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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

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)

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, 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	☐	Small 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 ☒

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 Global Select Market

As of April 24, 2019, the registrant had 41,094,832 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, 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 Quarterly 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 Quarterly Report titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward looking statements are subject to numerous risks, including, without limitation, the following:

- our status as a clinical-stage company and our expectation to incur losses in the future;
- our future capital needs and our need to raise additional funds, including our ability to continue as a going concern;
- our ability to build a pipeline of product candidates and develop and commercialize drugs;
- our unproven approach to therapeutic intervention;
- our ability to enroll patients in clinical trials, timely and successfully complete those trials and receive necessary regulatory approvals;
- the effect that the reduction in trial size for our ECOSPOR III trial will have on the results of the trial;
- our ability to maintain our manufacturing facilities and to receive or manufacture sufficient quantities of our product candidates;
- our ability to protect and enforce our intellectual property rights;
- federal, state, and foreign regulatory requirements, including U.S. Food and Drug Administration regulation of our product candidates;
- our ability to obtain and retain key executives and attract and retain qualified personnel; and
- our ability to successfully manage our growth.

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.

PART I – FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (unaudited)

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

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 53,600	$ 85,820
Accounts receivable	6,667	—
Prepaid expenses and other current assets	7,488	6,845
Total current assets	67,755	92,665
Property and equipment, net	24,571	26,294
Operating lease assets	13,202	—
Restricted investments	1,400	1,400
Restricted cash	114	113
Total assets	$ 107,042	$ 120,472
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 3,918	$ 6,415
Accrued expenses and other current liabilities	11,789	15,207
Operating lease liabilities	4,407	—
Deferred revenue - related party	18,685	20,419
Deferred revenue	2,770	—
Total current liabilities	41,569	42,041
Operating lease liabilities, net of current portion	19,066	—
Lease incentive obligation, net of current portion	—	6,776
Deferred rent	—	2,216
Deferred revenue, net of current portion - related party	111,959	116,840
Deferred revenue, net of current portion	3,637	—
Other long-term liabilities	644	644
Total liabilities	176,875	168,517
Commitments and contingencies (Note 11)		
Stockholders' deficit:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2019 and December 31, 2018; no shares issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at March 31, 2019 and December 31, 2018; 41,094,832 and 40,936,735 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	41	41
Additional paid-in capital	343,829	341,284
Accumulated deficit	(413,703)	(389,370)
Total stockholders' deficit	(69,833)	(48,045)
Total liabilities and stockholders' deficit	$ 107,042	$ 120,472

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

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

	Three Months Ended March 31,	
	2019	**2018**
Revenue:		
Collaboration revenue - related party	$ 6,615	$ 3,766
Grant revenue	446	205
Revenue	260	—
Total revenue	7,321	3,971
Operating expenses:		
Research and development expenses	22,887	23,460
General and administrative expenses	7,495	8,777
Restructuring expenses	1,492	—
Total operating expenses	31,874	32,237
Loss from operations	(24,553)	(28,266)
Other income (expense):		
Interest income (expense), net	220	347
Total other income (expense), net	220	347
Net loss	$ (24,333)	$ (27,919)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.59)	$ (0.69)
Weighted average common shares outstanding, basic and diluted	41,027,824	40,628,434
Net loss	(24,333)	(27,919)
Other comprehensive income:		
Unrealized gain on investments, net of tax of $0	$ —	$ 40
Total other comprehensive income	—	40
Comprehensive loss	$ (24,333)	$ (27,879)

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Par Value				
Balance at December 31, 2017	40,571,015	$ 40	$ 324,376	$ (263,571)	$ (146)	$ 60,699
Issuance of common stock upon exercise of stock options	48,053	—	32	—	—	32
Issuance of common stock upon vesting of RSUs, net of tax withholdings	51,500	—	—	—	—	—
Repurchase of common stock for employee tax withholdings	(17,900)	—	(197)	—	—	(197)
Stock-based compensation expense	—	—	4,236	—	—	4,236
Unrealized gain on investments	—	—	—	—	40	40
Adoption of new revenue standard (ASC 606)	—	—	—	(26,857)	—	(26,857)
Net loss	—	—	—	(27,919)	—	(27,919)
Balance at March 31, 2018	40,652,668	$ 40	$ 328,447	$ (318,347)	$ (106)	$ 10,034

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Par Value			
Balance at December 31, 2018	40,936,735	$ 41	$ 341,284	$ (389,370)	$ (48,045)
Issuance of common stock upon exercise of stock options	38,125	—	120	—	120
Issuance of common stock upon vesting of RSUs	73,500	—	153	—	153
Issuance of common stock under ESPP plan	46,472	—	207	—	207
Stock-based compensation expense	—	—	2,065	—	2,065
Net loss	—	—	—	(24,333)	(24,333)
Balance at March 31, 2019	41,094,832	$ 41	$ 343,829	$ (413,703)	$ (69,833)

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

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

	Three Months Ended March 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (24,333)	$ (27,919)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,065	4,236
Depreciation and amortization expense	2,006	1,941
Amortization of operating lease asset	535	-
Accretion of discount on investments	—	(50)
Changes in operating assets and liabilities:		
Accounts receivable	(6,667)	-
Prepaid expenses and other current assets	(643)	835
Deferred revenue	(208)	(3,592)
Accounts payable	(2,474)	(1,426)
Operating lease liabilities	(1,024)	—
Accrued expenses and other current liabilities	(1,650)	(788)
Net cash (used in) operating activities	(32,393)	(26,763)
Cash flows from investing activities:		
Purchases of property and equipment	(306)	(953)
Purchases of investments	—	(5,270)
Sales and maturities of investments	—	44,257
Net cash (used in) provided by investing activities	(306)	38,034
Cash flows from financing activities:		
Proceeds from exercise of stock options	120	32
Proceeds from issuance of common stock and restricted common stock	153	—
Payments of employee tax obligations related to vesting of restricted stock units	—	(197)
Issuance of common stock under ESPP plan	207	—
Net cash provided by (used in) financing activities	480	(165)
Net (decrease) increase in cash and cash equivalents	(32,219)	11,106
Cash, cash equivalents and restricted cash at beginning of period	85,933	37,601
Cash, cash equivalents and restricted cash at end of period	$ 53,714	$ 48,707
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment purchases included in accounts payable and accrued expenses	$ 134	$ 393

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

1. Nature of the Business and Basis of Presentation

Seres Therapeutics, Inc. (the "Company") was incorporated under the laws of the State of Delaware in October 2010 under the name Newco LS21, Inc. In October 2011, the Company changed its name to Seres Health, Inc., and in May 2015, the Company changed its name to Seres Therapeutics, Inc. The Company is a microbiome therapeutics platform company developing a novel class of biological drugs, which are designed to treat disease by restoring the function of a dysbiotic microbiome. The Company is developing SER-287 to treat ulcerative colitis ("UC"), a form of inflammatory bowel disease ("IBD"). SER-109, is designed to reduce recurrences of *Clostridium difficile*, or *C. difficile* infection ("CDI"), a debilitating infection of the colon, in patients who have received antibiotic therapy for recurrent CDI by treating the dysbiosis of the colonic microbiome, which, if approved by the U.S. Food and Drug Administration ("FDA"), could be a first-in-field oral microbiome drug. In addition, using its microbiome therapeutics platform, the Company is developing product candidates to treat diseases where the microbiome is implicated, including SER-301, a rationally designed, fermented IBD candidate, and SER-401, a microbiome therapeutic candidate for use with checkpoint inhibitors in patients with metastatic melanoma. The Company is also using its microbiome therapeutics platform to conduct research on various indications, including: infectious diseases, metabolic diseases, and inflammatory and immune diseases, including immuno-oncology.

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 candidates developed will obtain necessary government regulatory approval or that any approved products 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 March 31, 2019, the Company had an accumulated deficit of $413.7 million and cash and cash equivalents of $53.6 million. Management has assessed the Company's ability to continue as a going concern in accordance with the requirements of ASC 205-40 and determined that the Company's accumulated deficit, history of losses, and future expected losses meet the ASC 205-40 standard for raising substantial doubt about the Company's ability to continue as a going concern within one year of the issuance date of these condensed consolidated financial statements.

The Company's current financial resources and currently forecasted operating plan would allow the Company to meet forecasted operating plans into the fourth quarter of 2019. The Company has determined that its cash runway of less than 12 months along with its accumulated deficit, history of losses, and future expected losses meet the ASC 205-40 standard for raising substantial doubt about its ability to continue as a going concern within one year of the issuance date of its consolidated financial statements. The Company may not be successful in its mitigation efforts, which primarily consist of raising additional capital through some combination of equity or debt financings, and/or potential new collaborations and reducing cash expenditures. Lack of necessary funds may require the Company, among other things, to delay, scale back, or eliminate some or all of its planned clinical trials.

In February 2019, the Company implemented corporate changes to focus its resources on advancing its clinical-stage therapeutic candidates. As a result, the Company now intends to concentrate on completing the recently-initiated SER-287 Phase 2b study in mild-to-moderate UC, obtaining results from the ongoing SER-109 Phase 3 study for recurrent CDI, advancing the SER-401 Phase 1b study, in collaboration with the Parker Institute for Cancer Immunotherapy and MD Anderson Cancer Center, to evaluate augmenting checkpoint inhibitor response in patients with metastatic melanoma and advancing SER-301 into clinical development. In connection with the prioritization of these therapeutic candidates, the Company made changes to its management team and reduced headcount by approximately 30 percent.

If the Company is not able to secure adequate additional funding, the Company plans to make further reductions in spending. In that event, the Company may have to delay, scale back, or eliminate some or all of the Company's planned clinical trials and research stage programs. The actions necessary to reduce spending under this plan at a level that mitigates the factors described above is not considered probable, as defined in the accounting standards; as such, under the requirements of ASC 205-40, the full extent to which management may extend the Company's funds through these actions may not be considered in management's assessment of the Company's ability to continue as a going concern for the next 12 months as defined by ASC-205-40.

As a result, in accordance with the requirements of ASC 205-40, management has concluded that it is required to disclose that substantial doubt exists about the Company's ability to continue as a going concern for one year from the date these financial statements are issued.

The Company is eligible to receive contingent milestone payments under its license and collaboration agreement with Nestec Ltd. ("NHS"), an affiliate of Nestlé Health Science US Holdings, Inc. ("Nestlé Health Science"), a significant stockholder of the Company, if certain development milestones are achieved. However, these milestones 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 March 31, 2019 and for the three months ended March 31, 2019 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, 2018 included in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2018, which was filed with the SEC on March 6, 2019 (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, 2018 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 consolidated financial statements contain all adjustments which are necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for the periods presented. Such adjustments are of a normal and recurring nature. The results of operations for the three months ended March 31, 2019 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2019.

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, 2018, and the notes thereto, which are included in the Annual Report. There have been no material changes to the Company's significant accounting policies during the three months ended March 31, 2019 except for the adoption of the new lease accounting standard discussed in Note 9, *Leases.*

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 consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, revenue recognition, the accrual of research and development expenses and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Net Loss per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net 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.

The following potential common shares, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended March 31,	
	2019	2018
Stock options to purchase common stock	8,908,432	7,498,791
Unvested restricted stock units	150,400	302,665
Shares issuable under ESPP	6,911	—
	9,065,743	7,801,456

Leases

The Company evaluates arrangements at inception to determine if an arrangement is or contains a lease. Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The Company uses an incremental borrowing rate that the Company would expect to incur for a fully collateralized loan over a similar term under similar economic conditions to determine the present value of the lease payments.

