additional Clinical Study conducted solely by the Proposing Party at its expense as the basis for the grant of a new or expanded Regulatory Approval for Collaboration Products in the Licensed Territory, then the other Party shall reimburse the Proposing Party for [***] of the Regulatory Expenses incurred in the conduct of such regulatory activity. Notwithstanding the foregoing, to the extent that Licensee independently undertakes Life Cycle Management activities pursuant to Section 4.4(d), Seres shall undertake regulatory activities in connection with such Life Cycle Management activities, including the preparation and submission of Regulatory Filings and maintenance of Regulatory Approvals, on behalf of Licensee solely at Licensee's direction and cost (but subject to reimbursement pursuant to the immediately preceding sentence and Section 4.4).

(b) Regulatory Cooperation. The JDC shall discuss the overall regulatory strategy and positioning for Collaboration Products in the Licensed Territory. In connection with such discussion, Seres shall discuss with the JDC proposed Regulatory Filings and provide to the JDC [***]. Seres shall provide to Licensee, not later than [***] prior to submission (or as early as practicable of an earlier submission is required by Law or the applicable Regulatory Authority), [***], and Licensee may [***]. Anything to the contrary notwithstanding, any proposal in any Regulatory Filing relating to [***]. Each Party shall provide to the other Party [***]. If Licensee is required to respond to any [***]. In connection with Seres (i) conducting the Ongoing Clinical Studies; any Post-Approval Studies to be performed in accordance with Section 4.1(b); [***]; and

any Shared Clinical Studies to be performed pursuant to Section 4.4, (ii) communicating with Regulatory Authorities regarding the Collaboration Products, and (iii) making Regulatory Filings and seeking and maintaining Regulatory Approvals for the Collaboration Products, in each case, [***].

(c) Communications and Participation in Meetings with Regulatory Authorities. Except with respect to Commercialization activities or as otherwise may be required by applicable Law, as between the Parties, Seres will be the sole contact with the applicable Regulatory Authorities and will be solely responsible for all communications with such Regulatory Authorities concerning Regulatory Filings and Regulatory Approvals relating to Collaboration Products in the Licensed Territory. Except with respect to Commercialization activities or as otherwise may be required by applicable Law, [***]. Notwithstanding the foregoing, to the extent that Licensee independently undertakes Life Cycle Management activities pursuant to Section 4.4(d), [***] shall undertake communications with Regulatory Authorities relating to such Life Management Activities [***]. Seres shall provide Licensee with notice of all [***] concerning Regulatory Filings and/or Regulatory Approvals relating to Collaboration Products in the Licensed Territory [***], and in any event within [***], after such Party [***]. At all such [***], Licensee shall have the right to [***] by the applicable Regulatory Authority. Subject to the foregoing, Seres, [***], except with respect to [***], shall [***] with the relevant Regulatory Authority. In the case of [***], [***] shall determine [***], subject to the requirements of the applicable Regulatory Authority. However, if attendance at any [***] with a Regulatory Authority is [***], attendance shall be based on [***] Collaboration Product; provided that to the extent permitted by such Regulatory Authority, each Party shall be entitled to [***] at any such [***], and further provided that [***]. If for any reason, Licensee is unable to attend any [***], Seres shall provide Licensee with [***].

IV.7 Product Queries and Complaints; Safety Issues.

(a) Each Party shall maintain a record of all medical and technical Collaboration Product-related queries and complaints, as well as adverse event reports, it receives with respect to the Collaboration Products in the Licensed Territory. Each Party shall promptly notify the other Party of any such query, complaint or adverse event received by it in sufficient detail and in accordance with the timeframes and procedures for reporting to be established by the Parties in writing. [***] shall be responsible for investigating such technical Collaboration Product queries, complaints and adverse events and, following such investigation, the appropriate Party shall respond to such queries, complaints or adverse events.

(b) During the period prior to the grant of the first Regulatory Approval by the FDA for the first Collaboration Product, [***], shall be responsible for maintaining the global safety database in respect of each Collaboration Product (each, a "**Global Safety Database**").

(c) Notwithstanding anything to the contrary contemplated by Section 7.4 of the Existing Agreement, which the Parties expressly agree shall be modified by this Section 4.7(c), at least [***] prior to [***], the Parties shall enter into a pharmacovigilance agreement (the "**Pharmacovigilance Agreement**"), which shall provide that [***], and shall also delineate the specific rights and responsibilities of each Party with respect to the collection, management and

the exchange of safety information for the Collaboration Products. The Parties acknowledge and agree that such delineation shall leverage [***].

(d) [***] shall be responsible for, and shall have discretion with respect to, the implementation of any risk evaluation and mitigation strategy that is implemented as a commitment to a Regulatory Authority as a condition of, or in connection with obtaining or maintaining, a Regulatory Approval.

IV.8 Recalls. To the extent that: (a) any Regulatory Authority in the Licensed Territory issues a directive or order that any Collaboration Product be recalled or withdrawn in the Licensed Territory; (b) a court of competent jurisdiction orders a recall or withdrawal of any Collaboration Product in the Licensed Territory; or (c) either Party determines any Collaboration Product should be recalled or withdrawn voluntarily in the Licensed Territory, the Party first learning of such matter or making such determination will so notify the other Party in writing. Upon a required recall or withdrawal of any Collaboration Product in the Licensed Territory in accordance with the foregoing, or upon a voluntary recall or withdrawal of any Collaboration Product in the Licensed Territory determined to be conducted by a Party, [***] will have the right to conduct any such recall or withdrawal of such Collaboration Product and [***] shall [***].

IV.9 **Combination Products.** Either Party may propose for approval by the JSC the Development or Commercialization of a Combination Product for a particular country in the Licensed Territory. If such Development or Commercialization is approved by the JSC, then prior to commencing Development or Commercialization activities for such Combination Product in such country, the Parties shall agree in writing to an equitable adjustment to the Net Sales definition for such Combination Product to reflect the value of the Collaboration Product contained in such Combination Product relative to such Combination Product as a whole.

ARTICLE V
COMMERCIALIZATION

V.1 Commercialization Plans and Budgets.

(a) Attached hereto as Exhibit D is a plan setting forth the activities to be completed in furtherance of preparing for Commercialization of SER-109 in the United States (the "**Pre-Launch Plan**"). Each Party shall use Commercially Reasonable Efforts to carry out its activities in the Pre-Launch Plan in accordance with the Pre-Launch Plan, which activities shall be conducted at Seres' sole cost and expense, subject to the Pre-Launch Cap in Section 7.4(a). For the sake of clarity, no costs and expenses of Seres in carrying out activities contemplated in the Pre-Launch Plan shall constitute Allowable Expenses and, to the extent applicable, Seres shall reimburse Licensee for the costs and expenses incurred by Licensee and its Affiliates in carrying out any activities contemplated in the Pre-Launch Plan to be conducted by Licensee or any of its Affiliates, subject to the Pre-Launch Cap in Section 7.4(a).

(b) The Parties, through the JCC, will collaborate to develop the Commercialization strategy for Collaboration Products and Commercialize Collaboration Products in the United States and, if the Parties have mutually agreed in writing to Develop and Commercialize Collaboration Products in Canada, Canada, in accordance with the applicable

Commercialization Plan and Budget. In accordance with timing to be set by the JCC, Licensee shall prepare and send to the JCC for review a Commercialization Plan and Budget for each Collaboration Product. The initial Commercialization Plan and Budget for SER-109 shall be based on the high level, launch plan and budget that is attached to this Agreement as Exhibit E.

(c) Each Commercialization Plan and Budget shall contain, to the extent reasonably determinable [***]. Each Commercialization Plan and Budget shall be updated from time to time as agreed by the JCC, but in any event at least [***]. Either Party may propose an amendment to a Commercialization Plan and Budget for the JCC's review as set forth in Section 3.2(c)(ii).

(d) The internal costs contemplated for each Party in the budget comprising each Commercialization Plan and Budget shall be determined in accordance with the FTE Costs corresponding to the applicable activities.

V.2 Commercialization in the Licensed Territory. Subject to Seres' rights in this Article V, Licensee shall have the sole right to Commercialize the Collaboration Products in the Licensed Territory in accordance with the Commercialization Plan and Budget in effect from time to time and in accordance with the applicable Regulatory Approvals. Each Party shall, itself or through its Affiliates, licensees or Sublicensees, use Commercially Reasonable Efforts to Commercialize the Collaboration Products in the Licensed Territory in accordance with the then-applicable Commercialization Plan and Budget and in accordance with the applicable Regulatory Approvals. For clarity, neither Party shall have any obligations to use Commercially Reasonable Efforts to Commercialize Collaboration Products in Canada, unless and until the Parties mutually agree in writing to Develop and Commercialize Collaboration Products in Canada pursuant to Section 5.1(b). Each Party shall use Commercially Reasonable Efforts to perform any and all of its Commercialization activities with respect to each Collaboration Product that are assigned to it under the applicable Commercialization Plan and Budget, in good scientific manner and in compliance with all applicable Laws and Licensee's and its Affiliates' internal policies and procedures applicable to such Commercialization activities (of which Licensee shall advise Seres in writing), provided that Seres shall not be required to comply with such internal policies and procedures of Licensee if doing so would be reasonably expected to result in a failure to comply with applicable Law or ethics rules to which Seres is bound to comply. In allocating the responsibilities among the Parties in relation to the Commercialization of Collaboration Products, the Parties shall endeavor to leverage the use of the existing infrastructure and systems of the Parties in order to minimize the costs associated therewith.

V.3 Updates on Activities in the Licensed Territory. At each meeting of the JCC, each Party will share with the JCC a summary regarding the material activities conducted by or on behalf of such Party under each Commercialization Plan and Budget since the last JCC meeting. Each Party will also promptly provide notice to the other Party, through the JCC, of any significant Commercialization events under any Commercialization Plan and Budget that the reporting Party reasonably believes materially impacts the Commercialization activities of the other Party under such Commercialization Plan and Budget or otherwise under this Agreement. In addition to updates provided at JCC meetings, each Party will share updates to the other Party regarding Commercialization activities conducted by or on behalf of such Party in between JCC meetings, as reasonably requested by the other Party.

V.4 Booking of Sales; Sales and Distribution in Licensed Territory. Licensee shall book all revenues from sales of Collaboration Products in the Licensed Territory. Licensee shall also be responsible for warehousing and distributing all the Collaboration Products in the Licensed Territory and shall perform related distribution activities directly or through its local Affiliates where appropriate or through a distributor. Licensee shall be responsible for maintaining and, if applicable, creating or obtaining, the infrastructure necessary therefor. Licensee shall also be responsible for handling all returns, [***], order processing, invoicing and collection, and receivables with respect to Collaboration Products in the Licensed Territory. Licensee shall share with Seres on [***] basis informal reports on Net Sales and channel data as shall be agreed by the Parties, generated from booking sales of and warehousing and distributing Collaboration Products in the Licensed Territory; provided, that Licensee shall be under no obligation to create any such data that it does not otherwise generate in its ordinary course operations or organize or compile such data in any manner other than that which it organizes or compiles such data in its ordinary course operations.

V.5 Promotion in Licensed Territory.

(a) Each Commercialization Plan and Budget shall include the activities to be undertaken by Licensee and, if Seres elects to provide Details in accordance with Section 5.5(b), by Seres, with respect to promoting Collaboration Products in the United States and, if the Parties mutually agree in writing to Develop and Commercialize Collaboration Products in Canada, Canada, including the following matters, in each case, as applicable and agreed by the JCC and, in the case of the initial Commercialization Plan and Budget, consistent with Exhibit E hereto:

(i) the strategy and objectives of the Parties with respect to [***] the Collaboration Products for the Licensed Territory, including a [***];

(ii) [***], including the [***] to perform [***] for Collaboration Products, in the Licensed Territory in the Field;

(iii) designation of the [***];

(iv) [***] for such [***] during each [***] covered by the applicable [***];

(v) the conduct of [***] in the Licensed Territory, including the conduct of an [***];

(vi) the development of and updates to an [***] for the Licensed Territory;

(vii) [***] to be acquired and the acquisition of [***] for the Licensed Territory;

(viii) [***] strategies for the [***] with [***] and other applicable [***];

(ix) [***];

(x) other Market Access strategy and plans; and

(xi) [***] for the Collaboration Products.

For clarity, the activities in Section 5.5(a)(i)-(xi) for a Collaboration Product shall be included in the Commercialization Plan and Budget for such Collaboration Product to the extent agreed by the JCC and, in the case of the initial Commercialization Plan and Budget, consistent with Exhibit E.

(b) The Parties acknowledge and agree that, as of the Effective Date, the Parties intend that Licensee shall be responsible for performing all promotion activities and providing all Details for Collaboration Products in the Licensed Territory. At any time [***], Seres shall have the right to elect to provide up to [***] of all Details focused on [***]. If Seres elects to provide Details in accordance with the immediately preceding sentence, then the Commercialization Plan and Budget for such Collaboration Product shall be amended to include Seres' provision of Details for Collaboration Products in such country. If Seres makes the election to provide Details in accordance with the foregoing, but desires to provide more than [***] of all Details in [***] for a Collaboration Product, then the specific percentage of Details to be provided by Seres, if it makes such request shall be determined by the JCC, but for clarity, in no event shall the percentage Seres is entitled to provide be less than [***]. Licensee and, if Seres elects to provide Details, Seres, shall be responsible for performing Details allocated to such Party in accordance with the Commercialization Plan and Budget for a Collaboration Product. The Parties acknowledge that, at any given time, each Party may not necessarily have an equal role in promotion activities under this Agreement (for example, each Party may not provide an equal number of Sales Representatives who will Detail Collaboration Products in a country in the Licensed Territory). The Parties agree that the allocation of responsibility for calling on members of the Target Audience by the personnel performing Detailing activities shall take into account the existing resources of Licensee and shall seek to leverage those resources to the maximum extent practicable while still maintaining Seres' right to provide Details in accordance with this Section 5.5(b), if it makes the election to do so. During the first [***] following the First Commercial Sale of each Collaboration Product in the Licensed Territory, the Commercialization Plan and Budget for such Collaboration Product shall specify that no less than [***] of all Details for such Collaboration Product shall be either Exclusive Details or Primary Position Details.

(c) Licensee and, if Seres elects to provide Details in accordance with Section 5.5(b), Seres, shall perform its promotion obligations under each Commercialization Plan and Budget through Sales Representatives and other personnel under the direct and exclusive authority, supervision and control of such Party. A Party's Sales Representatives and other personnel performing activities under the Commercialization Plan and Budget shall (i) not be debarred by a relevant Regulatory Authority, (ii) pass all relevant background checks required by such Party's policies and procedures, and (iii) possess and maintain any required licenses, permissions or certifications required to Detail Collaboration Products to the Target Audience that he or she is expected to Detail, or perform other activities under the Commercialization Plan and Budget that such personnel is expected to perform. Each Party shall be solely responsible for any compensation that is payable to its Sales Representatives promoting Collaboration Products hereunder and its other personnel performing activities under the Commercialization Plan and Budget. Each Party agrees to include the Collaboration Products in its incentive compensation programs for its Sales Representatives in a manner reflecting the relative Detail position (e.g. Exclusive Details would receive the highest incentive compensation, Primary Position Details would receive the next

highest incentive compensation, and Secondary Position Details would receive lower incentive compensation). Each Party will hire and maintain a sufficient number of Sales Representatives and other personnel with appropriate expertise to permit such Party to perform fully the activities allocated to it for the Licensed Territory under this Section 5.5 and each applicable Commercialization Plan and Budget, in accordance with the job descriptions and time periods for hiring Sales Representatives and other personnel as set forth in the applicable Commercialization Plan and Budget. Compliance with such criteria will be monitored by the JCC pursuant to Section 3.2(c)(iv), including a determination of whether a Party has performed the required number of Details set forth in the applicable Commercialization Plan and Budget in each Calendar Quarter (the "**Target Level**"). If either Party fails at any time to meet the Target Level set forth in a Commercialization Plan and Budget (the percent of the Target Level number of Details that a Party has failed to provide, a "**Shortfall**"), then such Party shall, [***]. If the defaulting Party disputes whether a Shortfall has occurred, it may submit such dispute to the JCC for resolution.