The lease payments used to determine the Company's operating lease assets may include lease incentives and stated rent increases and are recognized in the Company's operating lease assets in the Company's condensed consolidated balance sheets. Operating lease liabilities are accreted over the term of the lease using the incremental borrowing rate and the associated expense is recorded to operating expenses in the condensed consolidated statement of operations and comprehensive loss. Operating lease assets are amortized to rent expense over the lease term and included in operating expenses in the condensed consolidated statement of operations and comprehensive loss. Variable lease payments are recognized as the associated obligation is incurred.

Restructuring

Restructuring costs are comprised of severance costs related to workforce reductions. The Company recognizes restructuring charges when the liability is incurred. Employee termination benefits are accrued at the date management has committed to a plan of termination and employees have been notified of their termination dates and expected severance payments.

Recently Issued Accounting Standards

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, ("Topic 842"), which establishes principles that lessees and lessors shall apply to report useful information to users of financial statements about the amount, timing and uncertainty of cash flows arising from a lease. The most notable change is lessees recognizing an asset and liability on their balance sheet for operating leases. In 2018, the FASB issued ASU 2018-01, and ASU 2018-11, which collectively adds two practical expedients, provides a second modified retrospective transition method which does not require retrospective adjustment of prior periods, and provides certain narrow scope improvements to the new lease guidance. ASU 2016-02 and the amending ASUs are effective for the Company for annual periods beginning after December 15, 2018 and interim periods therein, with early adoption permitted.

The Company adopted the new guidance as of January 1, 2019 using the modified retrospective transition approach with no restatement of prior periods or cumulative adjustment to accumulated deficit. Upon adoption, the Company elected the package of transition practical expedients, which allowed the Company to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. The Company also made an accounting policy election not to recognize leases with an initial term of 12 months or less within its condensed consolidated balance sheets and to recognize those lease payments on a straight-line basis in its condensed consolidated statements of operations and comprehensive loss over the lease term. Upon adoption of the new leasing standards, the Company recognized an operating lease asset of approximately $13,737 and a corresponding operating lease liability of approximately $24,497, which are included in the Company's condensed consolidated balance sheet. The adoption of the new leasing standards did not have any impact on the Company's condensed consolidated statements of operations and comprehensive loss. The impact to the Condensed Consolidated Balance Sheets for the opening balances is as follows (in thousands):

	As Previously Reported December 31, 2018	Adoption Adjustment	As reported under Topic 842 January 1, 2019
Operating lease assets	$ —	$ 13,737	$ 13,737
Accrued expenses and other current liabilities	15,207	(1,768)	13,439
Operating lease liabilities	—	4,285	4,285
Lease incentive obligation, net of current portion	6,776	(6,776)	—
Deferred rent	2,216	(2,216)	—
Operating lease liabilities, net of current portion	—	20,212	20,212

In June 2018, the FASB issued ASU 2018-07, "*Compensation – Stock Compensation* (Topic 718)" ("ASU 2018-07"). ASU 2018-07 simplifies the accounting for nonemployee share-based payment transactions. This ASU is effective for public entities for interim and annual reporting periods beginning after December 15, 2018. The Company adopted the ASU effective January 1, 2019, the impact of adoption of this standard was immaterial to the Company's condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"). This standard eliminates, adds and modifies certain disclosure requirements for fair value measurements as part of its disclosure framework project. ASU 2018-13 is effective for annual reporting periods beginning after December 15, 2019 and interim periods within those annual periods and early adoption is permitted. The Company is currently evaluating the impact of its adoption of ASU 2018-13 on its condensed consolidated financial statements.

In November 2018 the FASB issued ASU No. 2018-18, *Collaborative Arrangements* (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. This standard makes targeted improvements for collaborative arrangements as follows:

- Clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606, Revenue from Contracts with Customers, when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in ASC 606 should be applied, including recognition, measurement, presentation and disclosure requirements;
- Adds unit-of-account guidance to ASC 808, Collaborative Arrangements, to align with the guidance in ASC 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606; and
- Requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting that transaction together with revenue recognized under ASC 606 is precluded if the collaborative arrangement participant is not a customer.

This standard will be effective on January 1, 2020; however, early adoption is permitted. A retrospective transition approach is required for either all contracts or only for contracts that are not completed at the date of initial application of ASC 606, with a cumulative adjustment to opening retained earnings. The Company is currently evaluating the potential impact that this standard may have on its consolidated financial position and results of operations.

3. Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents are carried at fair value, determined according to the fair value hierarchy described above. The Company's investments in certificates of deposit are carried at amortized cost, which approximates fair value. Certain cash equivalents that are measured at fair value using the net asset value per share (or its equivalent) practical expedient have not been classified in the fair value hierarchy. The carrying values of the Company's accounts payable and accrued expenses approximate their fair value due to the short-term nature of these liabilities.

The following table presents information about the Company's assets as of March 31, 2019 and December 31, 2018 that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (note there were no liabilities measured at fair value on a recurring basis in either of the periods presented):

	Fair Value Measurements as of March 31, 2019 Using:				
	Level 1	Level 2	Level 3	Not Subject to Leveling (1)	Total
Assets:					
Cash Equivalents	$ —	$ —	$ —	$ 40,187	$ 40,187
	$ —	$ —	$ —	$ 40,187	$ 40,187

(1) Certain cash equivalents that are valued using the net asset value per share (or its equivalent) practical expedient have not been classified in the fair value hierarchy.

	Fair Value Measurements as of December 31, 2018 Using:				
	Level 1	Level 2	Level 3	Not Subject to Leveling (1)	Total
Assets:					
Cash Equivalents	$ —	$ —	$ —	$ 39,982	$ 39,982
	$ —	$ —	$ —	$ 39,982	$ 39,982

(1) Certain cash equivalents that are valued using the net asset value per share (or its equivalent) practical expedient have not been classified in the fair value hierarchy.

As of March 31, 2019 and December 31, 2018, the Company's cash equivalents consisted of money market funds with original maturities of less than 90 days from the date of purchase.

4. Investments

As of March 31, 2019 and December 31, 2018 the Company had no investments.

The Company had restricted investments of $1,400 as of March 31, 2019 and December 31, 2018 which consisted of a certificate of deposit as a security deposit on its building lease at 200 Sidney Street, Cambridge, Massachusetts. The cost of restricted investments approximates fair value.

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	March 31, 2019	December 31, 2018
Laboratory equipment	$ 14,806	14,695
Computer equipment	2,875	2,864
Furniture and office equipment	1,033	1,033
Leasehold improvements	27,977	27,977
Construction in progress	26	26
	46,717	46,595
Less: Accumulated depreciation and amortization	$ (22,146)	$ (20,301)
	$ 24,571	$ 26,294

Depreciation and amortization expense was $2,006 and $1,941 for the three months ended March 31, 2019 and 2018, respectively.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	March 31, 2019	December 31, 2018
Development and manufacturing costs	$ 6,779	$ 7,046
Payroll and payroll-related costs	3,550	5,020
Facility and other	1,460	3,141
	$ 11,789	$ 15,207

7. Stockholders' Equity Common Stock

Stock Options

The following table summarizes the Company's stock option activity since December 31, 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2018	7,561,719	$ 12.26	7.23	$ 4,958
Granted	2,148,250	6.16		
Exercised	(38,125)	3.14		
Forfeited	(763,412)	12.70		
Outstanding as of March 31, 2019	8,908,432	$ 10.79	7.57	$ 9,684
Options vested and expected to vest as of March 31, 2019	8,908,432	10.79	7.57	9,684
Options exercisable as of March 31, 2019	4,659,499	$ 12.56	6.14	$ 8,100

The weighted average grant-date fair value of stock options granted during the three months ended March 31, 2019 and 2018 was $4.60 and $7.02 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. As of March 31, 2019, 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 March 31, 2019, the Company did not record any expense for these stock options from the dates of issuance through March 31, 2019.

Restricted Stock Units

The Company has granted restricted stock units with time-based vesting conditions. The table below summarizes the Company's restricted stock unit activity since December 31, 2018:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted stock units as of December 31, 2018	226,900	$ 9.64
Granted	—	$ —
Forfeited	(3,000)	$ 8.07
Vested	(73,500)	$ 9.98
Unvested restricted stock units as of March 31, 2019	150,400	$ 9.51

Stock-based Compensation Expense

The Company recorded stock-based compensation expense related to stock options, restricted stock units and the Company's Employee Stock Purchase Plan ("ESPP") in the following expense categories of its condensed consolidated statements of operations and comprehensive loss:

	Three Months Ended March 31,	
	2019	2018
Research and development expenses	$ 1,448	$ 1,928
General and administrative expenses	617	2,308
	$ 2,065	$ 4,236

Employee Stock Purchase Plan

The ESPP provides that eligible employees may contribute up to 15% of their eligible earnings toward the semi-annual purchase of the Company's common stock. The ESPP is qualified under Section 423 of the Internal Revenue Code. The employee's purchase price is derived from a formula based on the closing price of the common stock on the first day of the offering period versus the closing price on the date of purchase (or, if not a trading day, on the immediately preceding trading day). The offering period under the ESPP has a duration of six months, and the purchase price with respect to each offering period beginning on or after such date is, until otherwise amended, equal to 85% of the lesser of (i) the fair market value of the Company's common stock at the commencement of the applicable six-month offering period or (ii) the fair market value of the Company's common stock on the purchase date. The Company recorded an immaterial amount of stock-based compensation expense under the ESPP for the three months ended March 31, 2019.

The total number of available ESPP shares is increased annually, which began in 2016 and will end in 2025. The ESPP allows for share replenishment equal to the lesser of (i) 400,000 shares and (ii) 1% of the number of shares of the Company's common stock outstanding on the last day of the preceding calendar year, or an amount determined by the board of directors. As of March 31, 2019, a total of 1.9 million shares were reserved and available for issuance under the ESPP.

8. Collaboration Revenue

NHS Collaboration Agreement

Summary of Agreement

In January 2016, the Company entered into a collaboration and license agreement with NHS ("License Agreement") 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. The 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 "Licensed Territory"). The Company has retained full commercial rights to its entire portfolio of product candidates with respect to the United States and Canada.

Under the License Agreement, the Company granted to NHS an exclusive, royalty-bearing license to develop and commercialize, in the 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 "NHS Collaboration Products"). The License Agreement sets forth the Company's and NHS' respective obligations for development, commercialization, regulatory and manufacturing and supply activities for the NHS Collaboration Products with respect to the licensed fields and the Licensed Territory.

Under the License Agreement, NHS 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 NHS Collaboration Products. NHS also agreed to pay the Company tiered royalties, at percentages ranging from the high single digits to high teens, of net sales of NHS Collaboration Products in the Licensed Territory.

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

Accounting Analysis

The Company assessed the License Agreement in accordance with ASC 606—*Revenue From Contracts with Customers* ("ASC 606") and concluded that NHS is a customer. The Company identified the following promises under the contract: (i) a license to develop and commercialize the NHS Collaboration Products in the 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 NHS 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 NHS 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 NHS 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 NHS in connection with the initiation of the Phase 2b study for SER-287. The transaction price as of March 31, 2019 was approximately $190,000.

During the three months ended March 31, 2019 and 2018, using the cost-to-cost method, which best depicts the transfer of control to the customer, the Company recognized $6,615 and $3,766 of Collaboration revenue – related party, respectively.

As of March 31, 2019 and December 31, 2018, there was $130,644, and $137,259, respectively, of deferred revenue related to the unsatisfied portion of the performance obligation under the License Agreement. As of March 31, 2019, the deferred revenue is classified as current or non-current in the 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 License Agreement are recorded in research and development expense in the condensed consolidated statements of operations and comprehensive 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 will conduct 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 furthering 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 will pay to the Company a total of $20,000 in three equal installments, the first of which the Company received in April 2019, and the second and third of which become due on January 2, 2020 and January 4, 2021, respectively. Such payments are payable even if the Research Agreement is terminated in accordance with its terms, unless the Research Agreement is terminated by AstraZeneca for the Company's uncured material breach. Additionally, AstraZeneca will bear its costs of conducting activities under the research plan and will 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 Agreement or coming into the control of the Company during the term of the 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 exercises an option during the Option Exercise Period, the parties will 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 is reached during the Negotiation Period, subject to certain other terms and conditions applicable for a one (1) year period, the Company is 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 continues in effect until the Research Agreement is 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.

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.

For the three months ended March 31, 2019, the Company recognized revenue of $260 based on the measured progress under the Research Agreement. The transaction price as of March 31, 2019 was approximately $33,900.

As of March 31, 2019, there was $6,407 of deferred revenue associated with the Research Agreement, with $2,770 presented as current and $3,637 as 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. All costs associated with the Research Agreement are recorded in research and development expense in the condensed consolidated statements of operations and comprehensive loss.

Contract Balances from Contracts with Customers

The following table presents changes in the Company's contract assets and contract liabilities during the three months ended March 31, 2019 and 2018:

	Balance as of December 31, 2018	Additions	Deductions	Balance as of March 31, 2019
Three months ended March 31, 2019				
Contract liabilities:				
Deferred revenue - related party	137,259	—	(6,615)	130,644
Deferred revenue	—	6,667	(260)	6,407

	Balance as of January 1, 2018	Additions	Deductions	Balance as of March 31, 2018
Three months ended March 31, 2018				
Contract liabilities:				
Deferred revenue - related party	123,783	175	(3,766)	120,192

During the three months ended March 31, 2019 and 2018 the Company recognized the following revenues as a result of changes in the contract liabilities balances in the respective periods (in thousands):

	Three Months Ended March 31,	
	2019	2018
Revenue recognized in the period from:		
Amounts included in the contract liability at the beginning of the period	6,615	3,766

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.

9. Leases

The Company leases real estate, primarily laboratory, office and manufacturing space. The Company's leases have remaining terms ranging from less than 1 year to 5 years. Certain leases include one or more options to renew, exercised at the Company's sole discretion, with renewal terms that can extend the lease from one year to five years. The Company evaluated the renewal options in its leases to determine if it was reasonably certain that the renewal option would be exercised, and therefore should be included in the calculation of the operating lease assets and operating lease liabilities. Given the Company's current business structure, uncertainty of future growth, and the associated impact to real estate, the Company concluded that it is not reasonably certain that any renewal options would be exercised. Therefore, the operating lease assets and lease liabilities only contemplate the initial lease terms. All of the Company's leases qualify as operating leases. The following table summarizes the presentation in the Company's condensed consolidated balance sheets of its operating leases:

	As of March 31, 2019
Assets:	
Operating lease assets	$ 13,202
Liabilities:	
Operating lease liabilities	$ 4,407
Operating lease liabilities, net of current portion	19,066
Total operating lease liabilities	$ 23,473

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

	For the Three Months Ended March 31, 2019
Operating lease costs	$ 1,154
Short-term lease costs	648
Variable lease costs	726
Total lease costs	$ 2,528

During the three months ended March 31, 2019, the Company made cash payments of $1,642 for operating leases.

The minimum lease payments for the next five years and thereafter is expected to be as follows (in thousands):

	As of March 31, 2019
2019 (remaining 9 months)	$ 4,951
2020	6,382
2021	6,461
2022	6,390
2023	5,158
2024 and thereafter	—
Total future minimum lease payments	$ 29,342
Less: interest	(5,869)
Present value of operating lease liabilities	$ 23,473

As of March 31, 2019, the weighted average remaining lease term was 4.56 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 11%.

ASC 840 Disclosures

The future minimum lease payments under the Company's operating leases as of December 31, 2018, were as follows (in thousands):

	As of December 31, 2018
2019	$ 6,342
2020	6,120
2021	6,221
2022	6,372
2023	5,158
2024 and thereafter	—
Total future minimum lease payments	$ 30,213

During the three months ended March 31, 2018, the Company recognized $1,099 of rental expense related to office, laboratory, and manufacturing space.

10. Restructuring

In February 2019, the Company implemented corporate changes to focus its resources on advancing its clinical-stage therapeutic candidates. As a result, the Company now intends to concentrate on completing the recently-initiated SER-287 Phase 2b study in mild-to-moderate UC, obtaining results from the ongoing SER-109 Phase 3 study for recurrent CDI, advancing the SER-401 Phase 1b study, in collaboration with the Parker Institute for Cancer Immunotherapy and MD Anderson Cancer Center, to evaluate augmenting checkpoint inhibitor response in patients with metastatic melanoma and advancing SER-301 into clinical development. In connection with the prioritization of these therapeutic candidates, the Company made changes to its management team and reduced headcount by approximately 30 percent.

During the three months ended March 31, 2019 the Company recorded charges of $1,492 related to severance and other termination benefits. Of that amount, the Company paid $608 during the first quarter of 2019 and it expects to pay approximately $884 in 2019.

The outstanding restructuring liabilities are included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. As of March 31, 2019, the components of the liabilities were as follows:

	Employee Severance and Other Benefits
Restructuring expenses	$ 1,492
Cash payments	$ 608
Liability included in accrued expenses and other current liabilities at March 31, 2019	$ 884

11. Income Taxes

The Company did not provide for any income taxes for the three months ended March 31, 2019 or 2018.

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 March 31, 2019 and December 31, 2018. Management reevaluates the positive and negative evidence at each reporting period.

As of March 31, 2019 and December 31, 2018, the Company had no accrued interest or tax penalties recorded. The Company files income tax returns in the United States and various state jurisdictions. The Company is no longer subject to U.S. federal income tax examinations by tax authorities for years before 2012. However, to the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent it is utilized in a future period. There are no currently ongoing or pending examinations in any jurisdictions.

12. Commitments and Contingencies

Leases

Refer to Note 9, *Leases*, for discussion of the commitments associated with the Company's lease portfolio.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of March 31, 2019 or December 31, 2018.

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 March 31, 2019 or December 31, 2018.

13. Related Party Transactions

As described in Note 8, in January 2016 the Company entered into the License Agreement with NHS 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. NHS is a related party since NHS is an affiliate of Nestlé Health Science, one of the Company's significant stockholders. During the three months ended March 31, 2019 and December 31, 2018, the Company recognized $6,615, and $3,766 of related party revenue associated with the License Agreement, respectively. As of March 31, 2019, there was $130,644 of deferred revenue related to the License Agreement, which is classified as current or non-current in the consolidated balance sheets. The Company has made no payments to NHS during the three months ended March 31, 2019 and 2018. There is no amount due from NHS as of March 31, 2019.

14. Subsequent Events

In April 2019, the Company, with the approval of the Seres/NHS Joint Steering Committee, as provided for in the License Agreement, modified the SER-109 clinical trial. As a result of this modification, the Company and NHS agreed, and informed the FDA, that the target study enrollment would be reduced from 320 subjects to 188 subjects. With this modification, the Company expects to complete enrollment by the end of 2019 and report top-line data in early 2020. The Company will account for this modification in the second quarter of 2019 through a cumulative catch-up adjustment because the modification did not add any additional goods or services and the remaining goods and services are not distinct. The modification will reduce the total estimated costs in the Company's cost-to-cost model for the License Agreement with NHS and, based on estimated costs expected for the second quarter of 2019, will result in the Company recognizing revenue of approximately $7,000 in the second quarter of 2019.

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 months ended March 31, 2019, 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 platform company developing a novel class of biological drugs, which are designed to treat disease by restoring the function of a dysbiotic microbiome. SER-287 is being developed to treat ulcerative colitis, or UC. SER-109, is designed to reduce recurrences of *Clostridium difficile* infection, or CDI, a debilitating infection of the colon, in patients who have received antibiotic therapy for recurrent CDI by treating the dysbiosis of the colonic microbiome and, if approved by the U.S. Food and Drug Administration, or FDA, could be a first-in-field oral microbiome drug. In addition, using our microbiome therapeutics platform, we are developing product candidates to treat diseases where the microbiome is implicated, including SER-301, a rationally designed, fermented inflammatory bowel disease, or IBD, candidate, and SER-401, a microbiome therapeutic candidate for use with checkpoint inhibitors in patients with metastatic melanoma. We are also using our microbiome therapeutics platform to conduct research on various indications, including: infectious diseases, metabolic diseases, and inflammatory and immune diseases, including immuno-oncology.

Since our inception in October 2010, we have devoted substantially all of our resources to developing our programs, building our intellectual property portfolio, developing our supply chain, business planning, raising capital and providing general and administrative support for these operations.

All of our product candidates other than SER-287, SER-109 and SER-401 are still in pre-clinical 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 $24.3 million for the three months ended March 31, 2019. As of March 31, 2019, we had an accumulated deficit of $413.7 million and cash and cash equivalents totaling $53.6 million. Based on our current plans and forecasted expenses, we believe that our existing cash and cash equivalents as of March 31, 2019 will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2019, raising a substantial doubt regarding our ability to continue as a going concern. 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. See "—Liquidity and Capital Resources".

In February 2019, we implemented corporate changes to focus our resources on advancing our clinical-stage therapeutic candidates. As a result, we now intend to concentrate on completing our recently-initiated SER-287 Phase 2b study in mild-to-moderate UC, obtaining results from our ongoing SER-109 Phase 3 study for the treatment of recurrent CDI, advancing our SER-401 Phase 1b study, in collaboration with the Parker Institute for Cancer Immunotherapy and MD Anderson Cancer Center, to evaluate augmenting checkpoint inhibitor response in patients with metastatic melanoma, and advancing SER-301 into clinical development. In connection with the prioritization of these therapeutic candidates, we made changes to our management team and reduced headcount by approximately 30 percent.

In March 2019, we entered into a Research and Collaboration and Option Agreement, or the Research Agreement, with MedImmune, LLC, a wholly owned subsidiary of AstraZeneca Inc., or AstraZeneca. Pursuant to the Research Agreement, we and AstraZeneca agreed to conduct certain research and development activities with the goal of advancing the mechanistic understanding of the microbiome in augmenting the efficacy of cancer immunotherapy, including potential synergy with AstraZeneca compounds in accordance with a mutually agreed research plan. AstraZeneca has agreed to bear all costs of conducting its activities under the Research Agreement and to reimburse us for certain costs incurred under the Research Agreement. Additionally, AstraZeneca has agreed pay to us a total of $20.0 million in three equal installments, the first of which we received in April 2019, and the second and third of which become due in January 2020 and January 2021. We granted AstraZeneca the exclusive option to negotiate certain exclusive license rights. If AstraZeneca exercises an option, we have agreed to enter into good faith negotiations with them for terms and conditions of such license agreement for a specified time period. See "—Liquidity and Capital Resources."