(d) If Licensee or, if Seres elects to provide Details in accordance with Section 5.5(b), Seres, desires to provide a greater number of Sales Representatives or other personnel to perform activities under a Commercialization Plan and Budget, or anticipates that the actual costs to perform activities set forth in a Commercialization Plan and Budget will exceed the applicable portion of the relevant Commercialization Plan and Budget, then such Party shall so notify the JCC. The JCC shall discuss in good faith the reason(s) for such increase or excess and, following such discussion, the JCC shall determine whether to recommend to the JSC for approval an amendment to such Commercialization Plan and Budget to incorporate such increase or excess. If such increase or excess is approved by the JSC, then such Commercialization Plan and Budget shall be updated to reflect such increase or excess, and the costs attributable to such additional Sales Representatives or personnel, or otherwise in excess of such budget shall be included in Commercialization Costs. If the JSC does not approve such increase, then the costs attributable to such additional Sales Representatives or personnel, or otherwise in excess of such budget, shall not be included in Commercialization Costs, and such Party shall be solely responsible for any such increased or excess costs. Anything to the contrary notwithstanding, any increase in the relative number of Details to be performed by each Party, or to either Party's Sales Representatives' Target Audience shall only be made pursuant to an amendment to the then-current Commercialization Plan and Budget, approved in accordance with this Agreement.

(e) Following the First Commercial Sale, Licensee and, if Seres elects to provide Details in accordance with Section 5.5(b), Seres, shall provide to the other Party on a [***] basis a report of the number of aggregate Details (including the positions of such Details) and other material Commercialization efforts carried out by its Sales Representatives and personnel in each Calendar Quarter in the Licensed Territory. Each such report will be delivered no later than [***]. In furtherance thereof, each Party shall require its Sales Representatives and other personnel conducting Commercialization activities in the Licensed Territory to provide information on an ongoing basis in accordance with such Party's customer relationship management or other systems, including without limitation call activity and account profiling information.

(f) [***] of the FTE Costs and Out-of-Pocket Costs of conducting an Exclusive Detail shall be included in Commercialization Costs. [***] of the FTE Costs and Out-of-Pocket Costs of conducting a Primary Position Detail shall be included in Commercialization Costs. The FTE Costs and Out-of-Pocket Costs of conducting a Secondary Position Detail that are included

in Commercialization Costs for a given Collaboration Product shall be determined by the JCC and approved by the JSC, but shall not exceed [***] of such FTE Costs and Out-of-Pocket Costs . For sake of clarity, the foregoing shall apply to Details conducted by Licensee or Seres, except that, [***], (i) [***], and (ii) if, at the time [***], then [***] shall be included in Commercialization Costs. Notwithstanding anything to the contrary, with respect to any Details provided by a Party, Commercialization Costs and Allowable Expenses shall exclude any costs or expenses incurred by such Party or its Affiliates to establish or scale up such Party's or its Affiliates' infrastructure or capabilities to provide such Details if, at the time such establishment or scale-up costs and expenses are incurred, the other Party has the infrastructure and capabilities necessary to provide such Details.

(g) Except as permitted hereby below, Licensee may not use any contract sales organizations to promote a Collaboration Product during the first [***] following the First Commercial Sale of such Collaboration Product. Thereafter, Licensee may use any contract sales organizations approved by the JCC to promote such Collaboration Product after consultation with the JCC. If Seres elects to provide Details in accordance with Section 5.5(b), except as otherwise permitted below, Seres may not use any contract sales organizations to promote a Collaboration Product during the first [***] following the First Commercial Sale of such Collaboration Product. Thereafter, Seres may use any contract sales organizations approved by the JCC to promote such Collaboration Product after consultation with the JCC. Notwithstanding anything herein to the contrary, either Party shall have the right to use personnel from contract sales organizations on a temporary basis (without the approval of the JCC) in connection with the promotion of Collaboration Products as part of its process of identifying and recruiting personnel.

V.6 Promotional Materials.

(a) Licensee shall be responsible for the preparation of marketing, advertising and promotional core materials, training manuals and educational materials for Collaboration Product for use in the Licensed Territory, in accordance with the Commercialization Plan and Budget for such Collaboration Product. Such manuals and materials shall be consistent with the Parties' internal policies and procedures and applicable Law. Except with respect to the Product Trademarks, Licensee shall own all right, title and interest in and to all such manuals and materials and intellectual property rights therein. Licensee shall provide core promotional materials and manuals, as determined by the JCC, to Seres reasonably in advance of finalization thereof by Licensee, its Affiliates and Sublicensees, so that Seres has a reasonable period of time to review and provide comments thereon for consideration. Licensee shall consider in good faith any reasonable comments thereon provided by Seres. Licensee shall be responsible for any submissions to the applicable Regulatory Authorities of marketing, advertising or promotional materials that may be required under applicable Law and communications with such Regulatory Authorities in connection therewith. Seres shall provide to Licensee such assistance as Licensee may reasonably request in connection with such submissions and communications.

(b) All materials and other information used in connection with Commercialization activities in the Licensed Territory, including Collaboration Product labeling, package inserts and informational materials distributed for use in promoting Collaboration Products, oral presentations, direct-to-consumer advertising, patient information materials and patient benefit programs, that identify a Party in connection with a Collaboration Product, shall

display the Seres and Licensee Corporate Names with equal prominence, and shall identify both Parties as jointly promoting the Collaboration Product, in each case to the extent permitted by applicable Law.

(c) Each Party shall, and shall cause its Sales Representatives and other personnel performing Commercialization activities for Collaboration Products to, (i) use and distribute only the materials prepared in accordance with Section 5.6(a); and (ii) not modify, alter, amend, adjust or mask any portion of such materials in any way. Each Party will promptly notify the other Party and take all necessary corrective action in the event such Party learns that any such modification, alteration, amendment, adjustment or masking, or any such use or distribution of unapproved marketing materials for Collaboration Products has taken place by it or its Sales Representatives.

V.7 Training.

(a) Licensee shall be responsible for developing and conducting training programs and materials for the Parties' Sales Representatives in relation to the Commercialization of the Collaboration Products in the Licensed Territory. The Parties agree to make their Sales Representatives and other personnel available for training from time to time including in connection with the launch of a Collaboration Product in the Licensed Territory for each of the initial indication and any subsequent indications. Such training shall also include training regarding healthcare compliance topics.

(b) All Sales Representatives will be required to achieve the same certification standards related to Collaboration Product and clinical knowledge, as determined by Licensee, before initiating Detailing of the Collaboration Products in the Licensed Territory.

V.8 Pricing. The JSC shall set the pricing, discounting and rebating strategy for each Collaboration Product in the Licensed Territory, including wholesale acquisition cost, list price, targeted net pricing, sales-weighted average discounts and rebates. The JCC will oversee the implementation of such decisions regarding costs, pricing, discounts and rebates and determine the optimal distribution flow of the Collaboration Products in the Licensed Territory, including which wholesalers, distributors and specialty pharmacies are eligible to buy and handle the Collaboration Products in the Licensed Territory. Licensee shall enter into contracts for the Collaboration Products with wholesalers, distributors, group purchasing organizations, specialty pharmacies, managed care organizations, pharmacy benefit managers, Centers for Medicare and Medicaid Services, U.S. Department of Veterans Affairs, U.S. Department of Defense, integrated delivery networks, accountable care organizations, and other applicable healthcare organizations. Licensee shall negotiate pricing and discounting for such Collaboration Product in the Licensed Territory with such entities in consultation with the JCC, and in accordance with the JSC-approved pricing, discounting and rebating strategy for such Collaboration Product. For clarity, [***].

ARTICLE VI
MEDICAL AFFAIRS ACTIVITIES

VI.1 Medical Affairs Activities Plan and Budget. The Parties will perform Medical Affairs Activities for Collaboration Products that are in Phase II Clinical Studies or more advanced Development or Commercialization stages in the Licensed Territory in accordance with the

applicable Medical Affairs Plan and Budget. In accordance with timing to be set by the JMAC, Seres shall prepare and send to the JMAC for review a Medical Affairs Plan and Budget for each such Collaboration Product. Each Medical Affairs Plan and Budget shall contain [***]. Each Medical Affairs Plan and Budget shall be updated from time to time as agreed by the JMAC, but in any event at least [***]. Either Party may propose for review by the JMAC an amendment to the Medical Affairs Plan and Budget to include any additional Medical Affairs Activities to be conducted in the Field in the Licensed Territory, including the conduct of Phase IV Clinical Studies with respect to the indication for which a Collaboration Product is approved. The Parties acknowledge and agree that where Licensee has existing medical affairs infrastructure and capabilities, the Parties will discuss opportunities to use such existing infrastructure and capabilities in the performance of Medical Affairs Activities for Collaboration Products in the Licensed Territory, provided that such use shall not exclude Seres from performing Medical Affairs Activities for Collaboration Products in the Licensed Territory.

VI.2 Conduct of Activities in the Licensed Territory. Each Party shall, itself or through its Affiliates, undertake all Medical Affairs Activities in support of Collaboration Products in the Licensed Territory as set forth in the applicable Medical Affairs Plan and Budget from time to time. Without limiting the foregoing, each Party shall perform any and all of its Medical Affairs Activities with respect to each Collaboration Product that are assigned to it under the applicable Medical Affairs Plan and Budget in good scientific manner and in compliance with all applicable Laws. In addition, each Party will hire and maintain a sufficient number of Medical Liaisons with appropriate expertise to permit it to perform fully the activities allocated to it for the Licensed Territory under the applicable Medical Affairs Plan and Budget, in accordance with the job descriptions and time periods for hiring Medical Liaisons set forth therein. Compliance with such criteria will be monitored by the JMAC pursuant to Section 3.2(d)(ii).

VI.3 Updates on Activities in the Licensed Territory. At each meeting of the JMAC, each Party will share with the JMAC a summary regarding the material activities conducted by or on behalf of it under each Medical Affairs Plan and Budget since the last JMAC meeting.

ARTICLE VII
PAYMENTS

VII.1 License Fee. In partial consideration for the rights and licenses granted by Seres to Licensee hereunder, Licensee shall pay to Seres a license fee equal to One Hundred Seventy-Five Million Dollars ($175,000,000) within [***] following the Effective Date in accordance with the payment provisions of Article VIII. Payment made in accordance with this Section 7.1 shall be non-refundable, non-creditable and non-cancellable.

VII.2 Milestone Payments.

(a) Development Milestone Payments. In further consideration for the rights and licenses granted by Seres to Licensee hereunder, Licensee shall pay to Seres the following non-refundable, non-creditable milestone payments set out below following the first achievement by Licensee, and/or any of its Affiliates or Sublicensees, of the corresponding milestone events set out below, in accordance with this Section 7.2 and the payment provisions in Article VIII:

Milestone Event	Milestone Payment
First Regulatory Approval by the FDA for the first Collaboration Product	$125,000,000
First Regulatory Approval for the first Collaboration Product in Canada	$10,000,000

(b) Sales Milestone Payments. In further consideration for the rights and licenses granted by Seres to Licensee hereunder, Licensee shall pay to Seres the following non-refundable, non-creditable milestone payments set out below following the first time that the Net Sales of Collaboration Products in the Licensed Territory reach the following thresholds, in accordance with this Section 7.2 and the payment provisions in Article VIII:

Sales Milestone Events	Milestone Payment
First Calendar Year in which annual Net Sales of Collaboration Products in the Licensed Territory equal or exceed $250,000,000	$50,000,000
First Calendar Year in which annual Net Sales of Collaboration Products in the Licensed Territory equal or exceed $500,000,000	$75,000,000
First Calendar Year in which annual Net Sales of Collaboration Products in the Licensed Territory equal or exceed $750,000,000	$100,000,000

VII.3 Reports and Payments of Milestones.

(a) Promptly following the achievement of a milestone set out in Section 7.2(a), Seres shall notify Licensee in writing and issue an invoice to Licensee for the corresponding milestone payment.

(b) With respect to the achievement of any sales milestone set out in Section 7.2(b), within [***] in which such sales milestone is achieved, Licensee shall notify Seres in writing and Seres shall issue an invoice to Licensee for the corresponding milestone payment.

(c) Each milestone payment shall be due within [***] following Seres' delivery of an invoice therefor. For the avoidance of doubt, if more than one of the milestone events in Section 7.2 should occur in one and the same Calendar Year, each of the respective payments shall become due.

I.2 Royalties; Other Payments.

(a) During each Calendar Quarter of the Term following the First Commercial Sale of the first Collaboration Product, Licensee shall, within [***] of receipt from Seres of the report contemplated by Section 7.4(b), generate a report (the "**Quarterly Royalty Report**") that calculates the Royalty Base Amount, if any, for the applicable Calendar Quarter. Seres shall be entitled to receive a royalty from Licensee in an amount equal to fifty percent (50%) of the Royalty Base Amount, if any, for each Calendar Quarter (such amount being referred to as the "**Royalty Payment Amount**"), which shall be paid in accordance with Section 7.4(b)(iii) and (iv). Notwithstanding anything to the contrary herein, Seres shall be responsible for all costs and expenses incurred by the Parties and their Affiliates in the performance of their obligations

hereunder during the Pre-Launch Period in connection with the activities set forth in the Pre-Launch Plan and no such amount shall be taken into account in the calculations contemplated by this Section 7.4(a), except with respect to [***], which shall be included in [***], subject to Section 9.2; provided that the Commercialization Costs, the Medical Affairs Activities Costs and other costs and expenses (excluding Development costs and expenses) for which Seres shall be solely responsible pursuant to this sentence shall not exceed an aggregate amount of [***] ("**Pre-Launch Cap**"); [***]. Any such Commercialization Costs and Medical Affairs Activities Costs and other costs and expenses (excluding Development costs and expenses) exceeding in the aggregate the Pre-Launch Cap shall be included in [***] and taken into account in the calculations contemplated by this Section 7.4. To the extent applicable, Seres shall reimburse Licensee for any such costs and expenses of Licensee or its Affiliates promptly following receipt of an invoice therefor from Licensee as necessary to effectuate the foregoing.

(b) Calculation and Payment of Royalty Payment Amount and True-Up Amount.

(i) Following the First Commercial Sale of the first Collaboration Product, each Party shall report to the other Party, within [***] after the end of each Calendar Quarter, Net Sales, Other Income and Allowable Expenses received or incurred by such Party during such Calendar Quarter in the Licensed Territory and, as applicable, on a line item basis consistent with the budgetary line items set forth in the Commercialization Plan and Budget (except that the first such report shall report with respect to Allowable Expenses incurred from the Effective Date through the end of such Calendar Quarter). Such report shall specify in reasonable detail all deductions allowed in the calculation of such Net Sales and all expenses included in Allowable Expenses for such period. If requested by a Party, any invoices or other supporting documentation for any payments to a Third Party in respect of Allowable Expenses that individually exceed [***] dollars (or such other amount as may be specified by the JSC from time to time) shall be promptly provided not more than [***] after receipt of a request therefor. Each Party shall calculate, and maintain records of, Allowable Expenses incurred by it in accordance with GAAP and using its standard accounting procedures, consistently applied.

(ii) Within [***] after the end of each Calendar Quarter (commencing with the Calendar Quarter during which Allowable Expenses are first incurred), the Parties shall reconcile all Allowable Expenses, Net Sales and Other Income paid, incurred or received by the Parties and their Affiliates during such Calendar Quarter as follows:

(A) the aggregate Allowable Expenses incurred or paid by each Party and its Affiliates (such Party's "**Party Allowable Expenses**") for such Calendar Quarter shall be deducted from the sum of the aggregate of all Net Sales and Other Income received by such Party and its Affiliates (such Party's "**Receipts**") for such Calendar Quarter, with the difference being such Party's "**Party Net Amount**" for such Calendar Quarter (which Party Net Amount may be a positive or negative number) and the Party having the lower Party Net Amount for the applicable Calendar Quarter being the

"**Deficit Party**" for such Calendar Quarter and the Party having the higher Party Net Amount for the applicable Calendar Quarter being the "**Surplus Party**" for such Calendar Quarter; and

(B) the absolute value of the difference between the two Party Net Amounts for such Calendar Quarter shall be determined, with such amount, in dollars, being referred to as the "**True-Up Delta**" and the "**True-Up Amount**" for a particular Calendar Quarter being the amount equal to [***] of the True-Up Delta, subject to adjustment and payment in accordance with clause (v), below;

provided that, for the avoidance of doubt, consistent with Section 1.155, (A) income and withholding taxes imposed on either of the Parties or their Affiliates, (B) any payments made by Licensee to Seres pursuant to Section 7.1 or 7.2 and (C) indemnification payments by a Party to the other Party or to an Indemnitee hereunder or under the Supply Agreement, will not be included in the calculation of either Party's Party Allowable Expenses or Receipts for any Calendar Quarter.