SER-287

SER-287 is an oral, donor-derived microbiome therapeutic candidate designed to normalize the gastrointestinal microbiome of individuals with UC. In December 2018, we commenced a three-arm placebo-controlled Phase 2b clinical trial to evaluate SER-287 in approximately 201 patients with mild-to-moderate UC. Two groups of patients will receive different doses of SER-287, both following pretreatment with a short course of oral vancomycin. A third study arm will receive placebo. The study's primary endpoint will evaluate clinical remission measured after 10 weeks of SER-287 administration. Patients then enter a 2-week exploratory maintenance follow-up period. Endoscopic improvement will be measured as a secondary efficacy measure. Based on feedback from the U.S. Food and Drug Administration, or FDA, if the data from this trial is positive, we expect that the Phase 2b clinical trial could be one of two pivotal trials to enable a Biologics License Application, or BLA, to be submitted for SER-287 for the treatment of UC. We expect to complete enrollment of the SER-287 Phase 2b ECO-RESET study in mid-2020 and report top-line data in the third quarter of 2020.

There are approximately 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. We believe that SER-287 may address underlying drivers of inflammation in UC and, based on the favorable tolerability profile observed in our clinical trials of SER-287, has the potential to be developed as both a foundational monotherapy, as well as a combination therapy with other UC drugs. SER-287 has been granted Fast Track Designation by the FDA for the induction and maintenance of clinical remission in adult subjects with active mild-to-moderate UC.

We believe that our continued development of SER-287 is supported by our Phase 1b clinical study of SER-287 in patients with mild-to-moderate UC in which we observed a beneficial impact on clinical remission and endoscopic improvement and various markers of SER-287 biological activity, including microbiome engraftment, detection of metabolomic markers, and biopsy transcriptional signals correlating with the clinical trial results. Of the 11 patients treated with SER-287 who achieved clinical remission in the Phase 1b clinical study, preliminary data showed that no patients experienced a disease flare in the 26 weeks following the end of treatment, which we believe is suggestive of a possible longer-term treatment effect. Additionally, there was no imbalance of adverse events between the treatment arm and placebo, the most common being gastrointestinal related, and no serious adverse events observed in the Phase 1b clinical study.

SER-109

SER-109 is an oral, donor-derived microbiome therapeutic candidate designed to restore the depleted, or dysbiotic, gastrointestinal microbiome of patients with recurrent CDI. SER-109 has been granted Breakthrough Therapy Designation and Orphan Drug Designation for the treatment of recurrent CDI.

We have been enrolling a 320 patient, placebo-controlled SER-109 Phase 3 study, ECOSPOR III, in patients with recurrent CDI. All patients entering ECOSPOR III have tested positive for *C. difficile* toxin. This inclusion criterion was implemented to ensure enrollment of only patients with active CDI. The original 320 patient trial was designed to evaluate SER-109 efficacy and develop a comprehensive safety database, in order to potentially serve as a single study supporting registration. Consistent with our recent actions to drive toward obtaining validating near-term clinical data, a revised ECOSPOR III study design has been implemented reducing the size of the study to 188 patients. The size and powering calculations of the modified study are informed by prior SER-109 study results, published CDI trial data utilizing toxin testing, and preliminary blinded and open label CDI recurrence rate data from the ongoing ECOSPOR III study.

In previous communications with the FDA regarding a potential reduction in ECOSPOR III study size, the agency indicated that if the statistical significance of the outcome of the study is insufficient for product registration, we may be required to obtain additional confirmatory evidence of efficacy, such as a second Phase 3 study. Reducing the study size may also require additional patient exposure to further establish safety. We believe ECOSPOR III is optimally designed to provide statistically rigorous efficacy data by the beginning of 2020.

As of April 30, 2019, we had enrolled 135 patients in ECOSPOR III. Following this reduction, we expect to complete enrollment of ECOSPOR III by the end of 2019 and report top-line data in early 2020.

SER-401

SER-401 is an oral microbiome therapeutic candidate comprising a bacterial signature similar to that observed in checkpoint inhibitor immunotherapy responders. In March 2019, the first patient was dosed in the Phase 1b clinical study with MD Anderson Cancer Center, or MD Anderson, The Parker Institute for Cancer Immunotherapy, or PICI, to evaluate SER-401's potential to augment the response of anti-PD-1 checkpoint inhibitor therapy. The study is designed to enroll 30 patients with metastatic melanoma

who are being treated with nivolumab, an anti-PD-1 therapy. Patients are randomized at a 2-to-1 ratio to either SER-401 or placebo. The study's primary endpoints are to evaluate safety and tolerability. Its secondary endpoints are to evaluate the correlation of microbiome biomarkers of response to various clinical and immunological outcome measures. We expect preliminary results in 2020.

SER-301

We are also advancing our next generation, rationally-designed, fermented microbiome drug discovery capabilities, focusing on advancing SER-301, a preclinical-stage therapeutic candidate for UC. We expect to submit an Investigational New Drug Application with the FDA and initiate clinical development of SER-301 in early 2020. In connection with the initiation of clinical development, we are entitled to receive a $10.0 million milestone payment under our collaboration with Nestec Ltd.

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:

- continue the clinical development of SER-287 in our Phase 2b clinical trial for the treatment of UC;
- continue the clinical development of SER-109 in our Phase 3 clinical study for the prevention of recurrent CDI;
- continue the clinical development of SER-401in our Phase 1b clinical trial for use with checkpoint inhibitors in patients with metastatic melanoma;
- conduct research and continue pre-clinical development of SER-301 for the treatment of UC;
- 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 the license and collaboration agreement with NHS;
- 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. 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. If we are unable to raise sufficient capital to fund our current operating plans in the next 12 months, we may need to further reduce our expenditures, potentially requiring us, among other things, to delay, scale back, or eliminate some or all of our planned clinical trials and other research and development programs.

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 2033. We plan on continuing to broaden our patent portfolio. Currently, we have 18 active patent application families, which includes 10 nationalized applications and 3 pending US provisional applications. To date, we have obtained 12 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 FDA, a 12-year period of exclusivity in the US may be obtained. In Europe, EMA 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 from collaborations have been derived primarily from our Collaboration and License Agreement with NHS, or the License Agreement. 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 License Agreement and the Research Agreement are recorded in research and development expense in the condensed consolidated statements of operations and comprehensive 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 March 31,	
	2019	2018
	(in thousands)	
Microbiome therapeutics platform	$ 15,899	$ 15,084
SER-109	2,649	6,144
SER-262	86	842
SER-287	4,253	1,390
Total research and development expenses	$ 22,887	$ 23,460

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 advance the clinical development of SER-287, conduct our ECOSPOR III Phase 3 clinical study of SER-109, continue to discover and develop additional product candidates, including SER-401 and SER-301 and pursue later stages of clinical development of our product candidates. See, however, "—Liquidity and Capital Resources" below for a discussion of our plans to potentially reduce our spending in the event we are unable to raise sufficient capital to fund our current operating plans in the next 12 months.

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 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.

Our general and administrative expenses may increase in the future if we increase our headcount to support the potential growth in our research and development activities and the potential commercialization of our product candidates. 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.

Restructuring

In February 2019, we implemented corporate changes to focus our resources on advancing our clinical-stage therapeutic candidates. As a result, we now intend to concentrate on completing our recently-initiated SER-287 Phase 2b study in mild-to-moderate UC, obtaining results from the ongoing SER-109 Phase 3 study for recurrent CDI, advancing the SER-401 Phase 1b study in collaboration with the Parker Institute for Cancer Immunotherapy and MD Anderson Cancer Center to evaluate augmenting checkpoint inhibitor response in patients with metastatic melanoma, and advancing SER-301 into clinical development. In connection with the prioritization of these therapeutics candidates, we made changes to our management team and reduced headcount by approximately 30 percent.

Other Income (Expense), Net

Interest Income (Expense), Net

Interest income consists of interest earned on our cash and cash equivalents.

Income Taxes

Since our inception in 2010, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. We did not provide for any income taxes in the three months ended March 31, 2019 or 2018.

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, 2018, filed with the SEC on March 6, 2019, or the Annual Report, are considered by management to be the most important to an understanding of the consolidated financial statements because of their significance to the portrayal of our financial condition and results of operations. There have been no material changes to that information disclosed in our Annual Report during the three months ended March 31, 2019 except for the adoption of the new leasing standard discussed in Note 9 to our Unaudited Condensed Consolidated Financial Statements included in this Quarterly Report.

Results of Operations

Comparison of Three Months Ended March 31, 2019 and 2018

The following table summarizes our results of operations for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,		
	2019	2018	Change
	(in thousands)		
Revenue:			
Collaboration revenue - related party	$ 6,615	$ 3,766	$ 2,849
Grant revenue	446	205	241
Revenue	260	—	260
Total revenue	7,321	3,971	3,350
Operating expenses:			
Research and development	22,887	23,460	(573)
General and administrative	7,495	8,777	(1,282)
Restructuring expense	1,492	-	1,492
Total operating expenses	31,874	32,237	(363)
Loss from operations	(24,553)	(28,266)	3,713
Other income (expense):			
Interest income (expense), net	220	347	(127)
Total other income (expense), net	220	347	(127)
Net loss	$ (24,333)	$ (27,919)	$ 3,586

Revenue

Total revenue was $7.3 million and $4.0 million for the three months ended March 31, 2019 and 2018, respectively. The revenue for both periods principally relates to the recognition of amounts received under the License Agreement with NHS. The increase is mainly due to increases in the transaction price under the License Agreement. Revenue for the three months ended March 31, 2019 relates to revenue recognized in connection with the Research Agreement with AstraZeneca.

Research and Development Expenses

	Three Months Ended March 31,		
	2019	2018	Change
	(in thousands)		
Microbiome therapeutics platform	$ 15,899	$ 15,084	$ 815
SER-109	2,649	6,144	(3,495)
SER-262	86	842	(756)
SER-287	4,253	1,390	2,863
Total research and development expenses	$ 22,887	$ 23,460	$ (573)

Research and development expenses were $22.9 million for the three months ended March 31, 2019, compared to $23.5 million for the three months ended March 31, 2018. The decrease of $0.6 million was due primarily to the following:

- an increase of $0.8 million in research expenses related to our microbiome therapeutics platform, due primarily to an increase in facility related expenses of $1.0 million, depreciation expense of $0.1 million, lab supplies of $0.1 million and IT related expenses of $0.1 million; the increases were partially offset by a decrease in employee and consulting related expenses of $0.5 million;
- a decrease of $3.5 million in expenses related to our SER-109 program due primarily to a decrease in clinical trial consulting expenses of $2.5 million, a decrease in contract manufacturing costs of $0.6 million and a decrease in lab consumables of $0.3 million;
- a decrease of $0.8 million in expenses for our SER-262 program due primarily to a decrease in clinical trial consulting expenses; and
- an increase of $2.9 million in expenses for our SER-287 program due primarily to an increase in clinical trial consulting expenses of $2.2 million and an increase in contract manufacturing of $1.1 million; these increases were partially offset by a decrease in sequencing costs of $0.2 million and a decrease in lab consumables of $0.2 million.

General and Administrative Expenses

	Three Months Ended March 31,		
	2019	2018	Change
	(in thousands)		
Personnel related (including stock-based compensation)	$ 3,088	$ 4,627	$ (1,539)
Professional fees	2,691	1,776	915
Facility-related and other	1,716	2,374	(658)
Total general and administrative expenses	$ 7,495	$ 8,777	$ (1,282)

General and administrative expenses were $7.5 million for the three months ended March 31, 2019, compared to $8.8 million for the three months ended March 31, 2018. The decrease of $1.3 million was primarily due to the following:

- a decrease in personnel related costs of $1.5 million primarily related to stock compensation expense;
- an increase in professional fees of $0.9 million due an increase in legal fees of $0.5 million and increase in consulting costs $0.4 million; and
- a decrease in facility-related and other costs of $0.7 million primarily due to a decrease in IT-related expenses.

Restructuring

During the three months ended March 31, 2019 we recorded charges of $1.5 million related to severance and other termination benefits. Of that amount, we paid $0.6 million during the first quarter of 2019 and expect to pay approximately $0.9 million in the remaining nine months of 2019.

Other Income (Expense), Net

Other income (expense), net for the three months ended March 31, 2019 and 2018 was $0.2 million and $0.3 million, respectively, and is primarily due to interest income from investing activities.

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.

As of March 31, 2019, we had cash and cash equivalents totaling $53.6 million and an accumulated deficit of $413.7 million. Based on our current plans and forecasted expenses, we believe that our existing cash and cash equivalents as of March 31, 2019, will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2019. 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. These factors raise substantial doubt about our ability to continue as a going concern.

As discussed in Note 1 to the Unaudited Condensed Consolidated Financial Statements included in this Quarterly Report, we have the responsibility to evaluate whether conditions or events raise substantial doubt about our ability to meet our future financial obligations as they become due within one year after the date the financial statements are issued. This evaluation initially cannot take into consideration the potential mitigating effects of plans that have not been fully implemented as of the date the financial statements are issued or potential contingent milestone payments under our collaboration agreements that we have not earned. As such, we have determined that our cash runway of less than 12 months along with our accumulated deficit, history of losses, and future expected losses raise substantial doubt about our ability to continue as a going concern within one year of the issuance date of the unaudited condensed consolidated financial statements included in this Quarterly Report. While we have plans in place to mitigate this risk, which primarily consist of raising additional capital through a combination of equity or debt financings, and, depending on the availability and level of additional financings, potentially new collaborations and reducing cash expenditures, there is no guarantee that we will be successful in these mitigation efforts. Lack of necessary funds may require us, among other things, to delay, scale back, or eliminate some or all of our planned clinical trials.

Collaboration Agreements

Agreement with NHS

In January 2016, we entered into the License Agreement with NHS, 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, NHS agreed to pay us an upfront cash payment of $120.0 million, which we received in February 2016. NHS 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 NHS Collaboration Products in markets outside of the United States and Canada, or the Licensed Territory. We have retained full commercial rights to the NHS Collaboration Products with respect to the United States and Canada, where we plan to build our own commercial organization. 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 NHS Collaboration Products. The full potential value of the up-front payment and milestone payments payable by NHS 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 License Agreement. In November 2018, we executed a letter agreement with NHS, or the Letter Agreement, modifying certain terms of the License Agreement. Under the Letter Agreement, NHS 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.

For the development of NHS 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 NHS bearing the remaining 33% of such costs. The Letter Agreement also provides scenarios under which NHS' 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 NHS Collaboration Products for IBD, we agreed to pay the costs of such activities to support approval in the United States and Canada, and NHS agreed to bear the cost of such activities to support approval of NHS Collaboration Products in the Licensed Territory.

With respect to development of NHS 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 NHS Collaboration Products other than SER-109 for CDI. We agreed to pay 67% and NHS agreed to pay 33% of other costs of Phase 3 clinical trials conducted for NHS Collaboration Products other than SER-109 for CDI under a global development plan. For other clinical development of NHS Collaboration Products for CDI, we agreed to pay costs of such development activities to support approval in the United States and Canada, and NHS agreed to bear the cost of such activities to support approval of NHS Collaboration Products in the Licensed Territory.

Agreement with AstraZeneca

In March 2019, we entered into the Research Agreement with AstraZeneca. Pursuant to the Research Agreement, we and AstraZeneca agreed to conduct certain pre-clinical and development activities and may conduct certain clinical research with the goal of advancing the mechanistic understanding of the microbiome in augmenting the efficacy of cancer immunotherapy, including potential synergy with AstraZeneca compounds in accordance with a mutually agreed research plan. Pursuant to the Research Agreement, we agreed not to conduct research or development of any microbiome products specifically designed by us during the term of the Research Agreement for the treatment of cancer with or on behalf of any third party without the prior approval of the joint steering committee for the Research Agreement until at least three years after the effective date of the Research Agreement.

AstraZeneca has agreed to bear all costs of conducting its activities under the research plan and to reimburse us for certain costs incurred under the research plan. Additionally, AstraZeneca has agreed to pay to us a total of $20.0 million in three equal installments, the first of which we received in April 2019, and the second and third of which become due in January 2020 and January 2021, respectively. Such payments are payable even if the Research Agreement is terminated in accordance with its terms, unless the Research Agreement is terminated by AstraZeneca for our uncured material breach.

We also granted AstraZeneca an exclusive option to negotiate exclusive license rights to certain of our technologies and assets. If AstraZeneca exercises this option, we have agreed to enter into good faith negotiations with them for terms and conditions of such license agreement for a specified time period.

Cash Flows

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

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Cash (used in) operating activities	$ (32,393)	$ (26,763)
Cash provided by (used in) investing activities	(306)	38,034
Cash provided by (used in) financing activities	480	(165)
Net decrease in cash, cash equivalents and restricted cash	$ (32,219)	$ 11,106

Operating Activities

During the three months ended March 31, 2019, operating activities used $32.4 million of cash, primarily due to a net loss of $24.3 million and cash used from changes in our operating assets and liabilities of $12.7 million, partially offset by non-cash charges of $4.6 million. Net cash used for changes in our operating assets and liabilities during the three months ended March 31, 2019 consisted of an increase in accounts receivable of $6.7 million, an increase in prepaid expenses and other current assets of $0.6 million, a decrease in deferred revenue of $0.2 million, a decrease in accounts payable of $2.5 million, a decrease in operating lease liabilities of $1.0 million, and a decrease in accrued expenses and other current liabilities of $1.7 million. The increase in accounts receivable was due to the upfront payment to be received from AstraZeneca. The decrease in accounts payable and accrued expenses and other current liabilities was due to timing of payments. The decrease in operating lease liabilities was due to amortization of operating leases.

During the three months ended March 31, 2018, operating activities used $26.8 million of cash, primarily due to a net loss of $27.9 million and cash used from changes in our operating assets and liabilities of $5.0 million, partially offset by non-cash charges of $6.1 million. Net cash used for changes in our operating assets and liabilities during the three months ended March 31, 2018 consisted of a decrease in accrued expenses and other current liabilities of $0.8 million, a decrease in accounts payable of $1.4 million, a decrease in deferred revenue of $3.6 million, and an increase in prepaid expenses and other current assets of $0.8 million. The decreases in accrued expenses and other current liabilities and accounts payable were due to the timing of payments. The decrease in deferred revenue was due to the recognition of $3.7 million in collaboration revenue during the three months ended March 31, 2018.

Investing Activities

During the three months ended March 31, 2019, net cash used in investing activities was $0.3 million, consisting of purchases of property and equipment.

During the three months ended March 31, 2018, net cash provided by investing activities was $38.0 million, consisting of sales and maturities of investments of $44.3 million. The increase was partially offset by purchases of investments of $5.3 million and purchases of property and equipment of $1.0 million.

Financing Activities

During the three months ended March 31, 2019, net cash provided by financing activities was $0.5 million in connection with the exercise of options to purchase our common stock.

During the three months ended March 31, 2018, net cash used in financing activities was $0.2 million in connection with payments for employee tax obligations relating to vesting of restricted stock units, partially offset by the exercise of options to purchase our common stock.

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:

- continue the clinical development of SER-287 in our Phase 2b clinical trial for the treatment of UC;
- continue the clinical development of SER-109 in our Phase 3 clinical study for the prevention of recurrent CDI;
- continue the clinical development of SER-401 in our Phase 1b clinical trial for use with checkpoint inhibitors in patients with metastatic melanoma;
- conduct research and continue preclinical development of SER-301 for the treatment of UC;
- 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 the Collaboration Agreement with NHS;
- 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 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. We do not currently have any committed external source of funds. 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. 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 and may 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.

Contractual Obligations and Commitments

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

Off-Balance Sheet Arrangements

As of March 31, 2019, 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 March 31, 2019, our cash and cash equivalents 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.

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 Principal Financial and Accounting Officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, 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 (the "Exchange Act")). Based on that evaluation, our Chief Executive Officer and Principal Financial and Accounting Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2019.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended March 31, 2019 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. We expect The University of Tokyo to appeal.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should consider carefully the risks described below, together with the other information included or incorporated by reference in this Quarterly Report on Form 10-Q. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline.

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. As a result, there is substantial doubt about our ability to continue as a going concern.

Since inception, we have incurred significant operating losses. Our net loss was $98.9 million for the year ended December 31, 2018, and $24.3 million for the three months ended March 31, 2019. As of March 31, 2019, we had an accumulated deficit of $413.7 million. To date, we have financed our operations through the initial public offering of our common stock, private placements of our preferred stock, milestone payments under the licensing agreement with Nestec, Ltd., or NHS, and loan financing. 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 Ecobiotic microbiome therapeutics, 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:

- continue the clinical development of SER-287 in our Phase 2b clinical trial for the treatment of UC and potential other studies of IBD;
- continue the clinical development of SER-109 in our Phase 3 clinical study for the prevention of recurrent CDI;
- continue the clinical development of SER-401 in our Phase 1b clinical trial for use with checkpoint inhibitors in patients with metastatic melanoma;
- conduct research and continue preclinical development of additional Ecobiotic microbiome therapeutic candidates, including SER-301 for the treatment of UC;
- make strategic investments in manufacturing capabilities;
- maintain and augment our intellectual property portfolio and opportunistically acquire complementary intellectual property;
- scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- perform our obligations under the collaboration agreement with NHS;
- 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.

As discussed in Note 1 of the Notes to the Unaudited Condensed Consolidated Financial Statements included in this Quarterly Report under Accounting Standards Update, or ASU, 2014-15, *Presentation of Financial Statements-Going Concern* (Subtopic 205-40), or, ASC 205-40, we have the responsibility to evaluate whether conditions and/or events raise substantial doubt about our ability to meet our future financial obligations as they become due within one year after the date the financial statements are issued. Under ASC 205-40, this evaluation initially cannot take into consideration the potential mitigating effects of plans that have not been fully implemented as of the date the financial statements are issued. Since we currently anticipate that our existing financial resources will enable us to meet forecasted operating plans into the fourth quarter of 2019, we have determined that our cash runway of less than 12 months along with our accumulated deficit, history of losses, and future expected losses meet the ASC 205-40 standard for raising substantial doubt about our ability to continue as a going concern within one year of the issuance date of our condensed consolidated financial statements. We may not be successful in our mitigation efforts, which primarily consist of raising additional capital through some combination of equity or debt financings, and/or potential new collaborations and reducing cash expenditures. Lack of necessary funds may require us, among other things, to delay, scale back, or eliminate some or all of our planned clinical trials.

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-287, including conducting the Phase 2b clinical study, continue the clinical development of SER-109, including conducting the Phase 3 clinical study, initiate clinical studies of SER-401, and continue to research, develop and initiate clinical trials of SER-301 and 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. Furthermore, we have incurred and expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We do not expect that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements for a one-year period from the issuance of these condensed consolidated financial statements. This estimate excludes net cash flows from future business development activities. 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 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, including SER-301;
- 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. 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 completed our Phase 1b and a Phase 2 clinical study of SER-109 and have reported top-line data in our Phase 1b studies of SER-287 and SER-262. We have not yet demonstrated our ability to successfully complete any Phase 3 clinical study or other pivotal clinical trials, obtain regulatory approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates

Other than SER-109, we are early in our development efforts and may not be successful in our efforts to use our microbiome therapeutics platform to build a pipeline of product candidates and develop marketable drugs.