(iii) Within [***] following the reconciliation set forth in Section 7.4(b)(ii), the Royalty Payment Amount and True-Up Amount for each Calendar Quarter shall be adjusted, and a corresponding payment made, as follows:

(A) If Licensee owes a Royalty Payment Amount for such Calendar Quarter and is the Surplus Party for such Calendar Quarter, then Licensee shall pay Seres such Royalty Payment Amount and, in addition to and concurrently therewith, shall pay Seres an amount equal to the difference of the True-Up Amount for such Calendar Quarter *minus* such Royalty Payment Amount;

(B) If Licensee owes a Royalty Payment Amount for such Calendar Quarter and is the Deficit Party for such Calendar Quarter, then (1) if the Royalty Payment Amount is greater than the True-Up Amount, Licensee shall pay to Seres an amount equal to such Royalty Payment Amount reduced by the True-Up Amount for such Calendar Quarter or (2) if such True-Up Amount exceeds such Royalty Payment Amount, Seres shall pay an amount equal to such excess to Licensee; and

(C) If no Royalty Payment Amount is owing for such Calendar Quarter, the Surplus Party shall pay an amount equal to the True-Up Amount for such Calendar Quarter to the Deficit Party.

(iv) Notwithstanding the foregoing, the Parties agree and acknowledge that certain elements of the Royalty Base Amount, Party Allowable Expenses and Receipts may be based on estimates during a Calendar Year (and as such, the foregoing amounts calculated on a quarterly basis are estimated amounts), and, as soon as reasonably practicable following the end of such Calendar Year, the Parties shall recalculate the Party Net Amounts as set forth in the foregoing provisions of

this Section 7.4(b) in order to take into account any changes to the estimates used to calculate the quarterly amounts. Thereafter, either Seres will make a payment to Licensee, or Licensee will make a payment to Seres, if and as necessary to ensure that each Party receives the amount to which it was entitled or pays the amount that it was required to pay, in each case, pursuant to Sections 7.4(a) and 7.4(b)(iii), as applicable, for such Calendar Year.

I.3 Third Party Licenses. If either Party, or any of its Affiliates or Sublicensees, determines in its good faith judgment that it is necessary during the Term to obtain a license to any Intellectual Property Right of a Third Party ("**Relevant Third Party Right**") in order to Exploit any Collaboration Product in the Licensed Territory, then such Party shall notify the other Party promptly upon such determination.

(a) [***] shall have the first right to negotiate the terms of a license under Relevant Third Party Rights for the Licensed Territory.

(b) If [***] does not exercise its first right under subsection (a), then [***] may do so.

(c) The terms of any such license shall permit the Party obtaining such license to grant to the other Party a sublicense thereunder to practice the same within the Licensed Territory. The negotiating Party shall keep the other Party updated with respect to its progress in negotiating and entering into such license and consider in good faith any comments of the other Party in connection therewith. For the avoidance of doubt, if such Third Party license agreement is entered into, then all Third Party payments due to such Third Party in the Licensed Territory [***] shall, if triggered by Commercialization of a Collaboration Product in the Licensed Territory, be included in the [***] for the Collaboration Product; provided that the [***] shall not exceed [***] (the "**Third Party License Payments Threshold**"). Any such Third Party payments exceeding the Third Party License Payments Threshold for the applicable Calendar Year shall be excluded from [***].

ARTICLE VIII
PAYMENTS; BOOKS AND RECORDS

VIII.1 Payment Terms. For clarity, any and all dollar amounts referred to in this Agreement shall mean U.S. dollars. Except as otherwise specifically provided in this Agreement, any and all payments due from one Party to the other pursuant to this Agreement shall be made in U.S. dollars by wire transfer of immediately available funds to such account or accounts and in accordance with such instructions as are provided by the payee Party from time to time. Conversion of Net Sales or reimbursable costs incurred hereunder that are recorded in local currencies to U.S. dollars by a Party, its Affiliates or its or their Sublicensees or licensees shall be at the rate of exchange as used by Seres or Licensee for its internal and external financial reporting.

VIII.2 Interest. Any amount required to be paid by a Party under this Agreement which is not paid on the date due shall bear interest at an annual rate equal to [***], as reported by The Wall Street Journal (New York edition) for the first Business Day of such month. Such interest shall be accrued daily.

VIII.3 **Taxes**.

(a) Each Party shall be entitled to deduct and withhold from any amounts payable under this Agreement such Taxes as are required to be deducted or withheld therefrom under any provision of applicable Law; provided, however, that notwithstanding anything to the contrary herein, absent a change in law after the Effective Date, [***]. The Party that is required by applicable Law to make such deduction or withholding shall deduct such amounts from such payment, promptly pay such amount on behalf of the other Party to the proper Governmental Authority, and promptly furnish the other Party with proof of payment on a timely basis following such payment.

(b) Notwithstanding the foregoing, if any Party (or its assignee pursuant to Section 18.8) required to make payments (the "**Paying Party**") to the other Party (the "**Payee Party**") [***].

(c) Each Party receiving payments under this Agreement shall provide to the other Party, at the time or times reasonably requested by such other Party or as required by applicable Law, such properly completed and duly executed documentation (for example, IRS Form W-9 or applicable Form W-8) as will permit payments made under this Agreement to be made without, or at a reduced rate of, withholding for Taxes.

(d) All payments between the Parties provided for in this Agreement are exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any such payments, the Paying Party shall pay such Indirect Taxes at the applicable rate in respect of any such payments following the receipt, where applicable, of an Indirect Taxes invoice issued by the Payee Party in respect of those payments. The Parties shall cooperate in good faith to minimize Indirect Taxes addressed in this Section 8.3 in accordance with applicable Law.

(e) [***].

VIII.4 Records; Audits.

(a) Each Party shall keep, and shall require its Affiliates and Sublicensees or licensees to keep, complete, true and accurate books of accounts and records for the purpose of determining the amounts payable pursuant to Article VII or confirming pursuant to Sections 4.4 and 4.6(a) any reimbursement of FTE Costs and Out-of-Pocket Costs. Such records shall be kept for the longer of (i) the period of time required by applicable Law in the Licensed Territory and (ii) [***] following the expiration or termination of this Agreement.

(b) Each Party shall have the right to examine and audit the other Party's and its Affiliates' and licensees' or Sublicensees' relevant books and records to verify the accuracy of any reports and payments prepared or delivered by the other Party pursuant to this Agreement. Any such audit shall be on at least [***] prior written notice, shall be limited to not more than [***], and shall be limited to the pertinent books and records for any Calendar Year ending not more than [***] before the date of the request. The audit shall be performed at the requesting Party's sole expense by an independent certified public accounting firm of internationally recognized standing that is selected by such requesting Party and reasonably acceptable to the other Party. The accounting firm shall be required to enter into a reasonable and customary confidentiality

agreement with the audited Party to protect the confidentiality of its books and records. The audited Party, its Affiliates and licensees or Sublicensees shall make the relevant books and records reasonably available during normal business hours for examination by the accounting firm. Except as may otherwise be agreed, the accounting firm shall be provided access to such books and records at the audited Party's and/or its Affiliates' or licensees' or Sublicensees' facilities where such books and records are normally kept. Upon completion of the audit, the accounting firm shall provide both Parties a written report disclosing whether or not the relevant reports or payments are correct, and the specific details concerning any discrepancies. The decision of the accounting firm shall be final and binding on the Parties absent manifest error. The accounting firm shall not provide to the requesting Party any additional information or access to the audited Party's or its Affiliates' or licensees' or Sublicensees' Confidential Information. If the accounting firm conducting an audit pursuant to this Section 8.4(b) concludes as a result of such audit that any additional amounts were due and payable to the requesting Party, such additional amounts shall be paid to such Party within thirty [***] of the date that the Parties receive such accountant's written report. In the event that the total amount of any underpayments by the audited Party to the requesting Party for the audited period exceeds [***] of the aggregate total amount that was properly due and payable to the requesting Party for the audited period, then the audited Party shall also reimburse the requesting Party for the documented, reasonable out of pocket Third Party expenses incurred in conducting the audit, except to the extent that such underpayment was due to any inaccurate or incomplete information provided to the audited Party by the requesting Party.

ARTICLE IX
PRODUCT MANUFACTURING AND SUPPLY

IX.1 Responsibility for Manufacturing and Supply for Development. Seres and/or its designated Affiliates shall be responsible for Manufacturing or having Manufactured, and for supplying or procuring supply of, Collaboration Products for Development in the Field in the Licensed Territory; provided that [***]. In connection therewith, promptly following the Effective Date, Seres shall prepare and send to the JSC for review and approval a budget for the Manufacturing activities to be conducted by Seres pursuant hereto and the Supply Agreement for the period ending on December 31 of the second Calendar Year following the Effective Date (a "**Manufacturing Budget**") for each Collaboration Product, which Manufacturing Budget Seres shall thereafter update and submit to the JSC for approval within [***] following the end of each subsequent Calendar Year. Without limiting the foregoing, Seres shall remain responsible for monitoring the performance of such Manufacturing activities by any Third Party contract manufacturers and shall use Commercially Reasonable Efforts to ensure such Third Party contract manufacturers comply with the terms of their agreements with Seres or its Affiliates. Seres shall not enter into any agreement with any Third Party contractors with respect to the Manufacturing or supply of a Collaboration Product in connection with this Agreement, or amend or modify the terms thereof, in any material respect, [***]. Notwithstanding the foregoing, if such agreements or amendments or modifications thereto relate to the Manufacturing or supply for the Licensed Territory of both a Collaboration Product and any other product of Seres not within the scope of this Agreement, then [***] shall not apply to any terms and conditions pertaining solely to such other product of Seres. [***].

IX.2 Commercial Supply Agreement. Subject to the terms and conditions of this Agreement, Seres shall supply, or secure the supply of, Licensee's requirements for Collaboration

Products for commercial purposes for the Licensed Territory and for the purposes of any Development activities Licensee undertakes in accordance with Section 4.4(d), in accordance with the Manufacturing Standards and the terms of this Agreement, pursuant to an arm's length supply agreement ("**Supply Agreement**") between the Parties or their respective Affiliates. The Parties shall enter into the Supply Agreement within [***] after the Effective Date. The Supply Agreement will include the terms set forth on Exhibit F and other customary terms and conditions for an agreement of a similar nature. Without limiting the foregoing, the Supply Agreement shall provide that the Collaboration Product supplied thereunder shall be supplied to Licensee at a price equal to Seres' Manufacturing Costs associated with the Collaboration Products supplied to Licensee under the Supply Agreement, *plus* a mark-up of [***] (such mark up [***], the "**Manufacturing Markup**" and such Manufacturing Markup *plus* Seres' Manufacturing Costs, the "**Supply Costs**"). Notwithstanding the foregoing, with respect to Collaboration Product Manufactured during the Pre-Launch Period for use in Commercialization activities after the Pre-Launch Period, (a) the Supply Costs therefor (the "**Pre-Launch Supply Costs**") for each such batch of such Collaboration Product shall be recalculated using Manufacturing Costs in an amount equal to [***], (b) [***] bear the portion of the Pre-Launch Supply Costs exceeding the updated Supply Costs as recalculated in (a), and (c) [***] for the excess portion in (b) no later than (i) the [***] of such date of receipt of first Regulatory Approval or (ii) [***] following the Pre-Launch Period, whichever is later. To implement the foregoing, the Parties will establish a mutually acceptable methodology, including periodic reconciliation processes to adjust the Supply Costs and, as needed, any related reconciliation of the Royalty Payment Amounts and True-Up Amounts to accommodate such adjustment to the Supply Costs.

IX.3 Quality Agreement. The Parties shall enter into a customary separate quality agreement ("**Quality Agreement**") governing quality matters in relation to the supply of the Collaboration Products by Seres to Licensee prior to any delivery of any Collaboration Product by Seres to Licensee.

IX.4 Compliance. Seres shall maintain in full force and effect all necessary licenses, permits and other authorizations required by applicable Law to carry out its Manufacturing and supply obligations under this Agreement.

ARTICLE X
CONFIDENTIALITY

X.1 Duty of Confidence. At all times during the Term and for a period of [***] thereafter, subject to the other provisions of this Article X:

(a) Without limiting the Parties' and their Affiliates' rights and obligations under the Existing Agreement, all Confidential Information of a Party (the "**Disclosing Party**") shall be maintained in confidence and otherwise safeguarded by the other Party (the "**Receiving Party**") and its Affiliates, and shall not be published or otherwise disclosed by the Receiving Party or its Affiliates to a Third Party except as expressly permitted by the terms of this Agreement or is necessary or reasonably useful for the performance of the Receiving Party's obligations or exercise of its rights under this Agreement. The terms of this Agreement shall be deemed to be the Confidential Information of both Parties (and both Parties shall be deemed to be the Receiving Party and the Disclosing Party with respect thereto).

(b) Without limiting the Parties' and their Affiliates' rights and obligations under the Existing Agreement, the Receiving Party may only use Confidential Information of the Disclosing Party for the purposes of performing its obligations or exercising its rights under this Agreement.

X.2 Exceptions. The obligations under Section 10.1 shall not apply to the extent that the Receiving Party can demonstrate that any information:

(a) is known by the Receiving Party at the time of its receipt without an obligation of confidentiality with respect to such information or any restriction on it use, and not through a prior disclosure by the Disclosing Party;

(b) is in the public domain before its receipt from the Disclosing Party, or thereafter enters the public domain through no fault of the Receiving Party;

(c) is subsequently disclosed to the Receiving Party or any of its Affiliates by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the Disclosing Party with respect to such information; or

(d) is developed by the Receiving Party or any of its Affiliates independently and without the use of, or reference to, any Confidential Information received from the Disclosing Party, and such independent development can be properly documented by the Receiving Party.

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party. Additionally, specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party.

X.3 Permitted Disclosures. Notwithstanding the obligations set forth in Section 10.1, a Party may disclose the other Party's Confidential Information (including this Agreement and the terms herein) to the extent:

(a) such disclosure: (1) is to a patent authority and is reasonably necessary for the filing, prosecuting, defending or enforcing Patent Rights as contemplated by, and in accordance with the terms of, Article XI, provided that reasonable measures shall be taken to assure confidential treatment of such Confidential Information to the extent practicable and consistent with applicable Law; or (2) is to a Regulatory Authority and is reasonably necessary in connection with Regulatory Filings for, the Development or Commercialization of, or the conduct of Medical Affairs Activities in respect of, Collaboration Products in the Field consistent with this Agreement, provided that reasonable measures shall be taken to assure confidential treatment of such Confidential Information to the extent practicable and consistent with applicable Law;

(b) such disclosure is reasonably necessary: (1) to its and its Affiliates', employees, contractors, consultants, advisors, clinicians, vendors, service providers and existing

or prospective Sublicensees and licensees in connection with the exercise of its rights or the performance of its obligations under this Agreement; (2) to such Party's directors, officers, attorneys, independent accountants or financial advisors for the sole purpose of enabling such directors, attorneys, independent accountants or financial advisors to provide advice to such Party relating to this Agreement; or (3) to actual or potential investors or acquirers of such Party solely for the purpose of evaluating or carrying out a bona fide investment in or acquisition of such Party; provided that in each case, (1), (2) and (3), such Person(s) to whom disclosure is made under this Section 10.3(b) shall be bound in writing prior to disclosure by confidentiality and non-use obligations substantially consistent with those contained in the Agreement (other than investors, who must be bound in writing prior to disclosure by commercially reasonable obligations of confidentiality and non-use); provided, further, that the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 10.3(b) to treat such Confidential Information as required under this Article 10;

(c) subject to Section 10.10, such disclosure is required by applicable Law, rules of a securities exchange or judicial or administrative process, if in the reasonable opinion of the Receiving Party's counsel, such disclosure is so required; provided that in such event such Party (to the extent legally permissible) shall promptly inform the other Party of such required disclosure and use reasonable efforts to provide the other Party an opportunity to challenge or limit the disclosure obligations; provided, further, that Confidential Information disclosed shall be limited to that information which is required under the relevant applicable Law, rule, judicial or administrative process or court or governmental order. Confidential Information that is so disclosed shall remain otherwise subject to the confidentiality and non-use provisions of this Article X, provided that the Party disclosing Confidential Information in such situation shall use reasonable efforts, including seeking confidential treatment or a protective order, to seek and obtain continued confidential treatment of such Confidential Information;

(d) is reasonably necessary for prosecuting or defending litigation or in establishing rights (whether through declaratory actions or other legal proceedings) or enforcing obligations under this Agreement;

(e) such disclosure is required by the terms of the [***] Agreement to be disclosed to [***] to satisfy Seres' obligations to report such required information, provided that [***] is bound in writing prior to disclosure by obligations of confidentiality and non-use; or

(f) subject to Sections 10.5 and 10.6, to relevant academics or healthcare professionals who are deemed to be "opinion leaders" in order to promote, or raise awareness of, any Collaboration Product; provided, however, that the dedicated Publications Working Group pursuant to Section 3.3(b)(ii) has approved such disclosure and provided, further, that, prior to such disclosure, the relevant opinion leader is bound by written obligations of confidentiality and non-use no less restrictive than the obligations set forth in this Article 10.

X.4 Scientific Papers and Scientific Meetings. The Parties, through the dedicated Publications Working Group pursuant to Section 3.3(b)(ii), shall discuss planned publications strategies and agree upon an annual medical and scientific communications plan which will address all Scientific Papers and Scientific Presentations to be submitted or made on an annual basis under Sections 10.5 and 10.6.

X.5 Scientific Papers. Each Party may present, disclose or publish any information, data (including Data), and other results related to Collaboration Products that have not previously been presented, disclosed or published ("**Product Information**") that are consistent with the medical and scientific communications plan contemplated in Section 10.4, through scientific publications in accordance with this Section 10.5.

(a) In accordance with such plan, each Party shall (i) discuss any proposed publications with the other Party through the dedicated Publications Working Group pursuant to Section 3.3(b)(ii), consider any comments provided by the other Party in good faith and provide periodic updates on the status of such proposed publication (ii) provide to the other Party, prior to submission for publication, a draft of a proposed submission concerning the Product Information, which has been prepared by or on behalf of such Party (or by a Clinical Study site contracted by Seres as sponsor of the relevant Clinical Study) (each a "**Scientific Paper**"), to be published in indexed medical and scientific journals and similar publications ("**Medical Journals**").

(b) Commencing with the receipt of such draft Scientific Paper, the receiving Party shall have [***] to review such draft Scientific Paper for consistency with the plan in Section 10.4 (it being understood that, during such [***] period, no submission for publication thereof shall take place).

(c) In the event the receiving Party confirms that such draft Scientific Paper is consistent with such plan, but has comments thereto, the Party proposing to publish such Scientific Paper shall, in good faith, consider the comments made by the receiving Party. In the event the receiving Party believes that such draft Scientific Paper is not consistent with such plan, then such disagreement shall be discussed and resolved through the dedicated Publications Working Group pursuant to Section 3.3(b)(ii).

(d) The receiving Party shall have the right to require that the publication of such Scientific Paper be [***] to permit a Patent to be filed using the Know-How covered in the proposed Scientific Paper.

(e) Neither Party will publish or present any Confidential Information it receives from or on behalf of the other Party without such other Party's prior written consent.

(f) The sending Party shall provide to the receiving Party copies of any final Scientific Paper accepted by a Medical Journal within [***] after the approval thereof, subject to applicable Medical Journal publisher's rules, guidelines and any other health care compliance guidelines.

(g) Prior to commencing the process set forth in this Section 10.5 for review and submission of drafts, each publishing Party agrees to provide, through the dedicated Publications Working Group pursuant to Section 3.3(b)(ii), notice of such Party's intent to publish and an outline of the proposed publication, sufficiently in advance for the other Party's member of such Working Group to comment on whether such proposed publication is consistent with the plan in Section 10.4 and the content in the outline. The publishing Party shall incorporate reasonable comments received in preparing the draft Scientific Paper.

X.6 Abstracts, Posters and Slide Decks. Each Party may present any Product Information that are consistent with the medical and scientific communications plan contemplated in Section 10.4, through publications, presentations, lectures, symposia or other meetings of healthcare professionals, or international congresses, conferences or meetings organized by a professional society or organization anywhere in the world (any such occasion, a "**Meeting**") in accordance with this Section 10.6.

(a) In accordance with such plan, each Party shall (i) discuss any proposed presentations with the other Party through the dedicated Publications Working Group pursuant to Section 3.3(b)(ii), consider any comments provided by the other Party in good faith and provide periodic updates on the status of such proposed presentations and (ii) provide to the other Party, prior to presentation and through the dedicated Publications Working Group pursuant to Section 3.3(b)(ii), an initial draft of the proposed presentation concerning the Product Information which has been prepared by or on behalf of such Party (or by a Clinical Study site contracted by Seres as sponsor of the relevant Clinical Study) (each a "**Scientific Presentation**") to be presented at a Meeting.

(b) Commencing with the receipt of any such draft Scientific Presentation, the receiving Party shall have [***] to inform the sending Party of its observations and suggestions with respect thereto (it being understood that, during such review period, as applicable, no presentation thereof shall take place) and the Parties shall discuss such observations and suggestions in good faith.

(c) The receiving Party may require that the Scientific Presentation [***] to permit a Patent to be filed using the Know-How covered in the proposed Scientific Presentation.

(d) Neither Party will present any Confidential Information received from or on behalf of the other Party without such other Party's prior written consent.

(e) The Party proposing to make a Scientific Presentation shall provide to the other Party copies of all final versions of the Scientific Presentation presented at a Meeting within [***] after the presentation thereof.

X.7 Clinical Study Website Registries. Seres shall be free to register the Clinical Studies it is sponsoring with respect to Collaboration Products on ClinicalTrials.gov or in similar clinical trial registries. Neither Party shall disclose or publish any Product Information on any website registries, unless required by applicable Law, without the other Party's prior written consent.

X.8 Press Releases. The Parties have agreed on a mutual press release to announce the execution of this Agreement in the form attached in Exhibit G. Except as required by applicable Law, including the rules of any securities exchange, the prior written approval of the other Party shall be required for any subsequent press release, and the Parties agree to consult with each other reasonably and in good faith with respect to the text of any subsequent press release no later than within [***] prior to the proposed date of issuance thereof. The contents of any press release or similar publicity that has been reviewed and approved by the reviewing Party in accordance with

this Section 10.8, and any publications made in accordance with Section 10.5, can be re-released or re-published by either Party without a requirement for re-approval.

X.9 Use of Name. No Party shall use the name, Trademark, trade name or logo of the other Party, its Affiliates or their respective employees in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, except as may be required by applicable Law, as provided in this Agreement or with the prior express written permission of the other Party.

X.10 Securities Filings. In the event either Party determines that it is required to file with the U.S. Securities and Exchange Commission (and/or the securities regulators of any state or other jurisdiction) a registration statement or any other disclosure document which describes any of the terms and conditions of this Agreement, such Party shall promptly notify the other Party of such requirement. The Party required to make such filing shall provide such other Party with a copy of relevant portions of the proposed filing not less than [***] (or such shorter period of time as may be required, under the circumstances, to comply with applicable Laws, but in no event less than [***]) prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), including any exhibits thereto relating to the terms and conditions of this Agreement. No such notice shall be required under this Section 10.10 if and to the extent that the specific information contained in the proposed filing has previously been included in any previous filing or disclosure made by either Party hereunder pursuant to this Article 10, or is otherwise approved in advance in writing by the other Party. If a Party determines that this Agreement is required to be filed by such Party with the U.S. Securities and Exchange Commission or of another securities regulatory authority, the Party required to file shall use diligent efforts to obtain confidential treatment of the terms and conditions of this Agreement that such other Party requests be kept confidential.

ARTICLE XI
PATENT PROSECUTION AND ENFORCEMENT

XI.1 Ownership of Inventions.

(a) Pre-existing IP. Subject only to the rights expressly granted to the other Party under this Agreement or the Existing Agreement, each Party shall retain all rights, title and interests in and to any Intellectual Property Rights that are owned by, or licensed or sublicensed to, such Party prior to the Effective Date or independently of this Agreement.

(b) Inventorship of Inventions shall be determined in accordance with U.S. patent Laws applicable to the determination of inventorship. Ownership of such Inventions shall be as follows in subsections (c) through (f).

(a) All Inventions that incorporate any Licensed Intellectual Property or that are improvements to any Licensed Intellectual Property, invented, discovered, generated or made (i) solely by either Party, its Affiliates or its or its Affiliates' employees, agents or independent contractors or (ii) jointly by both Parties, their Affiliates or their and their Affiliates' employees, agents or independent contractors, in each case of (i) and (ii), during the Term in the performance of any activity contemplated under this Agreement or otherwise in the exercise of its or their rights

or the carrying out of its or their obligations under this Agreement (collectively, "**Improvements**"), and all Intellectual Property Rights therein, shall be [***].

(b) All Inventions conceived, generated or otherwise made solely by employees, agents and independent contractors of Seres or its Affiliates pursuant to this Agreement, and all Intellectual Property Rights therein, shall be owned, as between the Parties, solely by the Seres.

(c) All Inventions, [***], that are conceived, generated or otherwise made solely by employees, agents and independent contractors of Licensee or its Affiliates or Sublicensees pursuant to this Agreement that are directly related to the Exploitation of a Collaboration Product, and all Intellectual Property Rights therein ("**Licensee Sole Inventions**"), shall be owned, as between the Parties, solely by Licensee. All Patents claiming Licensee Sole Inventions shall be referred to herein as "**Licensee Sole Patents**."

(d) All Inventions, [***], that are conceived, generated or otherwise made jointly by employees, agents and independent contractors of each Party or its Affiliates or sublicensees pursuant to this Agreement, and all Intellectual Property Rights therein ("**Joint Inventions**"), shall be owned jointly by the Parties such that each Party shall have an undivided interest therein. All Patents claiming Joint Inventions shall be referred to herein as "**Joint Patents**." Except to the extent either Party is restricted by the licenses granted to the other Party and covenants set forth herein or in the Existing Agreement, each Party shall be entitled to practice and exploit the Joint Inventions and the Intellectual Property Rights therein, [***].

(e) Each Party shall promptly disclose to the other Party in writing, and shall cause its Affiliates and sublicensees to so disclose, the discovery, making, conception or reduction to practice of any Invention conceived, generated or otherwise made by employees, agents and independent contractors of such Party, Affiliates and sublicensees pursuant to this Agreement. Each Party shall, and shall cause its sublicensees and Affiliates, and all independent contractors, employees and agents of such Party, to cooperate with the other Party and take all reasonable actions and execute such agreements, declarations, assignments, legal instruments and documents as may be reasonably required to perfect the other Party's right, title and interest in and to Inventions, and Patents thereon, and other Intellectual Property Rights as set forth in this Section 11.1. Each Party shall also include provisions in its relevant agreements entered into after the date of this Agreement with Third Parties that effect the intent of this Section 11.1.

I.2 Prosecution and Maintenance of Patents.

(a) Prosecution of Licensed Patents. As between Licensee and Seres, Seres shall have the first right, but not the obligation, for the filing, prosecution and maintenance of all Licensed Patents (for clarity, including Joint Patents) in the Licensed Territory at Seres' cost. If Seres proposes to not pursue or continue the filing, prosecution or maintenance of any such Patent in the Licensed Territory, Seres shall provide Licensee with a written notice of such intent at least [***] in advance of the relevant deadline. In such case, or if, at any time, Seres fails to initiate any such action within [***] after a request by Licensee that it do so (or if, after initiating any requested action, Seres at any time thereafter fails to use reasonable efforts to pursue such action): (i) Licensee will provide a written response to Seres at least [***] in advance of the relevant deadline if Licensee wishes to file, prosecute and maintain (in its sole discretion) such Patent in the Licensed

Territory at Licensee's cost; (ii) if Licensee provides the affirmative notice under clause (i) above, Seres shall promptly provide to Licensee copies of all files related to filing, prosecuting and maintaining such Patent to counsel designated by Licensee; and (iii) upon completion of the transfer of such files under clause (ii), Seres shall no longer be responsible for the costs and expenses relating to filing, prosecuting and maintaining (as applicable) such Patent in the Licensed Territory and Licensee shall reimburse Seres for any such costs it may incur. Notwithstanding the foregoing, [***].

(b) Prosecution of Licensee Sole Patents. As between Licensee and Seres, Licensee shall have the first right, but not the obligation, for the filing, prosecution and maintenance of all Licensee Sole Patents in the Licensed Territory at Licensee's cost, provided that, if Licensee intends to abandon, or not to file a patent application covering, any such Licensee Sole Patent, Licensee shall provide Seres with a written notice of such intent at least [***] in advance of the relevant deadline. In such case, or if, at any time, Licensee fails to initiate any such action within [***] after a request by Seres that it do so (or if, after initiating any requested action, Licensee at any time thereafter fails to use reasonable efforts to pursue such action): (i) Seres will provide a written response to Licensee at least [***] in advance of the relevant deadline if Seres wishes to file, prosecute and maintain (in its sole discretion) such Patent in the Licensed Territory at Seres' cost; (ii) if Seres provides the affirmative notice under clause (i) above, Licensee shall promptly provide to Seres copies of all files related to filing, prosecuting and maintaining such Patent to counsel designated by Seres; and (iii) upon completion of the transfer of such files under clause (ii), Licensee shall no longer be responsible for the costs and expenses relating to filing, prosecuting and maintaining (as applicable) such Patent in the Licensed Territory and Seres shall reimburse Licensee for any such costs it may incur.

(c) Cooperation. The Party having responsibility to file, prosecute and maintain a Patent pursuant to Sections 11.2(a) and 11.2(b) (the "**Prosecuting Party**") agrees to inform with sufficient advance notice and coordinate with the other Party through the Patent Working Group with respect to patent prosecution or other proceedings with respect to the Licensed Patents or Licensee Sole Patents, as applicable, in the Licensed Territory. The Prosecuting Party shall provide the other Party with copies of each draft patent application to be filed [***]. The Prosecuting Party shall notify the other Party as early as reasonably practicable, [***] concerning the Licensed Patents or Licensee Sole Patents, as applicable, in the Licensed Territory and shall permit the other Party to [***], and the [***] shall be taken into consideration in good faith by such Party and its patent counsel in connection with such filing. The Prosecuting Party shall also consider in good faith the other Party's [***]. Subject to the above good faith consideration, the Prosecuting Party is not required to [***].

I.3 Third Party Infringement Claims.

(a) Notice. Each Party will promptly notify the other Party in writing of (i) any actual or threatened infringement, misappropriation, or other violation by a Third Party of any (1) Licensed Intellectual Property or (2) Licensee Sole Patents or other Intellectual Property Rights within the Licensee Sole Inventions (together with Licensee Sole Patents, "**Licensee Sole IP**"), in each case in the Licensed Territory and of which it becomes aware ("**Third Party Infringement**"), and (ii) any allegation by a Third Party that any Intellectual Property Right owned by it is infringed, misappropriated, or otherwise violated by the Development, Manufacturing or Commercialization

of a Collaboration Product in the Licensed Territory, in each case of which it becomes aware ("**Third Party Challenge**").

(b) Licensed Intellectual Property. Seres shall have the first right (but not the obligation), at its own expense, to control enforcement of the Licensed Intellectual Property (for clarity, including Joint Intellectual Property) against any Third Party Infringement in the Licensed Territory. Seres shall give Licensee timely notice of any proposed settlement of any such suit, action or proceeding that Seres controls. Subject to [***] step-in rights with respect to enforcement of the [***] Patents under the [***] Agreement, Licensee shall have the right (but not the obligation) at its own expense, to control enforcement of such Licensed Intellectual Property against any Third Party Infringement if Seres provides Licensee with written notice that it is not exercising its right to control such enforcement, or if Seres fails to timely initiate or file the relevant response to (as applicable), a suit, action or proceeding with respect to such Third Party Infringement prior to the expiration of the [***] period following first receipt by either Party of notice from the other Party of such Third Party Infringement (or any shorter time period that is at least [***] prior to the expiration of any time periods required to commence such suit, action or proceeding under Law); provided that if Seres does not exercise its right to control such enforcement [***], Seres shall notify Licensee thereof, and Licensee shall in good faith consider such explanation in determining whether to enforce such Licensed Intellectual Property. In the event Licensee proceeds with enforcement of such Licensed Intellectual Property following such notification and explanation by Seres, Seres shall have the right, but not the obligation, to jointly control any such enforcement action so pursued by Licensee, [***].

(c) Licensee Sole IP. Licensee shall have the first right (but not the obligation) at its own expense, to control enforcement of the Licensee Sole IP against any Third Party Infringement in the Licensed Territory. Licensee shall give Seres timely notice of any proposed settlement of any such suit, action or proceeding that Licensee controls. Seres shall have the right (but not the obligation) at its own expense, to control enforcement of the Licensee Sole IP against any Third Party Infringement if Licensee provides Seres with written notice that it is not exercising its right to control such enforcement, or if Licensee fails to timely initiate or file the relevant response to (as applicable), a suit, action or proceeding with respect to such Third Party Infringement prior to the expiration of the [***] period following first receipt by either Party of notice from the other Party of such Third Party Infringement (or any shorter time period that is at least [***] prior to the expiration of any time periods required to commence such suit, action or proceeding under Law).

(d) The Party enforcing any Licensed Intellectual Property or Licensee Sole IP pursuant to Section 11.3(b) or 11.3(c) (the "**Enforcing Party**") shall have the right to settle the applicable Third Party Infringement, provided that [***] (the "**Non-Enforcing Party**").