We are using our microbiome therapeutics platform to develop Ecobiotic microbiome therapeutics. 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 prevent 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 preventing 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 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 therapeutic approach that is designed to prevent infection and treat disease by restoring the function of a dysbiotic microbiome. 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 Ecobiotic microbiome therapeutics may have different effectiveness rates in various indications and in different geographical areas. Finally, the FDA or other regulatory agencies 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 failed clinical trial can occur at any stage of testing. 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. 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. Preliminary or topline data remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or interim data we previously published. As a result, these data should be viewed with caution until the final data are available. Adverse changes between preliminary or interim data and final data could significantly harm our business prospects.

In addition, we cannot be certain as to what type and how many clinical trials the FDA, or other regulators, 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 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. For example, based on feedback from the FDA, the smaller study design of our Phase 3 clinical trial for SER-109 could require additional confirmatory evidence of efficacy, such as a second Phase 3 clinical trial.

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:

- regulators or institutional review boards 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;
- regulators or institutional review boards 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;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- regarding trials managed by any 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.

In June 2017, we initiated a Phase 3 clinical study of SER-109 (ECOSPOR III) in patients with multiple recurrent CDI. 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.

Our product development costs will increase if we 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.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. We are developing SER-109, to reduce recurrence of CDI in patients suffering from recurrent CDI. There is a limited number of patients from which to draw for clinical studies.

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. We continue to enroll the SER-109 Phase 3 study for patients with recurrent CDI despite the widespread use of unapproved, FMT to treat CDI. As interference from this uncontrolled procedure has impacted the enrollment rate of our placebo-controlled clinical trial, we are evaluating modification of the study design with the goal of expediting clinical results. Enrollment delays in our clinical trials would result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

The reduction in trial size of our ongoing Phase 3 trial of SER- 109 may make it make it necessary to conduct an additional clinical trial of SER-109 to generate sufficient safety and efficacy data to allow us to gain approval of SER-109.

The FDA has previously indicated that an ESCOPOR III trial could be sufficient to allow us to file a BLA for SER-109 if the trial demonstrated a sufficient level of statistical significance. The decrease of the statistical power of the trial resulting from the reduction in the size of the trial from 320 patients to 188 patients may reduce the likelihood that the trial demonstrates the heightened level of statistical significance required by the FDA. The FDA has also indicated that the smaller study could require additional confirmatory evidence of efficacy for approval, which may include conducting a second Phase 3 study prior to seeking approval of SER-109. Moreover, as a result of the smaller study we may also be required to treat additional patients with SER-109 in order to generate a sufficient safety database to allow us to seek approval of SER-109. The need to conduct additional clinical trials of SER 109 and any delay in gaining regulatory approval of SER-109 would increase our development costs and could cause the value of our company to decline and limit our ability to obtain additional financing.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we 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 by the EMA and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate in any jurisdiction will prevent us 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 Ecobiotic microbiome therapeutics. 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 agency'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. 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 agency 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 agency 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 agency 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 agency, 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 affecting our Ecobiotic microbiome therapeutics that could adversely affect our product 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 FDA 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 once a marketing application is filed. 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, 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 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, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, as well as priority review, where the agency aims to act on the application within eight months.

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.

Generally, 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. 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 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.

Orphan drug exclusivity for a product may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug 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.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency 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 agencies may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary government agencies, 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 agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA 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 Agreement, or the License Agreement, with NHS is important to our business. If we or NHS fail to adequately perform under the License Agreement, or if we or NHS terminate the License Agreement, the development and commercialization of our CDI and IBD product candidates, including SER-109, SER-262, SER-287, and SER-301, would be delayed or terminated and our business would be adversely affected.

The License Agreement may be terminated:

- by NHS in the event of serious safety issues related to SER-109, SER-262, SER-287, SER-301 or other specific products added under the License Agreement, or, collectively, the NHS Collaboration Products;
- by us if NHS challenges the validity or enforceability of any of our licensed patents; and
- by either NHS or us in the event of the other party's uncured material breach or insolvency.

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

Termination of the License Agreement could cause significant delays in our product development and commercialization efforts that could prevent us from commercializing our CDI and IBD product candidates, outside of the United States and Canada, 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 License Agreement, NHS agreed to provide funding for certain clinical development activities. If the License Agreement 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 License Agreement, we are dependent upon NHS to successfully commercialize any NHS Collaboration Products outside of the United States and Canada. We cannot directly control NHS' commercialization activities or the resources it allocates to our product candidates. Our interests and NHS' interests may differ or conflict from time to time, or we may disagree with NHS' level of effort or resource allocation. NHS 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, 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. Other countries' regulatory agencies 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 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.

We may be unable to establish any agreements with third-party manufacturers on acceptable terms or at all. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- 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. The contract manufacturers we rely on to produce our product candidates have never produced an FDA-approved therapeutic. If our manufacturers are unable to comply with cGMP regulation or if the FDA or other regulators 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. Except for our clinical production facility in Massachusetts, we do not currently have arrangements in place for redundant supply of product. We do not currently have a second source for 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.

We have no experience manufacturing our product candidates at commercial scale, 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 Ecobiotic microbiome therapeutics. The FDA and other comparable foreign regulatory agencies 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 may establish a manufacturing facility for our product candidates for production at a commercial scale. We have no experience in commercial-scale manufacturing of our product candidates. We currently intend to develop our manufacturing capacity in part by expanding our current facility or building additional facilities. This activity will require substantial additional funds and we would need to hire and train significant numbers of qualified employees to staff these facilities. We may not be able to develop commercial-scale manufacturing facilities that are adequate to produce materials for additional later-stage clinical trials or 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 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 are unable to establish effective sales, marketing and distribution capabilities or enter into agreements with third parties with such capabilities, we may not be successful in commercializing 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 the future, we expect to build a focused sales and marketing 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 cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our 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 NHS, 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 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 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. As a result, its ultimate impact is subject to uncertainty. The FDA has issued several guidance documents to date discussing the biosimilar pathway, and the FDA approved the first biosimilar under the BPCIA in March 2015. However, the FDA continues to implement the BPCIA, 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 will 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 could be subject to post- marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

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 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 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 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. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products outside of their approved indications, we may be subject to enforcement action for off-label marketing or promotions. Violations of the FDA's restrictions relating to the promotion of prescription drugs 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 agency or we 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 agency may impose restrictions on the products or us, including requiring withdrawal of the product from the market. Any failure 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 regulations, policies or guidance may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. For example, in December 2016, the 21st Century Cures Act was signed into law, which is intended, among other things, to modernize the regulation of biologics and to spur innovation, though its ultimate implementation remains unclear. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues. If regulatory sanctions are applied or if regulatory approval is withheld or withdrawn, the value of our company and our operating results will be adversely affected.

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 adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. For example, certain policies of the current Presidential administration may impact our business and industry. Namely, the current Presidential administration has taken 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 regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval or marketing applications. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. 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 lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

Our 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 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 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. 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 (described below);
- the false claims and civil monetary penalties laws, including the federal False Claims Act, which, 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or 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 its implementing regulations, 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, certain other healthcare professionals 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 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.

The risk of our 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 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.

There have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future, particularly in light of the current Presidential administration and Congress. Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA as well as recent efforts by the current Presidential administration to repeal or replace certain aspects of the ACA. For example, President Trump has signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act of 2017, the remaining provisions of the ACA are invalid as well. While the current Presidential administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the Texas District Court Judge issued an order staying the judgment pending appeal, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and 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 2027 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. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain.

We expect that the ACA, as well as 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 countries of the EU, the pricing of prescription 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. 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 currently have, 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 18 active patent application families. Of these, 10 applications have been nationalized and 3 are pending at the provisional stage. While we have obtained 12 issued U.S. patents to date, 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*." 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. We expect The University of Tokyo to appeal.

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

Our new corporate strategy and restructuring may not be successful.

On February 7, 2019, following a strategic business review, we announced our new strategy to focus our resources on advancing our highest-priority, clinical-stage microbiome therapeutic candidates. As a result, we plan to concentrate on completing the SER-287 Phase 2b study in mild-to-moderate UC, obtaining results from the ongoing SER-109 Phase 3 study for recurrent CDI, advancing the SER-401 Phase 1b study, in collaboration with the Parker Institute for Cancer Immunotherapy and MD Anderson Cancer Center, to evaluate augmenting checkpoint inhibitor response in patients with metastatic melanoma and advancing SER-301 into clinical development. The success of this strategic shift will depend on our ability to successfully advance our therapeutic candidates,

complete our ongoing studies, retain senior management or other highly qualified personnel, prioritize competing projects and efforts and obtain sufficient resources, including additional capital. Accordingly, there are no assurances our change in strategic focus will be successful, which may have an adverse effect on our results of operations and financial condition.

Also, on February 7, 2019, we announced the restructuring of our executive team and a reduction in our workforce by approximately 30 percent. The positions eliminated are primarily related to research, manufacturing, and general and administrative services. Following the reduction in workforce, we expect to have approximately 100 full-time employees, and we believe we will be appropriately resourced to continue executing on our current strategy. However, our workforce may not be sufficient to fully execute our strategic shift, and we may not be able to effectively retain the management or personnel needed to fully implement our strategy. Our restructuring and reduction in workforce activities may also result in unexpected risks or costs, such as employee claims and contractual disputes, and the risk that the actual financial and other impacts of the reductions could vary materially from the outcomes anticipated, which may have a material adverse effect on our results of operations or financial condition.

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.

We will continue to incur increased 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 after we are no longer an emerging growth 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 may 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.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are unable to maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a public company or comply with the requirements of the Securities and Exchange Commission or Section 404. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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 plan to rely on collaborators, including NHS, to commercialize any approved products outside of the United States. 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.

Our business and operations would suffer in the event of information technology and other system failures.

Despite the implementation of security measures, our internal computer systems and data and those of our current and future contractors and consultants are vulnerable to damage or compromise from computer viruses, unauthorized access, human error, loss of data privacy, natural disasters, terrorism, war and telecommunication and electrical failures. While we are not aware of any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture our product candidates and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of our product candidates could be delayed.

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 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.

Comprehensive tax reform bills could adversely affect our business and financial condition.

The U.S. government recently enacted comprehensive federal income tax legislation that includes significant changes to the taxation of business entities. These changes include, among others, (i) a permanent reduction to the corporate income tax rate, (ii) a partial limitation on the deductibility of business interest expense, (iii) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a territorial system (along with certain rules designed to prevent erosion of the U.S. income tax base) and (iv) a one-time tax on accumulated offshore earnings held in cash and illiquid assets, with the latter taxed at a lower rate. Notwithstanding the reduction in the corporate income tax rate, the overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected. We urge our stockholders to consult with their legal and tax advisors with respect to any such legislation and the potential tax consequences of investing in our common stock.

Risks Related to Our Common Stock

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.

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 78% 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. Moreover, holders of an aggregate of approximately 18.3 million shares of our common stock, as of April 24, 2019 have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 promulgated under the Securities Act of 1933, as amended, or the Securities Act, or until the rights terminate pursuant to the terms of the investors' rights agreement between us and such holders. 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 an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the closing of the initial public offering of our common stock. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to include audited financial statements in our selected financial data and in any future registration statements under the Securities Act for any period prior to the earliest audited financial statements presented in our registration statement on Form S-1 for the initial public offering of our common stock;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved and from having to disclose the ratio of compensation of our chief executive officer to the median compensation of our employees.

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. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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.

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. Furthermore, 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. We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision 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 to be inapplicable or unenforceable in such action.

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. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference			Filing Date	Filed/ Furnished Herewith
		Form	File No.	Exhibit		
3.1	Restated Certificate of Incorporation, filed on July 1, 2015	8-K	001-37465	3.1	7/1/15	
3.2	Amended and Restated Bylaws	8-K	001-37465	3.2	7/1/15	
4.1	Amended and Restated Investors' Rights Agreement, dated December 19, 2014, by and between the Registrant and each of the investors listed on Schedule A thereto	S-1	333-204484	4.1	5/27/15	
10.1^	Research Collaboration and Option Agreement, dated March 11, 2019, by and between the Registrant and MedImmune, LLC					*
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 Principal Financial and Accounting Officer					*
32.1	Section 1350 Certification of Chief Executive Officer					**
32.2	Section 1350 Certification of Principal Financial and Accounting Officer					**
101.INS	XBRL Instance Document					*
101.SCH	XBRL Taxonomy Extension Schema Document					*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					*

* Filed herewith.
** Furnished herewith.
^ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Regulation S-K, Item 601(b)(10). Such omitted information is not material and would likely cause competitive harm to the registrant if publicly disclosed. Additionally, 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: May 2, 2019

By: /s/ Marcus Chapman
Marcus Chapman
Vice President, Finance and 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 excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

Execution Copy

RESEARCH COLLABORATION AND OPTION AGREEMENT

between

MEDIMMUNE, LLC

and

SERES THERAPEUTICS, INC.

RESEARCH COLLABORATION AND OPTION AGREEMENT

This RESEARCH COLLABORATION AND OPTION AGREEMENT (the " **Agreement**") is made as of the date of last signature hereunder (the "**Effective Date**"), by and between MedImmune, LLC., a limited liability company organized and existing under the laws of Delaware, having an office located at One MedImmune Way Gaithersburg, MD 20878, USA ("**MedImmune**"), and Seres Therapeutics, Inc., a corporation incorporated and existing under the laws of the State of Delaware, having an office located at 200 Sidney Street, Cambridge, MA 02139, USA ("**Seres**"). MedImmune and Seres are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

WHEREAS, Seres is developing, and owns or controls certain patent rights, technology, know-how and other intellectual property relating to medicinal products to treat diseases resulting from functional deficiencies in the microbiome;

WHEREAS, the Parties wish to collaborate with one another in respect of the research of the role of the microbiome in cancer and cancer treatments; and

WHEREAS, each Party wishes to obtain, and the other Party is willing to grant, certain licenses under intellectual property controlled by the other Party in connection with such research, including certain licenses thereunder to enable each Party and its Affiliates and sublicensees to research and develop products related thereto, subject to and in accordance with the terms of this Agreement.

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

ARTICLE 1
DEFINITIONS

1.1 Definitions. The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, shall have the respective meanings either set forth below or another part of this Agreement.

"**Affiliate**" of a Party means an entity that (directly or indirectly) is controlled by, controls, or is under common control with such Party where control means the direct or indirect ownership of voting securities entitled to cast at least fifty percent (50%) of the votes in the election of directors, or such other relationship as results in the power to control the management, business, assets, and affairs of an entity.

"**Agreement**" has the meaning set forth in the preamble hereto.

"**Bankruptcy Code**" means, as applicable, the U.S. Bankruptcy Code, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder or the bankruptcy laws of any Governmental Authority, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder or any applicable bankruptcy laws of any other country or competent Governmental Authority, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder.

"**BLA**" means (i) 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, (ii) in the EU, a marketing authorization application, as defined in applicable regulations of the EMA, and (iii) in any other country, the relevant equivalent to the foregoing.

"**Business Combination**" has the meaning set forth in Section 14.3.

"**Business Day**" means a day other than Saturday, Sunday or any day on which commercial banks located in New York, New York, are authorized or obligated by applicable Law to close.

"**Calendar Quarter**" means, with respect to any given Calendar Year, the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31.

"**Calendar Year**" means each successive period of twelve (12) consecutive months commencing on January 1 and ending on December 31.

"**Claim**" means any charge, complaint, action, suit, proceeding, hearing, investigation, claim or demand.

"**Clinical Trial**" means a clinical trial in human subjects that has been approved by a Regulatory Authority and an institutional review board or ethics committee, and is designed to measure the safety and/or efficacy of a product.

"**CMC**" means the chemistry, manufacturing, and controls sections (together with all supporting documentation and records) of any BLA or the comparable portions of other applications for Regulatory Approval.

"**Confidential Information**" means 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 such Party or its Affiliates to the other Party or its Affiliates in connection with this Agreement, including the terms of this Agreement, any Microbiome Oncology Product or MedImmune Study Product, any exploitation of any Microbiome Oncology Product or MedImmune Study Product, any know-how with respect thereto developed by or on behalf of the disclosing Party or its Affiliates, or the scientific, regulatory or business affairs or other activities of either Party. Information within the Joint Intellectual Property Rights shall be deemed to be the Confidential Information of both Parties.

"**Controlled**" or "**Control**", when used in reference to any intellectual property, intellectual property right, material, know-how or information, means the legal authority or right of a Party hereto (or its Affiliates) to: (i) grant, or procure the grant of, a license or sublicense, to the extent provided for herein, of the intellectual property, intellectual property right, material, know-how or information to the other Party; or (ii) in relation to material, know-how and information only, disclose or provide access to, to the extent provided for herein, such material, know-how or information to the other Party, and in each case without (1) breaching the terms of any agreement with a Third Party, (2) misappropriating the material, know-how or information of a Third Party, or (3) triggering a payment obligation that the other Party has not agreed in writing to bear with respect to its practice of a sublicense thereunder or access thereto.

"**CPI**" means the Consumer Price Index – Urban Wage Earners and Clerical Workers, U.S. City Average, All Items, published by the United States Department of Labor, Bureau of Labor Statistics (or its successor equivalent index) in the United States.

"**Disclosing Party**" has the meaning set forth in Section 10.1.

"**Dispute**" has the meaning set forth in Section 13.1.

"**DMF**" has the meaning set forth in Section 4.6.

"**Effective Date**" means the effective date of this Agreement as set forth in the preamble hereto.

"**EMA**" means the European Medicines Agency, or any successor agency thereto.

"**Enforcing Party**" has the meaning set forth in Section 9.3.3.

"**European Union**" or "**EU**" means, at any given time during the Term, the then current member states of the European Union.

"Exclusive Option Negotiation Period" has the meaning set forth in Section 6.3.1.

"**Exclusivity Period**" means the period commencing on the Effective Date and ending on the later of (a) three (3) years after the Effective Date or (b) [***].

"**FD&C Act**" means 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).

"**FDA**" means the U.S. Food and Drug Administration, or any successor agency thereto.

"**Field**" means the treatment of cancer, [***].

"**FTE Costs**" of an activity within a period of time means [***] by a Party's or its Affiliate's employees on such activity during such period, multiplied by the FTE Rate, provided, however, that no amount shall be included in FTE Costs with respect to (i) [***] (or such other number as may be agreed by the Parties), (ii) [***] or (iii) [***].

"**FTE Rate**" means, with respect to a Party's or its Affiliate's employees performing Development activities under this Agreement, a rate equal to $[***] per year, subject to an annual percentage increase starting on January 1, 2020 equal to the percentage increase in the CPI reported for the immediately preceding Calendar Year.

"Grant" has the meaning set forth in Section 6.3.2(i).

"**Good Clinical Practices**" or "**GCP**" means 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 and comparable regulatory standards, practices, and procedures

promulgated by the EMA or other Regulatory Authority applicable to the Territory, as such standards, practices, and procedures may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

"**Good Laboratory Practices**" or "**GLP**" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards promulgated by the EMA or other Regulatory Authority applicable to the Territory, as such standards may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

"**Good Manufacturing Practices**" or "**GMP**" means the standards relating to current Good Manufacturing Practices for fine chemicals, API, intermediates, bulk products or finished pharmaceutical products set forth in (i) 21 U.S.C. 351(a)(2)(B), in FDA regulations at 21 C.F.R. Parts 210 and 211 and in The Rules Governing Medicinal Products in the European Community, Volume IV, Good Manufacturing Practice for Medicinal Products, or (ii) 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.

"Good Pharmacovigilance Practices" or "GVP" means, in addition to the provisions under the Pharmacovigilance Agreement, all applicable good pharmacovigilance practices promulgated and published by the FDA, EMA or any other applicable Regulatory Authority including, as applicable, major pharmacovigilance process and product and/or population specific considerations as defined in (a) European Commission Regulation code relating to medicinal products for human use, Directives 2010/84/EU and 2012/26/EU, as well as by the Commission Implementing Regulation (EU) No 520/2012 on the Performance of Pharmacovigilance Activities provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC, Title IX and Article 108a(a) and principles detailed in the ICH guidelines for pharmacovigilance as well as (b) principles detailed in the United States 21 CFR and Guidance for Industry Good Pharmacovigilance Practices and Pharmacoepidemiological Assessment.

"**Governmental Authority**" means any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

"**ICH**" means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"**ICH Guidelines**" means the guidelines of the ICH.

"**IND**" means an Investigational New Drug Application (as such term is defined in the FD&C Act and the regulations promulgated thereunder), Clinical Trial Authorisation (as such term is defined in the Directive 2001/20/EC, as amended) 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.

"**Indemnified Party**" has the meaning set forth in Section 11.3.1.

"**Indemnifying Party**" has the meaning set forth in Section 11.3.1.

"Indirect Tax" means VAT, sales taxes, consumption taxes and other similar taxes required by Law to be disclosed on the invoice.

"Individual Program Option" has the meaning set forth in Section 6.1.

"**Information**" means all technical, scientific and other know-how and information, inventions, discoveries, trade secrets, knowledge, technology, means, methods, processes, formulations, practices, formulae, instructions, skills, techniques, procedures, experiences, expressed ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results, materials (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical, and analytical), pre-clinical, clinical, safety, manufacturing and quality control data and information (including study designs and protocols), and assays and biological methodology, in each case, whether or not confidential, proprietary or patentable, and in written, electronic, or any other form now known or hereafter developed.

"**Invention**" means any new invention or discovery that is first conceived or made during the Term and as a result of or in connection with the activities performed pursuant to this Agreement.

"**Joint Intellectual Property Rights**" has the meaning set forth in Section 9.1.3.

"**Joint Patents**" has the meaning set forth in Section 9.1.3.

"**Joint Steering Committee**" or "**JSC**" has the meaning set forth in Section 3.1.

"**Knowledge**" means, with respect to a Party, the actual knowledge of the directors, senior managers, and key employees of such Party.

"**Laws**" means all laws, statutes, rules, regulations, ordinances, and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision.

"**License Option Exercise Notice**" has the meaning set forth in Section 6.2.