(e) Cooperation and Rights of Non-Enforcing Party. The Non-Enforcing Party shall, and shall cause its Affiliates to, assist and cooperate with the Enforcing Party of a Third Party Infringement action, as such Enforcing Party may reasonably request from time to time; provided that [***]. Without limiting the foregoing, and notwithstanding anything to the contrary herein, the Non-Enforcing Party shall [***]. The Non-Enforcing Party shall [***]. Each Party shall keep the other Party reasonably informed of all material developments in connection

with any Third Party Infringement suit, action or proceeding described in Section 11.3(b) and Section 11.3(c).

(f) Recovery. Recoveries received by either Party or their Affiliates in respect of actions contemplated by this Section 11.3 shall be allocated as follows: If applicable, any amounts due to [***] pursuant to the [***] Agreement shall be paid to [***]. Thereafter, Seres and Licensee shall recover their respective actual out-of-pocket expenses (including attorneys' fees), or equitable proportions thereof, associated with any litigation against infringers undertaken pursuant to Sections 11.3(b)-(c) or settlement thereof, from any resulting recovery made by either Party. Any excess amount of such a recovery shall be allocated [***] to Seres and [***] to Licensee.

(g) Infringement or Misappropriation Claims by Third Parties. The Party against whom a Third Party Challenge is filed shall have all authority with respect to such Third Party Challenge (the "**Defending Party**"), including the right to control of the defense of any such suit, action or proceeding and the exclusive right to compromise, litigate, settle or otherwise dispose of any such suit, action, or proceeding at its own expense; provided that the Defending Party shall keep the other Party (the "**Non-Defending Party**") timely informed of the proceedings and filings, and provide the Non-Defending Party with copies of all communications pertaining to each such Third Party Challenge, and the Defending Party shall [***]. The Non-Defending Party shall, and shall cause its Affiliates to, assist and cooperate with the Defending Party, as such Defending Party may reasonably request from time to time, in connection with its activities set forth in this Section 11.3(g), including [***]. Notwithstanding anything to the contrary, [***].

I.4 Invalidity or Unenforceability Defenses or Actions.

(a) Notice. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity, patentability or unenforceability of any of the Licensed Patents or Licensee Sole Patents by a Third Party, including any oppositions and post-grant proceedings, in each case in the Licensed Territory and of which such Party becomes aware.

(b) Responsibility for Licensed Patents and Licensee Sole Patents. The Prosecuting Party of a Licensed Patent or Licensee Sole Patent pursuant to Sections 11.2(a) and 11.2(b) shall have the first right, but not the obligation, to defend and control the defense of the validity, patentability and enforceability of such Patent in the Licensed Territory, at its own expense, subject to Section 11.4(d). If the Party with the first right to defend a Patent as set forth in this Section 11.4(b) elects not to defend or control the defense of such Patent in a suit brought in the Licensed Territory, or otherwise fails to initiate and maintain the defense of any such claim, suit, or proceeding in a timely manner, then the other Party may conduct and control the defense of any such claim, suit, or proceeding, at its own expense, subject to Section 11.4(d). Unless the Parties otherwise agree, for any such proceeding, only counsel(s) mutually agreeable to both Parties will be engaged to defend any Patent claim, suit or proceeding pursuant to this Section 11.4(b).

(c) Cooperation. Each Party shall assist and cooperate with the other Party as such other Party may reasonably request from time to time in connection with its activities set forth in this Section 11.4, including by providing access to relevant documents and other evidence, and making its employees available at reasonable business hours; provided that [***]. In

connection with any such defense, the Party having responsibility to defend a Patent pursuant to Section 11.4(b) shall consider in good faith any comments from the other Party and shall keep the other Party reasonably informed of any material development in such defense.

(d) Notwithstanding anything to the contrary in the foregoing, any costs and expenses incurred by Licensee or its Affiliates in the defense of a Licensed Patent pursuant to this Section 11.4 shall be [***], provided that [***].

I.5 Patent Marking. To the extent required by applicable Laws, each Party agrees to mark, and have its Affiliates and Sublicensees mark, all patented Collaboration Products it or they sell(s) or distribute(s) pursuant to this Agreement in accordance with the applicable patent statutes or regulations in the Licensed Territory.

ARTICLE XII
TRADEMARKS

XII.1 Branding; Ownership of Product Trademarks.

(a) Prior to the anticipated First Commercial Sale of any Collaboration Product in the Licensed Territory, the JCC shall prepare a branding strategy with respect to such Collaboration Product in the Licensed Territory and determine the Trademarks to be used on or in connection with such Collaboration Product in the Licensed Territory (the "**Product Trademarks**"), taking into consideration the mutual desire of the Parties to establish global branding for such Collaboration Product.

(b) The Product Trademarks shall be owned by [***]. [***], be responsible for procurement, maintenance, enforcement and defense of all Product Trademarks in the Licensed Territory. [***] shall maintain all registrations of the Product Trademarks in the Licensed Territory, with the assistance of [***] as may be necessary [***], and [***] shall not file any registrations or other filings in respect of any of Product Trademark without [***] prior written consent. Seres and Licensee agree to cooperate [***] with respect to the execution and delivery of such additional instruments or documents as shall be necessary to ensure [***] rights and interest in and to the Product Trademarks.

XII.2 License to Product Trademarks. Subject to the terms and conditions of this Agreement and the Existing Agreement, [***] hereby grants [***] a Co-Exclusive, fully paid up license to use the Product Trademarks in the Licensed Territory solely for the purposes of Developing and Commercializing Collaboration Products in the Licensed Territory as permitted by this Agreement. [***] agrees to comply with applicable Law and conform to the customary guidelines of [***] with respect to manner of use, and to maintain the quality standards of [***] with respect to the goods sold and services provided in connection with the Product Trademarks, and to submit materials bearing the Product Trademarks to [***] for review as to conformance with [***] guidelines. [***] recognizes and agrees that no ownership rights are vested or created by the limited rights of use granted pursuant to this Section 12.2, and that all goodwill developed by virtue of the use of the Product Trademarks in accordance with this Section 12.2 inures to the benefit of [***].

XII.3 Other Marks. Subject to the terms and conditions of this Agreement, each Party hereby grants to the other Party a non-exclusive, non-transferable, non-sublicensable (except to Affiliates) right to use in the Licensed Territory its Corporate Name or any other trademarks, trade names, service marks, logos, slogans, trade dress or domain names Controlled by such Party or any of its Affiliates ("**Other Marks**") (other than the Product Trademarks) relevant to the subject matter covered by this Agreement for the Term that are approved by the JCC for use in connection with Collaboration Products, solely for use in connection with the Commercialization activities provided for in this Agreement. Each Party agrees to comply with applicable Law and conform to the customary guidelines of the other Party with respect to manner of use, and to maintain the quality standards of such other Party with respect to the goods sold and services provided in connection with the granting Party's Other Marks, and to submit materials bearing the granting Party's Other Marks to such granting Party for review and approval as to conformance with the granting Party's guidelines prior to such use. Each Party recognizes and agrees that no ownership rights are vested or created by the limited rights of use granted pursuant to this Section 12.3, and that all goodwill developed by virtue of the use of the granting Party's Other Marks in accordance with this Section 12.3 inures to the benefit of such granting Party.

TERM AND TERMINATION

XIII.1 Term. This Agreement shall commence on the Effective Date and, unless terminated earlier pursuant to this Article XIII, shall continue in full force and effect until all Development and Commercialization activities under this Agreement for all Collaboration Products in the Licensed Territory have permanently ceased; provided that, for clarity, [***] would not constitute a determination to cease permanently all Development and Commercialization of Collaboration Products (the "**Term**"). For additional clarity, this Agreement shall be in effect and shall not expire so long as any Collaboration Product is sold in the Licensed Territory, whether by Licensee itself and by its Affiliates or any permitted Sublicensees or distributors.

XIII.2 Termination for Material Breach. Either Party shall have the right to terminate this Agreement in the event the other Party has materially breached or defaulted in the performance of any of its material obligations hereunder and such breach (i) has affected, or is reasonably likely to affect, in a material and adverse way the Development, Manufacturing or Commercialization of the Collaboration Products in the Licensed Territory considering the totality of the circumstances taken as a whole, and (ii) continues for sixty (60) days after written notice thereof, specifying the nature of the purported breach in reasonable detail, was provided to the breaching Party by the non-breaching Party (the "**Notice of Termination**"). Any such termination shall become effective at the end of such sixty (60) day period if, prior to the expiration of the sixty (60) day period, the breaching Party has not disputed or cured any such breach or default. Such sixty (60) day period may be extended if the breaching party communicates to the non-breaching Party a written remediation plan reasonably designed to cure such breach or default within a reasonable additional time period, not to exceed an additional [***] following expiration of the foregoing sixty (60) day period. If the allegedly breaching Party disputes in good faith the material breach set forth in a Notice of Termination provided by the non-breaching Party in accordance with this Section 13.2 and provides written notice of such dispute to the non-breaching Party within the sixty (60) day cure period, the non-breaching Party shall not have the right to terminate this Agreement, unless and until the existence of such material breach by the allegedly breaching Party has been

determined in accordance with Article XVII, and subject to the breaching Party's right to cure the breach under this Section 13.2. It is understood and acknowledged that during the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

XIII.3 Termination for Bankruptcy. Either Party shall have the right to terminate this Agreement upon written notice to the other Party: (a) if such other Party is declared insolvent or bankrupt by a court of competent jurisdiction; (b) if a voluntary or involuntary petition in bankruptcy is filed in any court of competent jurisdiction against such other Party and such petition is not dismissed within [***] after filing; (c) if such other Party shall make or execute an assignment of substantially all of its assets for the benefit of creditors; or (d) substantially all of the assets of such other Party are seized or attached and not released within [***] thereafter. All licenses granted under this Agreement are deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to intellectual property as defined in Section 101 of such Code. The Parties agree that Licensee may fully exercise all of its rights and elections under the U.S. Bankruptcy Code and any foreign equivalent thereto in any country having jurisdiction over a Party or its assets. The Parties further agree that, in the event Licensee elects to retain its rights as a licensee under such Code, Licensee shall be entitled to complete access to any Licensed Intellectual Property and all embodiments of such technology.

XIII.4 Termination for Convenience. Licensee shall have the right to terminate this Agreement at will, as follows:

(a) with twelve (12) months' prior written notice, which termination shall be effective only on or after the third (3rd) anniversary of First Commercial Sale of the first Collaboration Product in the Licensed Territory,

(b) if the First Commercial Sale of the first Collaboration Product in the Licensed Territory has not occurred by the fifth (5th) anniversary of the Effective Date, with one hundred eighty (180) days' prior written notice, such notice to be provided at any time during the [***] period following the [***] of the Effective Date, provided that [***], or

(c) if the FDA does not grant Regulatory Approval for SER-109 after submission by Seres of a Regulatory Filing seeking first Regulatory Approval as set forth in the initial Development and Regulatory Activity Plan, and the Parties fail to agree during the [***] discussion period set forth in Section 4.3(a) (as extended if applicable) on the conduct of additional Clinical Study(ies) for SER-109 or on the allocation of costs therefor in accordance with Section 4.3(a), within [***] after the expiration of such discussion period, with one hundred eighty (180) days' prior written notice.

XIII.5 Termination for Patent Challenge by Licensee. Seres shall have the right to terminate this Agreement immediately upon written notice if Licensee or its Affiliate challenges in a court of competent jurisdiction, the validity, scope or enforceability of, or otherwise opposes, any Licensed Patent in the Licensed Territory (other than in connection with Licensee's or its Affiliate's defense of any claim brought against it that is not a claim by Seres that Licensee's or its Affiliate's exploitation of the Licensed Patents in the Licensed Territory is outside the scope of the license under this Agreement). Licensee shall use reasonable efforts to include provisions in

all agreements under which a Third Party obtains a license under any Licensed Patent providing that, if the Sublicensee challenges the validity, scope or enforceability of or otherwise opposes any such Licensed Patent under which the Sublicensee is sublicensed in the manner contemplated in this Section 13.5, then Licensee may terminate such sublicense agreement with such Sublicensee, and Licensee shall, upon request by Seres, enforce such right if such Sublicensee breaches such restriction (if applicable).

ARTICLE XIV
EFFECTS OF TERMINATION; RIGHTS IN LIEU OF TERMINATION

XIV.1 Accrued Obligations. Except as otherwise set forth in this Article XIV or elsewhere in this Agreement, the expiration or termination of this Agreement for any reason shall not release either Party from any liability which, at the time of such expiration or termination, has already accrued to the other Party or which is attributable to a period prior to such expiration or termination, nor will any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, or at law or in equity, with respect to a breach of this Agreement.

XIV.2 Rights on Termination of Agreement. In case of any termination of this Agreement by either Party, this Section 14.2 shall apply:

(a) Wind-down Period.

(i) For a period of [***] after termination ("**Transition Period**"), Licensee shall have the right to sell its remaining inventory of Collaboration Products in the Licensed Territory; provided that Licensee fulfills its payment obligations under this Agreement in connection with such inventory sell-off.

(ii) Each Party shall use commercially reasonable efforts to cooperate with the other Party and/or its designee to effect a smooth and orderly wind down or transition to Seres or Seres' designee of all Commercialization and other activities undertaken by Licensee and its Affiliates under this Agreement that are related to Collaboration Products in the Licensed Territory during the Transition Period.

Unless otherwise expressly provided, Licensee's costs to effect a smooth termination of the Agreement pursuant to this Section 14.2(a) shall be borne by [***]; otherwise such costs shall be borne by [***] unless otherwise expressly provided.

(b) Termination of License to Licensee. Subject to Section 14.2(a), upon termination of this Agreement all licenses granted by Seres to Licensee shall become non-exclusive upon the effective date of such termination and shall terminate upon expiration of the Transition Period.

(c) License to Seres. Effective automatically upon Seres' written request provided within [***] after the effective date of any termination of this Agreement, Licensee shall and hereby does grant to Seres an exclusive, worldwide, royalty-free, transferable, perpetual and irrevocable license, with the right to sublicense through multiple tiers, under any Intellectual Property Rights Controlled by Licensee claiming Inventions that are necessary or reasonably

useful for, or other inventions actually practiced in connection with, the Commercialization of Collaboration Products as they exist at the time of such termination of this Agreement, solely to Exploit the Collaboration Products.

(d) **Return of Confidential Information**. Within [***] after the end of the Transition Period upon request by Seres, Licensee shall either return to Seres or destroy all tangible items comprising, bearing or containing Confidential Information of Seres, that are in Licensee's possession, subject to Licensee's right to keep one copy for archiving purposes.

(e) **Trademarks**. Effective upon the end of the Transition Period, [***] shall cease to use all Product Trademarks in the Licensed Territory, and all rights granted to [***] hereunder with respect to such Trademarks in the Licensed Territory shall terminate.

(f) **Inventory Transfer**. At the end of the sell-off period set forth in Section 14.2(a)(i), Licensee shall transfer to Seres any and all remaining inventory of Collaboration Products. All such inventory shall be purchased by Seres at a price equal to [***].

(g) **Marketing and Promotional Materials**. Licensee will transfer to Seres or, upon written election of Seres, destroy, all marketing, advertising and promotional materials, samples and other sales or sales training materials relating to Collaboration Products in the possession of Licensee and its Sales Representatives and sales management as promptly as practicable after the end of the Transition Period.

(h) **Transfer of Data and Records**. Licensee shall, as promptly as practicable following the effective date of termination, transfer to Seres all data, reports, records, materials and files, including patent prosecution files generated in the course of Licensee's filing, prosecuting and maintaining Patents pursuant to Sections 11.2(a) and 11.2(b), Controlled by Licensee, that are reasonably necessary for the Exploitation of the Collaboration Products under the rights granted to Seres in Section 14.2(c) and to the extent such data, reports, records, materials or files relate solely to the Collaboration Products and not to any other products Controlled by Licensee.

(i) **Transfer of Agreements**. To the extent permitted under the relevant agreement at the time of termination, Licensee shall promptly provide Seres with a copy (which may be redacted if required to protect confidential information of Licensee or a Third Party) of any agreements between Licensee or any of its Affiliates, on the one hand, and any Affiliate or Third Party, on the other hand, that solely relate to the Collaboration Products or Commercialization thereof. Licensee shall assign or sublicense such agreements to Seres upon written request by Seres and to the extent Licensee has the right to do so under the relevant agreement without Licensee needing to make any payments in connection therewith. If Licensee does not have the right to assign or sublicense such agreement to Seres, Licensee will provide Seres with contact information for the Third Party to such agreement so that Seres may pursue an agreement directly with such Third Party with respect to the Collaboration Products.

(j) **Milestone Payments**. In the event of any termination of this Agreement in its entirety by either Party pursuant to Article XIII, Licensee shall not be obligated to make any milestone payment contemplated under Section 7.2 that would otherwise be owing after the

terminating Party notifies the other Party in writing of its intention to so terminate; provided, however, that if this Agreement is not ultimately terminated pursuant to such notice, any such milestone payments that would have become due following such notice shall be due and payable at such time as it is determined that such termination shall not occur.

XIV.3 Licensee's Rights in Lieu of Termination. If Licensee is entitled to terminate this Agreement pursuant to Section 13.2 or Section 13.3, then, in lieu of terminating this Agreement, Licensee may elect to continue this Agreement subject to the following provisions by providing written notice to Seres of such election:

(a) the licenses and rights granted to Licensee pursuant to Section 2.1 under the Licensed Intellectual Property to (i) Develop, Commercialize, and conduct Medical Affairs Activities in respect of Licensed Products in the Licensed Territory in the Field and to use Licensed Products in connection therewith, and (ii) Develop, Commercialize, and conduct Medical Affairs Activities in respect of Collaboration Products in the Licensed Territory in any field or indication and to use Collaboration Products in connection therewith, shall remain in effect for the duration of the Term and shall become exclusive and cease to be Co-Exclusive, subject to the other terms and conditions of this Agreement, provided, however that Seres and its Affiliates shall retain a non-exclusive right under the Licensed Intellectual Property to carry out any remaining obligations they may have pursuant to this Agreement following such termination.

(b) commencing on the date of Licensee's notice of election pursuant to this Section 14.3, (i) Royalty Payment Amounts payable to Seres pursuant to Section 7.4(a) shall be reduced by [***] and, in any Calendar Quarter in which Licensee is the Surplus Party, the True-Up Amount for such Calendar Quarter shall be reduced by [***] and (ii) any milestone payment contemplated by Section 7.2(a) or 7.2(b) that becomes payable after the date of Licensee's notice of election shall be reduced by [***]; provided that, if Licensee is entitled to terminate this Agreement pursuant to Section 13.2, then this Section 14.3(b) shall apply only until [***].

(c) Licensee shall have the right, by providing written notice in accordance with this Section 14.3, to take over [***]. In such case, Seres shall transfer to Licensee the right and responsibility to conduct all such activities to be assumed by Licensee, and shall, [***], effect an orderly transition to Licensee or Licensee's designee of the relevant activities. With respect to any [***] that Licensee has the right to take over, but elects not to exercise such right, Seres shall have the right to continue such [***].

(d) all Committees shall disband and [***]. For clarity, this Section 14.3(d) shall not apply to the TWG.

(e) Seres shall assign to Licensee (at Licensee's option) all Regulatory Filings (including all INDs and BLAs) and Regulatory Approvals relating exclusively to the Collaboration Products in the Field in the Licensed Territory and all related Regulatory Documentation relating exclusively to the Licensed Territory, and Seres shall provide Licensee with one (1) copy of the foregoing documents, together with the raw and summarized data for any preclinical studies and Clinical Studies of such Collaboration Product(s) in the Field (and where reasonably available, electronic copies thereof).

(f) promptly following the date of Licensee's notice of election pursuant to this Section 14.3 and of its election to assume [***] activities pursuant to Section 14.3(c), the Parties shall establish a working group comprised of an equal number of representatives of each Party, which representatives shall have the requisite seniority, authority and experience level to make recommendations in accordance with this Section 14.3 (the "**Transition Working Group**" or the "**TWG**"). The TWG shall meet promptly following its formation to discuss and, as applicable, facilitate the transitioning of then-ongoing [***] activities in respect of the Collaboration Products to be assumed by Licensee (as further discussed below) and make recommendations to the Parties with respect thereto. To the extent, following the date of Licensee's notice of election pursuant to this Section 14.3, there are any then-ongoing [***] which relate exclusively to a Collaboration Product in the Licensed Territory, then Section 14.3(c) shall apply. If such then-ongoing [***] activities relate to a Collaboration Product in both the Licensed Territory and the ROW Territory, then, except as otherwise provided in the Existing Agreement or as the Parties may otherwise agree taking into consideration the recommendations of the TWG, (x) if Licensee's termination right does not relate to a material breach on the part of Seres relating to its conduct of such [***] activities, Seres shall complete such then-ongoing [***] activities in accordance with this Agreement, or (y) if Licensee's termination right does relate to a material breach on the part of Seres relating to its conduct of such [***] activities, Licensee shall have the right, at its election and in its discretion, to require the transition of such [***] activities to Licensee. Notwithstanding anything to the contrary contained herein, but subject to the Existing Agreement, Seres shall be permitted to continue any [***] activity which has been conducted solely by Seres prior to the date of Licensee's notice of election pursuant to this Section 14.3 and which relates exclusively to the ROW Territory and would not reasonably be expected to impact the Licensed Territory. In furtherance of the foregoing:

(i) If any applicable [***] activity is to be continued pursuant to this Section 14.3(f), then the Party that is to conduct such activity, in accordance with the foregoing, shall carry out such activity under the applicable [***] then in effect and each Party shall retain its rights to use data derived from such [***] activity as provided under this Agreement.

(ii) If Licensee elects to have a particular [***] activity which has previously been conducted by Seres under the applicable [***] transitioned to Licensee in accordance with the foregoing, then Seres shall, [***], effect an orderly transition to Licensee or Licensee's designee of such [***] activity.

(g) at Licensee's request, Seres shall use Commercially Reasonable Efforts to terminate or to assign to Licensee or its designated Affiliate any agreement (other than a license agreement) solely relating to [***], provided that such agreement is in effect as of the date of Licensee's notice of election pursuant to this Section 14.3 and in the case of an assignment, if assignment is permitted under the relevant agreement or consented to by the applicable Third Party. To the extent any such agreement is not terminated or assigned to Licensee, then after the date of Licensee's notice of election pursuant to this Section 14.3, Seres or its Affiliate shall continue to exercise its rights under and in accordance with such agreement with respect to the Collaboration Products and the Licensed Territory, as directed by and for the benefit of Licensee until such time as Licensee obtains an agreement with such Third Party.

(h) Licensee may continue to purchase the Collaboration Products then Manufactured by Seres for Licensee under and in accordance with the terms of the Supply Agreement for the term of such agreement. However, if the Supply Agreement has not yet been executed, unless the Parties enter into the Supply Agreement within [***] after Licensee exercises its rights under this Section 14.3, [***], including providing [***]. Such technology transfer may be implemented by means of [***]. Each such Third Party manufacturer [***]. Recognizing the importance of [***]. With effect from the date of any such election by Licensee [***].

(i) at Licensee's election, in its sole discretion, and upon Licensee's written notice of such election to Seres, Seres' right to provide Details under Section 5.5(b) [***].

(j) anything to the contrary notwithstanding, Licensee shall have the right to make all decisions regarding [***].

XIV.4 Survival. Upon the expiration or termination of this Agreement, all rights and obligations of the Parties under this Agreement shall terminate except those which are expressly or by their nature set to survive termination as well as those described in the following provisions: Sections 2.7, 8.1 through 8.3 (in each case, solely to the extent payments accrued but remain unpaid as of the effective date of termination), 8.4, 11.1, 11.4(d), 12.1(b) (first sentence only), 14.1, 14.2, 14.4 and 15.5, and Articles X, XVI, XVII and XVIII (other than Sections 18.1, 18.8 and 18.9).

ARTICLE XV
REPRESENTATIONS, WARRANTIES AND COVENANTS

XV.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that, as of the Effective Date:

(a) it is duly organized, validly existing and is in good standing under its Laws of incorporation or formation, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent such Party from performing its obligations under this Agreement;

(b) it has validly executed and delivered this Agreement and, assuming the valid authorization, execution and delivery of this Agreement by the other Party, this Agreement is a legal and valid obligation binding upon such Party and enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity);

(c) the execution, delivery and performance of this Agreement by such Party have been duly authorized by all necessary corporate or other legal entity action and do not and will not: (i) require the consent or approval of such Party's stockholders or violate its charter documents, bylaws, or other organizational documents; (ii) violate any Law, rule, regulation, order, writ, judgment, decree, determination or award of any court, governmental body or administrative or other agency having jurisdiction over it; nor (iii) conflict with, or constitute a default under, any

agreement, instrument or understanding, oral or written, to which it is a party or by which it is legally bound;

(d) all necessary consents, approvals, waivers, orders and authorizations of, or registrations, declarations or filings with, all Regulatory Authorities, other Governmental Authorities and other persons or entities required to be obtained or made by it in order to execute, deliver or perform this Agreement have been obtained; and

(e) Neither such Party nor its Affiliates' employees who have been, or who such Party currently expects to be, involved in the Development or Commercialization of the Collaboration Products, or, to such Party's knowledge, any of their respective licensees, contractors, agents and consultants or their respective employees, consultants or contractors who have been, or who such Party currently expects to be, involved, on behalf of such Party, in the Development or Commercialization of the Collaboration Products:

(i) are debarred under Section 306(a) or 306(b) of the FD&C Act or by the analogous applicable Laws of any Regulatory Authority;

(ii) have been charged with, or convicted of, any felony or misdemeanor within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(l)-(3), or pursuant to the analogous applicable Laws of any Regulatory Authority, or are proposed for exclusion, or the subject of exclusion or debarment proceedings by a Regulatory Authority; or

(iii) are excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any U.S. or non-U.S. healthcare programs (or have been convicted of a criminal offense that falls within the scope of 42 U.S.C. §1320a-7 but such entity or individual is not yet excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred by a Regulatory Authority from participation, or otherwise ineligible to participate, in any procurement or non-procurement programs.

XV.2 Representations and Warranties of Seres. Seres represents and warrants to Licensee that, as of the Effective Date:

(a) Seres has the right and authority to grant the rights and licenses it grants or purports to grant to Licensee herein, and it has not previously granted any right, license or interest in or to the Licensed Intellectual Property that would conflict with or limit the scope of any of the rights or licenses granted to Licensee under this Agreement;

(b) except as provided in the [***] Agreement, the Licensed Patents and Licensed Know-How are not subject to any liens in favor of, or claims of ownership by, any Third Party;

(c) there are no actual, pending, or, to Seres' knowledge, alleged or threatened, actions, suits, claims, judgments, disputes, judicial, legal, administrative or other proceedings, interferences or governmental investigations involving the Collaboration Products or the Licensed Intellectual Property by or against Seres or any of its Affiliates in the Licensed Territory, which could reasonably be expected to adversely affect or restrict (i) the ability of Seres to consummate

or perform the transactions contemplated under this Agreement, or (ii) the Licensed Intellectual Property or Seres' Control thereof or the Collaboration Products;

(d) to Seres' knowledge, no Third Party is infringing, violating or misappropriating the Licensed Intellectual Property in the Licensed Territory;

(e) to Seres' knowledge, the Exploitation of, and the conduct of Medical Affairs Activities in respect of, the Collaboration Products existing as of the Effective Date do not and will not infringe, violate, or misappropriate the valid Intellectual Property Rights of any Third Party and Seres has not received any claim alleging any such infringement;

(f) the conception, development and reduction to practice of the Licensed Patents and Licensed Know-How existing as of the Effective Date has not constituted or involved the misappropriation of trade secrets or other proprietary rights or property of any Third Party;

(g) (i) to Seres' knowledge, none of the granted Patents within the Licensed Patents are invalid or unenforceable, in whole or in part, (ii) no claim has been issued or served, and Seres has not received any written threat of a claim or litigation made by any Person, against Seres or any of its Affiliates that alleges that any Licensed Patent is invalid or unenforceable, and (iii) all Licensed Patents are being diligently prosecuted in the applicable patent offices in accordance with applicable Law and have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment;

(h) the Patents listed on Exhibit B constitute a true, accurate and complete list of all Licensed Patents in existence as of the Effective Date, and such Patents are free and clear of all mortgages, pledges, claims, liens, security interests and charges of any kind except as provided in the [***] Agreement with respect to the [***] Patents;

(i) Seres has (i) prosecuted and maintained each of the Licensed Patents in good faith and complied with all duties of disclosure with respect thereto and (ii) submitted all material prior art with respect to the Licensed Patents to the appropriate patent authority in each jurisdiction to the extent required by such patent authority;

(j) (i) Seres has made available to Licensee all material Regulatory Documentation owned or possessed by Seres regarding or related to the Collaboration Products, including, any minutes of meetings (including by teleconference) with Regulatory Authorities and any material correspondence with Regulatory Authorities, any notice of inspection, inspection report, warning letter, deficiency letter or similar communication and (ii) Seres has prepared, maintained or retained all material Regulatory Documentation relating to Collaboration Products that is required to be maintained or reported pursuant to Regulatory Authorities and such items have been prepared in accordance with the applicable requirements of GLP and GCP, as applicable, to the extent required, and applicable Law, and to Seres' knowledge, such Regulatory Documentation does not contain any materially false or misleading statements;

(k) to Seres' knowledge, none of Seres, any of its Affiliates, or any of their respective officers, employees or agents has made, with respect to the Collaboration Products existing as of the Effective Date, an untrue statement of a material fact to any Governmental

Authority or failed to disclose a material fact required to be disclosed to such Governmental Authority;

(l) (i) all individuals who participated in the invention or authorship of any of the inventions claimed in the Licensed Patents existing as of the Effective Date that are owned solely by Seres have made effective assignments to Seres of all ownership rights therein either pursuant to a written agreement or by operation of applicable Law and (ii) no Person who, to Seres' knowledge, claims to be an inventor of an invention claimed in a Licensed Patent is not identified as an inventor of such invention in the filed patent documents for such Licensed Patent;

(m) all Data with respect to the Collaboration Products that have been provided to a Regulatory Authority as of the Effective Date have been generated in compliance with applicable Laws, including GLP, GCP and GMP, in all material respects;

(n) the [***] Agreement is in full force and effect, and Seres and its Affiliates are, and to Seres' knowledge, [***] is, in compliance with the [***] Agreement;

(o) (i) all Development and Manufacturing activities conducted by or for the benefit of Seres and its Affiliates with respect to the Collaboration Products, have been and are being conducted in all material respects in compliance with all applicable Laws, including cGMP, and (ii) to Seres' knowledge, no contract manufacturer of Seres or its Affiliates with respect to the Collaboration Products has received any written communication from any Governmental authority that alleges that Seres, its Affiliates or such contract manufacturer is, with respect to the Collaboration Products, in violation of any applicable Law;

(p) to Seres' knowledge, in the course of the Development of the Collaboration Products existing as of the Effective Date, Seres has not used any employee or consultant who has been debarred by any Regulatory Authority, or was the subject of debarment proceedings by a Regulatory Authority, and to Seres' knowledge, no such employees or consultants have been used by any Third Party contractor of Seres in connection with the Development of such Collaboration Products;

(q) other than the Existing Agreement, neither Seres nor any of its Affiliates are bound by any non-competition agreements related to the Collaboration Products;

(r) Seres and its Affiliates have, and, to Seres' knowledge, their respective contractors, agents and consultants have, conducted all Development with respect to the Collaboration Products that has been conducted prior to the Effective Date in accordance with GLP, GCP, and GMP, to the extent applicable;

(s) Seres has disclosed to Third Parties the Licensed Know-How only pursuant to continuing obligations of confidentiality owed to Seres or its Affiliates for at least the duration of the Term, except as would not adversely affect Licensee's ability to Exploit the Collaboration Products in the Field in the Licensed Territory in any material respect; and

(t) Seres has disclosed to Licensee of all material safety issues arising in the Development of the Collaboration Products (including with respect to any of its ingredients) that

are known to Seres, and Seres has informed Licensee of all adverse drug reactions reported in all Clinical Studies that are known to Seres relating to the Collaboration Products or their use.

XV.3 Mutual Covenants. Each Party covenants to the other Party that:

(a) such Party shall, and shall require all Third Parties that it engages to perform activities directed to the Collaboration Products pursuant to this Agreement shall, comply in all material respects with all applicable Laws with respect to the performance of its activities and obligations under this Agreement and the Supply Agreement;

(b) it will not knowingly utilize, in conducting Development, Manufacturing or Commercialization of Collaboration Products, any Person that at such time is debarred by FDA or any other Regulatory Authority in the Licensed Territory, or that, at such time, is, to such Party's knowledge, under investigation by FDA for debarment action pursuant to the provisions of the Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335) or any other equivalent Laws in the Licensed Territory;

(c) all employees, officers, contractors, and consultants of such Party or its Affiliates performing activities in connection with this Agreement shall execute or have executed agreements requiring assignment to such Party of all right, title and interest in and to their inventions and discoveries invented or otherwise discovered or generated during the course of and as a result of such activities, whether or not patentable, if any, prior to commencing such activities;

(d) it, its subsidiaries, and its Affiliates at all times during the Term shall remain in compliance with, all applicable antibribery or anticorruption Laws. Neither such Party nor any of its subsidiaries or Affiliates will authorize, offer, promise, or make payments or otherwise provide anything of value directly or indirectly to: (i) an executive, official, employee or agent of a government, governmental department, agency or instrumentality, (ii) a director, officer, employee or agent of a wholly or partially government-owned or controlled entity, (iii) a political party or official thereof, or candidate for political office, or (iv) an executive, official, employee or agent of a public international organization ("**Government Official**") for purposes of (A) (1) improperly influencing any act or decision of such Government Official in his or her official capacity, (2) inducing such Government Official to do or omit to do any act in violation of the lawful duty of such Government Official, or (3) securing any improper advantage; or (B) inducing such Government Official improperly to use his or her influence in order to assist such Party or any of its subsidiaries or Affiliates in obtaining or retaining business or to direct business to any Person;

(e) its compensation programs for its Sales Representatives will not provide financial incentives that facilitate the promotion of Collaboration Products in violation of applicable Laws; and

(f) neither Party shall, during the Term, provide anything of value to any person that would reasonably be expected to be considered a bribe, kickback, an illegal influence payment, or other illegal payment.

XV.4 Seres Covenants. Seres will, and will cause its Affiliates to, (a) not breach or be in default under the [***] Agreement in a manner that would permit [***] to terminate the [***]

Agreement or otherwise diminish the scope or exclusivity of the sublicenses granted to Licensee under the [***] Patents; and (b) not amend the [***] Agreement in any manner that adversely affects Licensee's interests in the Collaboration Products pursuant to this Agreement without first obtaining Licensee's prior written consent. If Seres or its Affiliate receives notice of an alleged breach by Seres or its Affiliates under the [***] Agreement, then Seres will promptly provide written notice thereof to Licensee.

XV.5 EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OR VALIDITY OF ANY PATENTS ISSUED OR PENDING.

ARTICLE XVI
INDEMNIFICATION AND INSURANCE

XVI.1 Indemnification of Seres. Licensee shall indemnify and hold harmless each of Seres, its Affiliates and the directors, officers, and employees of such entities and the successors and assigns of any of the foregoing (the "**Seres Indemnitees**"), from and against any and all (a) liabilities, damages, penalties, fines, costs, expenses (including, reasonable attorneys' fees and other expenses of litigation) ("**Liabilities**") from any claims, actions, suits or proceedings brought by a Third Party (a "**Third Party Claim**") incurred by any Seres Indemnitee, arising from, or occurring as a result of: (i) the gross negligence of or willful misconduct of Licensee, its Affiliates, subcontractors or Sublicensees in performing any of Licensee's obligations under this Agreement; (ii) breach by Licensee of any representation, warranty, obligation or covenant as set forth in this Agreement; or (iii) any violation of applicable Law in connection with the performance of activities by Licensee or its Affiliates under this Agreement; or (b) Product Liability Losses arising from, or occurring as a result of any of the matters described in clause (a) of this Section 16.1, except, in each case (clauses (a) and (b)), to the extent such Third Party Claims arise from the circumstances for which Seres shall indemnify Licensee Indemnities pursuant to Section 16.2 or Section 16.3.

XVI.2 Indemnification of Licensee. Seres shall indemnify and hold harmless each of Licensee, its Affiliates and Sublicensees and the directors, officers and employees of such entities and the successors and assigns of any of the foregoing (the "**Licensee Indemnitees**"), from and against any and all (a) Liabilities from any Third Party Claims incurred by any Licensee Indemnitee, arising from, or occurring as a result of: (i) the Exploitation of any Collaboration Products by or on behalf of Seres, its Affiliates or licensees in the ROW Territory, or in the Licensed Territory prior to the Effective Date or after termination of this Agreement to the extent activities are conducted after termination, including any products liability claim arising therefrom; (ii) any Ongoing Clinical Studies and Additional Clinical Studies conducted unilaterally by Seres in accordance with Section 4.4(d); (iii) the gross negligence or willful misconduct of Seres, its Affiliates, subcontractors or sublicensees in connection with the performance of activities under this Agreement, including the license granted to Seres under Section 2.4; (iv) breach by Seres of any representation, warranty, obligation or covenant as set forth in this Agreement; or (v) any violation of applicable Law in connection with the performance of activities by Seres or its Affiliates under this Agreement; or (b) Product Liability Losses arising from, or occurring as a

result of any of the matters described in clause (a) of this Section 16.2; except, in each case (clauses (a) and (b)), to the extent such Third Party Claim arises from the circumstances for which Licensee shall indemnify Seres Indemnities pursuant to Section 16.1.

XVI.3 Indemnification for Infringement of IP. Seres shall indemnify and hold harmless each of the Licensee Indemnitees from and against any and all Liabilities incurred by any Licensee Indemnitee arising from, or occurring as a result of, (a) Third Party Claims relating to [***], or (b) Third Party Challenges arising from [***], provided that [***], and therefore shall be excluded from the Liabilities to which Licensee is entitled to indemnification by Seres under this Section 16.3.

XVI.4 **Procedure**. A Party that intends to claim indemnification under Section 16.1, Section 16.2 or Section 16.3 (the "**Indemnitee**") shall promptly notify the other Party (the "**Indemnitor**") in writing of any Third Party Claim, in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense and/or settlement, provided the [***] and provided, further, that the Indemnitor shall keep the Indemnitee regularly informed of the status of the defense of the Third Party Claim and shall take into consideration the Indemnitee's reasonable comments thereon. The Indemnitor shall retain counsel reasonably acceptable to the Indemnitee (such acceptance not to be unreasonably withheld, refused, conditioned or delayed) to represent the Indemnitee and [***]. In any such proceeding, the Indemnitee shall have the right to participate (but not control) and be represented in any suit or action by advisory counsel of its selection and [***]. The indemnity arrangement in this Section 16.4 shall [***]. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall not relieve such Indemnitor of any liability to the Indemnitee under this Article 16 except to the extent that the Indemnitor is materially prejudiced thereby. The Indemnitee under this Section 16.4 shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Third Party Claim covered by this indemnification. Notwithstanding the foregoing, if the Indemnitor notifies the Indemnitee in writing that it does not intend to assume the defense of any Third Party Claim subject to indemnification hereunder in accordance with the foregoing or fails to assume the defense of any Third Party Claim at least [***] before any deadline the passing of which could adversely affect the outcome without responsive action by or on behalf of the Indemnitee (or, if the Indemnitor receives less than [***] notice of such deadline, if it fails to assume such defense as soon as practicable following receipt of notice), the Indemnitee shall have the right to assume and control such defense and shall have the right to settle or compromise the same without the Indemnitor's consent, and [***] by the Indemnitee in connection therewith, including [***].

XVI.5 **Indemnification of** [***]. Licensee agrees to indemnify and hold harmless [***] and its trustees, directors, officers, medical and professional staff, employees, students, and agents, and their respective successors, heirs and assigns from any claims covered by Section 10.1 of the [***] Agreement arising out of or resulting from the performance of activities by or on behalf of Licensee under this Agreement in the Licensed Territory; [***].

XVI.6 **Disclaimer of Liability for Consequential Damages**. EXCEPT WITH RESPECT TO BREACH OF CONFIDENTIALITY OBLIGATIONS UNDER SECTIONS 10.1-10.3, AND WITHOUT LIMITING THE PARTIES' INDEMNITY OBLIGATIONS UNDER

SECTIONS 16.1, 16.2 AND 16.3, IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS RESPECTIVE AFFILIATES AND THEIR RESPECTIVE OFFICERS, DIRECTORS AND EMPLOYEES BE LIABLE UNDER THIS AGREEMENT TO THE OTHER PARTY FOR SPECIAL, EXEMPLARY, INDIRECT, PUNITIVE, DAMAGES BASED UPON A MULTIPLE OF EARNINGS, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS, LOSS OF USE, DAMAGE TO GOODWILL, OR LOSS OF BUSINESS) SUFFERED BY THE OTHER PARTY UNDER THIS AGREEMENT, OF ANY KIND WHATEVER AND HOWEVER CAUSED, AND WHETHER BASED ON AN ACTION OR CLAIM IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT LIABILITY), BREACH OF STATUTORY DUTY OR OTHERWISE, AND EVEN IF FORESEEABLE OR SUFFERED IN CIRCUMSTANCES WHERE A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSSES.

XVI.7 During the Term and thereafter for a period of [***], each Party shall procure and maintain adequate insurance coverage with international reputable company(ies) or a program of self-insurance (which shall be of types and amounts sufficient to cover the liabilities hereunder, contingent or otherwise of such Party and its Affiliates, including product liability insurance and have such terms as are customary in the biopharmaceutical industry in the Licensed Territory). Any Party maintaining any such Third Party insurance coverage shall ensure that the other Party is named as an additional insured thereunder and shall provide a certificate evidencing such coverage to the other Party upon request. It is understood that such insurances shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article XVI. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least [***] prior to the cancellation, non-renewal or material change in such insurance.

ARTICLE XVII
DISPUTE RESOLUTION

XVII.1Referral to Senior Executives. The Parties recognize that a dispute arising out of or in connection with this Agreement ("**Dispute**") may from time to time arise during the Term. Any such Dispute which cannot be resolved by good faith negotiations shall be referred, by written notice from either Party to the other, to the Senior Executives (or their respective designees) for resolution. Except with respect to matters subject to a Party's final decision-making authority under Section 3.4(b)(iv)(A) and Section 3.4(b)(iv)(B), the Senior Executives (or their respective designees) shall negotiate in good faith to resolve such Dispute through discussions promptly following such written notice. If the Senior Executives cannot resolve the Dispute within [***] of such written notice, or either Party concludes that the matter will not be so resolved, then the provisions of Section 17.2 shall apply; provided that any Disputes regarding a Party's proper use of its casting vote under Section 3.4(b)(iv) shall also be subject to Section 17.2. If the Parties should resolve such Dispute pursuant to the procedures in this Section 17.1, a memorandum setting forth their agreement will be prepared and signed by both Parties, if requested by either Party.

XVII.2Arbitration. Subject to Sections 17.2(f) and 17.2(g), any Dispute not resolved under Section 17.1 (and not subject to a Party's final decision-making authority under Section 3.4(b)(iv)(A) and Section 3.4(b)(iv)(B)) or any Dispute about a Party's proper use of its casting vote under Section 3.4(b)(iv), as well as any related claims or other disputes arising out of or in

connection with this Agreement including any question regarding its existence, validity or termination, whether for breach of contract, tortious conduct or otherwise and whether predicated on common law, statute or otherwise (collectively, the "**Related Claims**") shall thereafter be referred to and finally resolved by arbitration under the London Court of International Arbitration (the "**LCIA**") rules (the "**Rules**"), which Rules are deemed to be incorporated by reference into this clause. The number of arbitrators shall be [***], appointed in accordance with the Rules. The seat or legal place of arbitration shall be London, England. The language to be used in the arbitral proceedings shall be English.

(a) Within [***] after the appointment of the arbitrator by the LCIA, the arbitrator and the Parties shall meet, and each Party shall provide to the arbitrator a written summary of: [***]. The arbitrator shall set a date for a hearing, which shall be no later than [***] after the appointment of the arbitrator by the LCIA, for the presentation of evidence and legal arguments concerning each of the issues identified by the Parties; provided, however, that the Parties may jointly agree in writing to extend the foregoing deadlines, or the arbitrator may unilaterally extend this deadline if he or she determines in his or her sole discretion that this is required in the interests of justice.

(b) The arbitrator shall use his or her best efforts to rule on each disputed issue within [***] after the completion of the hearing described in Section 17.2(a); provided, however, that the Parties may jointly agree in writing to extend the foregoing deadlines, or the arbitrator may unilaterally extend this deadline if he or she determines in his or her sole discretion that this is required in the interests of justice. Nothing contained herein shall be construed to permit the arbitrator to: [***].

(c) The arbitration proceedings, the facts and circumstances surrounding the underlying dispute, and any awards issued by the arbitrator shall be kept confidential by the Parties, and the Parties shall work with the arbitrator to take such steps as are reasonably necessary to preserve the confidentiality thereof, except to the extent otherwise required by applicable Law.

(d) The arbitrator shall have the power to grant any remedy or relief that he or she deems just and equitable, including but not limited to [***].

(e) Any award rendered by the arbitrator shall be final and binding on the Parties, and each Party hereto waives to the fullest extent permitted by law any right it may otherwise have under the laws of any jurisdiction to any form of appeal of, or collateral attack against, such award. Judgment upon any awards rendered by the arbitrator may be entered in any court having jurisdiction thereof, including any court having jurisdiction over any of the parties or their assets.

(f) Notwithstanding anything in this Section 17.2, any dispute to determine [***] shall be [***].

(g) The Parties agree that any arbitration proceeding commenced pursuant to this Section 17.2 shall, to the extent possible, be consolidated with any arbitration proceedings commenced under the Existing Agreement, such that all disputes and claims arising under both of these agreements will, to the extent possible, be heard and resolved by the same arbitration

panel. Whether to consolidate two or more arbitration proceedings shall be subject to the final approval of the arbitration panel constituted in the arbitration that is filed first.

ARTICLE XVIII
GENERAL PROVISIONS

XVIII.1 Force Majeure. If the performance of any part of this Agreement (except for any payment obligation under this Agreement) by either Party is prevented, restricted, interfered with or delayed by reason of any cause beyond the reasonable control of such Party (including, fire, flood, earthquake, tsunami, embargo, power shortage or failure, acts of war, insurrection, riot, terrorism, strike, lockout or other labor disturbance, acts of God, epidemic, or pandemic), the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay; provided that the affected Party shall use its reasonable efforts to avoid or remove such causes of non-performance and mitigate the effect of such occurrence and shall continue performance with the utmost dispatch whenever such causes are removed. When such circumstances arise, the Parties shall negotiate in good faith any modifications of the terms of this Agreement that may be necessary or appropriate in order to arrive at an equitable solution.

XVIII.2 Governing Law. This Agreement and all questions regarding its validity or interpretation, or the breach or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of the Commonwealth of Massachusetts, without reference to conflict of law principles. The Parties hereby agree that the provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement and are strictly excluded.

XVIII.3 Waiver of Breach. The failure of either Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

XVIII.4 Modification. No amendment or modification of any provision of this Agreement shall be effective unless in writing signed by both Parties hereto. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by both Parties hereto.

XVIII.5 Severability. In the event any provision of this Agreement should be held invalid, illegal, or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions of this Agreement shall remain in full force and effect in such jurisdiction. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

XVIII.6 Entire Agreement; Amendments. This Agreement (including the Exhibits attached hereto), together with the Existing Agreement, the Quality Agreement, the Supply

Agreement and the Pharmacovigilance Agreement (in each case, when executed) constitute the entire agreement between the Parties relating to the subject matter hereof and supersede all prior and contemporaneous agreements, representations and/or understandings. No terms or provisions of this Agreement shall be varied or modified by any prior or subsequent statement, conduct or act of either of the Parties, except that the Parties may amend this Agreement by written instruments specifically referring to and executed in the same manner as this Agreement.

XVIII.7 Notices. Unless otherwise agreed by the Parties or specified in this Agreement, all communications between the Parties relating to, and all written documentation to be prepared and provided under, this Agreement shall be in the English language. Any notice required or permitted under this Agreement shall be (a) delivered personally, (b) sent by air mail or express courier service providing evidence of receipt, postage pre-paid where applicable, or (c) sent by electronic transmission or facsimile (complete transmission confirmed and a copy promptly sent by another permissible method of providing notice described in clause (a) or (b) above), to the following addresses of the Parties (or such other address for a Party as may be specified by like notice):

To Seres:
Seres Therapeutics, Inc.
200 Sidney Street
Cambridge, MA 02139

Attention:

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

Latham & Watkins LLP
John Hancock Tower
200 Clarendon Street
Boston, MA 02116
Attention: [***]

To Licensee:
NHSc Pharma Partners
c/o Société des Produits Nestlé S.A.
55 Avenue Nestle
1800 Vevey, Switzerland
Email: [***]
Attention: [***]

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

Mayer Brown LLP
1221 Avenue of the Americas
New York, NY 10020
Email: [***]
Attention: [***]

Any notice required or permitted to be given concerning this Agreement shall be effective upon receipt by the Party to whom it is addressed.

XVIII.8 Assignment. Neither this Agreement nor any of the rights or obligations created herein may be assigned by either Party, in whole or in part, without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed except that either Party shall be free to assign this Agreement (a) to an Affiliate of such Party (for clarity, such assignment to an Affiliate will terminate, and all rights so assigned will revert to the assigning Party, if and at the time such Affiliate ceases to be an Affiliate of the assigning Party) provided that such Party shall remain liable and responsible to the other Party for the performance and observance of all such duties and obligations by such Affiliate, or (b) in connection with any merger, consolidation or sale of such Party or sale of all or substantially all of the assets of the Party that relate to this Agreement, in each case without the prior consent of the non-assigning

Party. Any assignment of this Agreement in contravention of this Section 18.8 is null and void. This Agreement shall bind and inure to the benefit of the successors and permitted assigns of the Parties hereto. Notwithstanding anything to the contrary in this Agreement, in the event of any permitted assignment under this Section 18.8, [***].

XVIII.9 **Change of Control**. If there is a Change of Control, then the Party experiencing such Change of Control ("**Acquired Party**") shall provide written notice thereof to the other Party ("**Non-Acquired Party**") within [***] after completion of such Change of Control, subject to any confidentiality obligations of the Acquired Party then in effect. Following consummation of the Change of Control, the Non-Acquired Party and the Change of Control Group shall adopt in writing reasonable procedures to prevent the disclosure of Non-Acquired Party's Know-How, Patents, or Confidential Information, or Joint Intellectual Property (collectively, "**Sensitive Information**") beyond the Acquired Party's personnel who need to know the Sensitive Information solely for the purpose of fulfilling the Acquired Party's obligations under this Agreement. In the event that the Change of Control Group is engaged in [***] (a "**Competing Program**"), then the Acquired Party shall promptly inform the Non-Acquired Party thereof in writing. The Acquired Party shall [***]. If the Acquired Party is Seres, [***]. The term "separate" means, for the purposes of this Section, with respect to a Competing Program, to separate the development and commercialization activities relating to such Competing Program from Development and Commercialization activities with respect to any Collaboration Products by [***]. Without limiting the foregoing, in the event of a Change of Control, the Acquired Party shall take all reasonable actions to ensure compliance with anti-trust and competition laws in connection with the disclosure, sharing, use and storage of Information.

XVIII.10 **Performance**. Unless expressly otherwise provided hereunder, each Party may perform its obligations hereunder through its Affiliates or Third Party subcontractors, provided that such Party shall have entered into a written agreement with its subcontractors which shall be consistent with the terms and conditions of this Agreement, and shall contain confidentiality and non-use provisions no less restrictive than those set forth in Article 10. Notwithstanding the foregoing, such Party shall remain liable under this Agreement for the performance of all its obligations under this Agreement by its Affiliates and Third Party subcontractors, and shall be responsible for and liable for compliance by its Affiliates and Third Party subcontractors with the applicable provisions of this Agreement.

XVIII.11 **No Partnership or Joint Venture**. Nothing in this Agreement is intended, or shall be deemed, to establish a joint venture or partnership between Licensee and Seres. Neither Party to this Agreement shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, or to bind the other Party to any contract, agreement or undertaking with any Third Party.

XVIII.12 **Interpretation**. The captions to the several Articles and Sections of this Agreement are not a part of this Agreement, but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) the word "or" shall be interpreted to mean "and/or" unless the context requires otherwise; (c) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear; and (d) the singular shall include the plural and

vice versa. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under GAAP, but only to the extent consistent with its usage and the other definitions in this Agreement. This Agreement shall not confer any benefits on any Third Parties and no Third Party may enforce any term of this Agreement.

XVIII.13 **Compliance with Laws**. Notwithstanding anything to the contrary contained herein, all obligations of Seres and Licensee are subject to compliance with all applicable Laws, such as but not limited to export, anti-corruption, Data Protection Law, anti-trust or competition laws, and to obtaining all necessary approvals required by the applicable agencies of the United States government, and any other relevant countries. Seres and Licensee shall cooperate with each other and shall provide assistance to the other as reasonably necessary to obtain any required approvals.

XVIII.14 **Counterparts; Other Matters**. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Signatures to this Agreement delivered by facsimile or similar electronic transmission will be deemed to be binding as originals. This Agreement is established in the English language. Any translation in another language shall be deemed for convenience only and shall never prevail over the original English version.

[Signature Page Follows]

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

Seres Therapeutics, Inc.

BY: /s/ Eric D. Shaff
NAME: Eric D. Shaff
TITLE: CEO

NHSc Pharma Partners
By: Société des Produits Nestlé S.A,
Its: Managing Partner

BY: [***]
NAME: [***]
TITLE: [***]

EXHIBIT A

FTE RATES

[***]

EXHIBIT B

LICENSED PATENTS

[***]

EXHIBIT C

DEVELOPMENT AND REGULATORY ACTIVITY PLAN

[***]

EXHIBIT D

PRE-LAUNCH PLAN

[***]

EXHIBIT E

SER-109 LAUNCH PLAN AND BUDGET

[***]

EXHIBIT F

TERMS OF SUPPLY AGREEMENT

[***]

EXHIBIT G

PRESS RELEASE

SERES THERAPEUTICS, NESTLÉ HEALTH SCIENCE ANNOUNCE SER-109 CO-COMMERCIALIZATION LICENSE AGREEMENT

- Companies Agree to Jointly Commercialize SER-109 Investigational Microbiome Therapeutic to Treat Recurrent *C. difficile* Infection, Leading the Way for Entirely New Treatment Modality
- Deal calls for more than $500 million in upfront and contingent milestone payments
- Seres Therapeutics to conduct a conference call at 8:30 a.m. ET

CAMBRIDGE, Mass. and LAUSANNE, Switzerland -- July 1, 2021 -- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, announced today that it has entered into an agreement with Nestlé Health Science to jointly commercialize SER-109, Seres' investigational oral microbiome therapeutic for recurrent *Clostridioides difficile* infection (CDI), in the United States (U.S.) and Canada. If approved, SER-109 would become the first-ever FDA-approved microbiome therapeutic.

Under the terms of the agreement, Nestlé Health Science will utilize its global pharmaceutical business Aimmune Therapeutics and will assume the role of lead commercialization party. Seres will receive license payments of $175 million up front, and an additional $125 million upon FDA approval of SER-109. The agreement also includes sales target milestones which, if achieved, could total up to $225 million. Seres will be responsible for development and pre-commercialization costs in the U.S. Upon commercialization, Seres will be entitled to an amount equal to 50% of the commercial profits.

The agreement to co-commercialize SER-109 in the U.S. and Canada represents the expansion of an existing strategic collaboration between the companies. Nestlé Health Science already has commercial rights to Seres' investigational treatments for CDI and inflammatory bowel disease outside of the U.S. and Canada, and with this expansion, Nestlé Health Science becomes Seres' global collaborator in SER-109.

A leading cause of hospital-acquired infections in the U.S., CDI is associated with debilitating diarrhea and claims the lives of more than 20,000 Americans each year. SER-109 is comprised of purified Firmicutes spores, based on their modulatory role in the life cycle of *C. difficile* and disease pathogenesis. The bacterial consortium in SER-109 rapidly repopulates the microbiome in the gut to produce compositional and functional changes that are critical to a sustained clinical response.

“Nestlé Health Science has been a terrific collaborator in our quest to develop a new treatment option for patients suffering from recurrent *C. difficile* infection, and their support over the past few years has been critical in advancing SER-109 to address this unmet need,” Seres Therapeutics CEO, Eric Shaff, said. "We conducted a competitive process to select a collaborator for SER-109. As we prepare for potential approval and commercialization, we are

eager to embark side-by-side on our next phase with a company that believes as fervently as we do in the potential of this transformative approach to reduce the recurrence of CDI."

"We are excited to expand our existing collaboration with Seres Therapeutics at this pivotal time, given the promise SER-109 holds for patients trapped in the debilitating cycle of recurrent *C. difficile* infection," CEO of Nestlé Health Science, Greg Behar, added. "Nestlé Health Science is focused on the fast-developing areas of gut health, food allergies and metabolic health within our global pharmaceutical business, Aimmune Therapeutics. We look forward to leveraging Aimmune's existing, fully integrated commercial infrastructure and capability to launch this important medicine, once approved."

Nestlé Health Science continues to make significant investments in innovation while leveraging leading-edge science. Its pharma arm, Aimmune Therapeutics, has a strong presence in the field of gastroenterology, allowing it to lead the commercialization of SER-109 while providing Seres the ability to retain a strategic role and actively participate in the launch.

SER-109 Clinical & Regulatory Milestones

- In August 2020, Seres announced that SER-109 had met the primary endpoint from the pivotal Phase 3 ECOSPOR III study, showing a highly statistically significant reduction in the rate of CDI recurrence compared to placebo at 8 weeks, with an absolute reduction of 27% and a relative risk reduction of 68%. In a separate measure, approximately 88% of patients achieved sustained clinical response at week 8.
- The Company expects that the ECOSPOR III efficacy results should support a BLA filing as a single pivotal trial once the SER-109 safety database includes at least 300 treated subjects monitored for 24 weeks, based on feedback from the FDA.
- A SER-109 open-label study is ongoing and continues to contribute to the SER-109 safety database. Completion of target enrollment is anticipated in Q3 of 2021.

Responsibility for oversight of activities to support SER-109 will be governed by a Joint Steering Committee composed of an equal number of members from each company. Seres is responsible for the manufacturing and supply of SER-109 for all geographies contemplated in the collaboration in addition to ex-North America. Seres will lead medical affairs activities pre-launch and Aimmune Therapeutics will lead commercialization and medical affairs activities post-launch.

Conference Call Information

Seres' management team will host a conference call today, July 1, 2021, at 8:30 a.m. ET. To access the conference call, please dial 844-277-9450 (domestic) or 336-525-7139 (international) and reference the conference ID number 5382249. To join the live webcast, please visit the "Investors and News" section of the Seres website at www.serestherapeutics.com.

A webcast replay will be available on the Seres website beginning approximately two hours after the event and will be archived for at least 21 days.

About Seres Therapeutics
Seres Therapeutics, Inc., (Nasdaq: MCRB) is a leading microbiome therapeutics company

developing a novel class of multifunctional bacterial consortia that are designed to functionally interact with host cells and tissues to treat disease. Seres' SER-109 program achieved the first-ever positive pivotal clinical results for a targeted microbiome drug candidate and has obtained Breakthrough Therapy and Orphan Drug designations from the FDA. The SER-109 program is being advanced for the treatment of recurrent *C. difficile* infection and has potential to become a first-in-class FDA-approved microbiome therapeutic. Seres' SER-287 program has obtained Fast Track and pediatric Orphan Drug Designations from the FDA and is being evaluated in a Phase 2b study in patients with active mild-to-moderate ulcerative colitis. Seres is evaluating SER-301 in a Phase 1b study in patients with ulcerative colitis and SER-155 in a Phase 1b study to address gastrointestinal infections, bacteremia and graft-versus-host disease. For more information, please visit www.serestherapeutics.com.

About Nestlé Health Science and Aimmune Therapeutics

Nestlé Health Science, a leader in the science of nutrition, is a globally managed business unit of Nestlé. We are committed to redefining the management of health, offering an extensive portfolio of science-based consumer health, medical nutrition, pharmaceutical therapies, and vitamin and supplement brands. Our extensive research network provides the foundation for products that empower healthier lives through nutrition. Headquartered in Switzerland, we have more than 7,000 employees around the world, with products available in more than 140 countries. www.nestlehealthscience.com

Aimmune Therapeutics, Inc., a Nestlé Health Science Company, is a biopharmaceutical company developing and commercializing treatments for potentially life-threatening gastrointestinal, metabolic, and food-mediated allergic conditions. www.aimmune.com

Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including our development plans; the timing and results of the SER-109 safety data; the ability of our clinical trials to support approval of SER-109; the size of the market for SER-109; our ability to achieve the targets and receive any milestones payments from Nestlé Health Science; Nestlé Health Science's obligation to share responsibility and costs for the commercialization of SER-109; and the potential benefits of our collaboration with Nestlé Health Science.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but 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, including, but not limited to, the following: we have incurred significant losses, are not currently profitable and may never become profitable; our need for additional funding; our limited operating history; the impact of the COVID-19 pandemic; our unproven approach to therapeutic intervention; the lengthy, expensive and uncertain process of clinical drug development; our reliance on third parties and collaborators to conduct our clinical trials, manufacture our product candidates and develop and commercialize our product candidates, if approved; and our ability to retain key personnel and to manage our growth. These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on May 4, 2021, and our other reports filed with the SEC could cause

actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

Seres Therapeutics:
PR Contact

Kristin Ainsworth
kainsworth@serestherapeutics.com

IR Contact

Carlo Tanzi, Ph.D.
ctanzi@serestherapeutics.com

Nestlé Health Sciences:

PR/IR Contact:

Jacquelyn Campo
Jacquelyn.Campo@Nestle.com

EXHIBIT 10.2

Seres Therapeutics, Inc.
200 Sidney Street
Cambridge, MA 02139

November 4, 2021

Dear Dr. Ege,

Seres Therapeutics, Inc. (the "***Company***") has agreed to pay you a one-time special cash bonus in the lump sum amount of $131,000 (the "***Special Bonus***"), less tax withholdings required by law, subject to the terms hereof. The Special Bonus will be paid to you within thirty (30) days following the date of this letter, subject to your continued service to the Company until the date of the payment of the Special Bonus.

In the event that your employment with the Company is terminated by the Company for Cause or by your resignation without Good Reason (as such capitalized terms are defined in the Amended and Restated Employment Agreement, dated January 29, 2021, by and between the Company and you), in either case, within two years following the payment of the Special Bonus, you will, within ten (10) days following your termination, repay to the Company the net amount of the Special Bonus paid to you. You agree that the Company may, but will not be required to, deduct the amount of the Special Bonus you are required to repay from any other amounts payable by the Company to you on an after-tax basis.

This letter agreement may be amended only by an instrument in writing signed by the parties hereto, and any provision hereof may be waived only by an instrument in writing signed by the party against whom or which enforcement of such waiver is sought. This letter agreement is binding on and is for the benefit of the parties hereto and their respective successors, assigns, heirs, executors, administrators and other legal representatives. You may not assign, transfer, alienate, sell, pledge or encumber, whether voluntarily, involuntarily or by operation of law your rights under this letter agreement. This letter agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to conflict of law principles that would result in the application of any law other than the law of the Commonwealth of Massachusetts. This letter agreement constitutes the entire agreement among the parties hereto with respect to the subject matter hereof, and supersedes any prior understandings or agreements with respect thereto. This letter agreement may be executed in several counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same instrument. A facsimile, email, .pdf or other electronic transmission of a signature shall be deemed to be and have the effect of an original signature.

Please indicate your acknowledgement of, and agreement with, the foregoing by countersigning the enclosed copy of this letter in the space provided below and returning the same to the Company.

Sincerely,
Seres Therapeutics, Inc.

By: /s/ Thomas J. DesRosier
Name: Thomas J. DesRosier
Title: Chief Legal Officer and Executive Vice President

Accepted and agreed:

/s/ David Ege
David Ege, Ph.D.

SERES THERAPEUTICS, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

(as amended effective June 16, 2021)

Non-employee members of the board of directors (the "***Board***") of Seres Therapeutics, Inc. (the "***Company***") shall receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program (this "***Program***"). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "***Non-Employee Director***") who is entitled to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors. No Non-Employee Director shall have any rights hereunder, except with respect to stock options granted pursuant to the Program. This Program shall become effective on the date of the effectiveness of the Company's Registration Statement on Form S-1 relating to the initial public offering of common stock (the "***Effective Date***").

I. CASH COMPENSATION

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

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

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

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

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

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

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

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

II. Equity Compensation

Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Company's 2015 Incentive Award Plan or any other applicable Company equity incentive plan then-maintained by the Company (the "***Equity Plan***") and shall be granted subject to award agreements, including attached exhibits, in substantially the form previously approved by the Board. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein, and all grants of stock options hereby are subject in all respects to the terms of the Equity Plan and the applicable award agreement. For the avoidance of doubt, the share numbers in Sections II(A) and II(B) shall be subject to adjustment as provided in the Equity Plan, including without limitation with respect to any stock dividend, stock split, reverse stock split or other similar event affecting the Company's common stock that is effected prior to the Effective Date.

A. Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall receive an option to purchase 35,000 shares of the Company's common stock on the date of such initial election or appointment. The awards described in this Section II(A) shall be referred to as "***Initial Awards***." No Non-Employee Director shall be granted more than one Initial Award.

B. Subsequent Awards. A Non-Employee Director who (i) has been serving as a Non-Employee Director on the Board for at least six months as of the date of any annual meeting of the Company's stockholders after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall be automatically granted an option to purchase 23,000 shares of the Company's common stock on the date of such annual meeting. The awards described in this Section II(B) shall be referred to as "***Subsequent Awards***." For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an annual meeting of the Company's stockholders shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Award on the date of such meeting as well.

C. Termination of Service of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section II(A) above, but to the extent

that they are otherwise entitled, will receive, after termination from service with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section II(B) above.

D. Terms of Awards Granted to Non-Employee Directors

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

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

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

* * * * *

Exhibit 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 10, 2021

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 10, 2021

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, 2021 (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 10, 2021

/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, 2021 (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 10, 2021

/s/ David Arkowitz

David Arkowitz

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