"**Losses**" means any and all damages (including, but not limited to, all loss of profits, diminution in value, and incidental, indirect, consequential, special, reliance, exemplary, punitive, statutory, and treble damages), awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations, taxes, liens, losses, and expenses (including, but not limited to, court costs, interest, and reasonable fees of attorneys, accountants, and other experts) incurred by or awarded to Third Parties and required to be paid to Third Parties with respect to a Claim by reason of any judgment, order, decree, stipulation or injunction, or any settlement entered into in accordance with the provisions of this Agreement, together with all documented out-of-pocket costs and expenses incurred in contesting any Third Party Claim or complying with any judgments, orders, decrees, stipulations, and injunctions that arise from or relate to a Third Party Claim.

"[***]" has the meaning set forth in the [***] Collaboration definition.

"[***] **Collaboration**" means [***], as such agreement may be amended from time to time.

"**MedImmune**" has the meaning set forth in the preamble hereto.

"**MedImmune Arising Inventions and Information**" means all Inventions and Information which are conceived, discovered, or otherwise made by or on behalf of the Parties (or their Affiliates or sublicensees), whether solely or jointly, in the course of performing activities pursuant this Agreement, including the conduct of Clinical Trials pursuant to the Research Plan, which are [***] and are neither (i) [***] nor (ii) [***]. MedImmune Arising Inventions and Information shall further include all Inventions and Information which are conceived, discovered, or otherwise made by or on behalf of the Parties (or their Affiliates or sublicensees), whether solely or jointly, in the course of performing activities pursuant to this Agreement and that are [***] but are neither (A) [***] nor (B) [***].

"**MedImmune Excluded [***] Know-How**" means all Information Controlled by MedImmune or its Affiliates as of the Effective Date of this Agreement or from time to time during the Term that [***].

"**MedImmune Know-How**" means all Information Controlled by MedImmune or its Affiliates as of the Effective Date of this Agreement or from time to time during the Term that is necessary or reasonably useful for the performance of the research activities in accordance with the Research Plan, except that MedImmune Know-How excludes MedImmune Excluded [***] Know-How.

"**MedImmune Patents**" means all Patents except for the Joint Patents that (i) are Controlled by MedImmune or its Affiliates as of the Effective Date of this Agreement or from time to time during the Term (including without limitations Patents which claim or cover the MedImmune Arising Inventions and Information), and (ii) claim or cover inventions, the practice of which are otherwise necessary or reasonably useful for the performance of the research activities in accordance with the Research Plan.

"MedImmune Study Products" means those therapeutic products owned or Controlled by MedImmune and that are the subject of the research activities (including [***]) to be conducted under the Research Plan and that are not Microbiome Oncology Products.

"Microbiome Oncology Collaboration Option" has the meaning set forth in Section 6.1.

"**Microbiome Oncology Product**" means any product for which the active ingredient is a Microbiome Product which is specifically designed by Seres during the Term for use in the Field.

"**Microbiome Product**" means a product consisting of a [***], and in any formulation or composition.

"**Microbiome Technology"** means all Information and/or Inventions, whether or not patented or patentable, comprising or relating to (a) the composition of matter, formulation or method of use or manufacture, of a Microbiome Product, (b) [***], (c) [***], and/or (d) the prevention or treatment of diseases and conditions through use of a Microbiome Product. Microbiome Technology includes without limitation [***].

"[***]" has the meaning set forth in the [***] Collaboration definition.

"[***] **Collaboration**" means the [***], as such agreement may be amended from time to time.

"**Non-Enforcing Party**" has the meaning set forth in Section 9.3.3.

"**Non-Product Option**" has the meaning set forth in Section 6.1.

"**Notice of Dispute**" has the meaning set forth in Section 13.1.

"Options" has the meaning set forth in Section 6.1.

"**Option Period**" has the meaning set forth in Section 6.2.

"**Party**" or "**Parties**" has the meaning set forth in the preamble hereto.

"**Patents**" means (a) all national, regional, and international patents and patent applications, including provisional patent applications, (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and requests for continued examinations, (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, innovation patents, petty patents and design patents, and certificates of invention, (d) any and all revalidations, reissues, re-examinations, and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b), and (c)), and (e) all international equivalents of the foregoing.

"[***]" has the meaning set forth in the [***] Collaboration definition.

"**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, foundation, joint venture or other similar entity, organization or combination thereof, including a government or political subdivision, department, or agency.

"[***]" means [***].

"**Pricing Approval**" means the governmental approval, agreement, determination or decision establishing prices for a therapeutic product that can be charged in regulatory jurisdictions where the applicable Regulatory Authorities or other governmental authorities approve or determine the price of pharmaceutical products.

"**Prior CDA**" has the meaning set forth in Section 14.10.

"**Publication**" has the meaning set forth in Section 10.5.

"**Receiving Party**" has the meaning set forth in Section 10.1

"**Regulatory Approval**" means, with respect to any therapeutic product in any country or regulatory jurisdiction, any and all approvals from the applicable Regulatory Authority sufficient for the import, distribution, marketing, use, offering for sale, and sale of such product for use in the Field in such country or jurisdiction in accordance with applicable Laws, but excluding any applicable Pricing Approvals.

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

"**Regulatory Filing**" means 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 therapeutic product in connection with the initiation or conduct of Clinical Trials, and/or to seek Regulatory Approval for such product in the Field, including, without limitation, any INDs, drug master files, manufacturing master files, BLAs, or any supplements thereto.

"**Relevant Third Party Assets and Intellectual Property Rights**" has the meaning set forth in Section 14.3.1.

"**Research Plan**" means the mutually agreed research plan setting forth all research activities (including without limitation Clinical Trials) to be performed by Seres and/or MedImmune.

"**Research Plan Data**" has the meaning set forth in Section 4.6.

"**Resultant Entity**" has the meaning set forth in Section 14.3.

"**Senior Officers**" has the meaning set forth in Section 13.1.

"**Seres**" has the meaning set forth in the preamble hereto.

"**Seres Arising Inventions and Information**" means all Inventions and Information which are conceived, discovered, or otherwise made by or on behalf of the Parties (or their Affiliates or sublicenses), whether solely or jointly, in the course of performing activities pursuant to this Agreement, including the conduct of Clinical Trials pursuant to the Research Plan, which are [***] but not [***]. Seres Arising Inventions and Information shall further include all Inventions and Information which are conceived, discovered, or otherwise made by or on behalf of the Parties (or their Affiliates or sublicenses), whether solely or jointly, in the course of performing activities pursuant to this Agreement and (i) that are [***], or (ii) that are [***], but in each case that are not [***].

"**Seres Know-How**" means all Information Controlled by Seres or its Affiliates as of the Effective Date of this Agreement or from time to time during the Term that is necessary or reasonably useful for the (i) performance of the research activities in accordance with the Research Plan and/or (ii), solely for the purposes of Article 6, further development and commercialization of Microbiome Oncology Products, except that Seres Know-How excludes Seres Excluded [***] Know-How.

"**Seres Excluded [***] Know-How**" means all Information Controlled by Seres or its Affiliates as of the Effective Date of this Agreement or from time to time during the Term that [***].

"**Seres Patents**" means all Patents except for the Joint Patents that (i) are Controlled by Seres or its Affiliates as of the Effective Date of this Agreement or from time to time during the Term (including without limitation Patents which claim or cover the Seres Arising Information and Inventions), and (ii) claim or cover inventions, the practice of which are otherwise necessary or reasonably useful for the (y) performance of the research activities in accordance with the Research Plan and/or (z), solely for the purposes of Article 6, further development and commercialization of Microbiome Oncology Products.

"**Seres R&D Costs**" means (i) FTE Costs incurred by or on behalf of Seres or its Affiliates in the performance of its activities in accordance with the Research Plan, as applicable, and (ii) amounts paid by Seres [***] to Third Parties for goods and services required in order for Seres to perform such activities, in both case (i) and (ii) excluding (a) any FTE Costs incurred by or on behalf of Seres or its Affiliates with respect to activities under the [***] Collaboration and [***] Collaboration and (b) amounts paid by Seres [***] to Third Parties with respect to activities under the [***] Collaboration and [***] Collaboration, in both case (a) and (b).

"**Term**" has the meaning set forth in Section 12.1.

"**Territory**" means the entire world.

"**Third Party**" means any entity other than MedImmune, Seres, and their respective Affiliates.

"**Third Party Claim**" has the meaning set forth in Section 11.3.1.

"**United States**" or "**U.S.**" means the United States of America, including its territories and possessions.

ARTICLE 2
GRANT OF LICENSE AND RIGHTS; EXCLUSIVITY

2.1 Licenses Granted.

2.1.1 License to MedImmune. Subject to the terms and conditions of this Agreement, including without limitation Section 2.2 hereof, Seres hereby grants to MedImmune, and MedImmune accepts, a non–exclusive, royalty-free license, with the right to grant sublicenses as provided in 2.1.2, under the Seres Patents, the Seres Know-How, and Seres Arising Inventions and Information, solely to perform the activities assigned to MedImmune under the Research Plan.

2.1.2 Sublicensing by MedImmune. MedImmune shall have the right to grant sublicenses of the rights granted to it by Seres under Section 2.1.1 to its Affiliates without Seres' prior consent and to Third Parties performing activities as independent contractors on behalf of MedImmune; provided, however, that MedImmune shall ensure that the terms of any sublicense granted pursuant to this Section 2.1.2 are consistent with the terms and conditions of this Agreement. MedImmune 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 such sublicense(s).

2.1.3 License to Seres. Subject to the terms and conditions of this Agreement, MedImmune hereby grants to Seres, and Seres accepts, a non–exclusive, royalty-free license, with the right to grant sublicenses as provided in 2.1.4, under the MedImmune Patents, MedImmune Know-How, and MedImmune Arising Inventions and Information, solely to perform the activities assigned to Seres under the Research Plan.

2.1.4 Sublicensing by Seres. Seres shall have the right to grant sublicenses of the rights granted to it by MedImmune under Section 2.1.3 to its Affiliates without MedImmune's prior consent and to Third Parties performing activities as independent contractors on behalf of Seres; provided, however, that Seres shall ensure that the terms of any sublicense granted pursuant to this Section 2.1.4 are 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 such sublicense(s).

2.2 Exclusivity. Seres hereby covenants that, during the Exclusivity Period, Seres and its Affiliates shall not conduct research and/or development on Microbiome Oncology Products in the Field in the Territory in collaboration with or on behalf of any Third Party company (other than an independent contractor performing services for Seres or its Affiliates) and shall not knowingly assist any Third Party company to do so, without the prior approval of the JSC. Notwithstanding anything to the contrary in the foregoing, Seres, itself or with or through any Affiliate or Third Party, directly or indirectly, shall have the right to continue its activities under agreements existing as of the Effective Date, including, without limitation, under the [***] Collaboration and [***] Collaboration.

2.3 No Implied Licenses. No license or other right is or shall be created or granted hereunder by implication, estoppel or otherwise. All such licenses and rights are or shall be granted only as expressly provided in this Agreement.

2.4 Transfer of Know-How. From time to time after the Effective Date, as reasonably necessary or useful to enable the conduct of the Research Plan, each Party shall provide the other with copies of and/or reasonable access to all existing material Seres Know-How and MedImmune Know-How, as applicable, that is reasonably required by such other Party to perform the activities assigned to it under the Research Plan, except to the extent that such Seres Know-How or MedImmune Know-How, as applicable, has previously been provided to such other Party. Such Seres Know-How or MedImmune Know-How, as applicable, may be provided and/or made accessible to the other Party 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. During the Term, each Party will provide the other Party with copies of or reasonable access to any additional material Seres Know-How or MedImmune Know-How, as applicable, obtained or generated by or on behalf of Seres or its Affiliates or MedImmune or its Affiliates, as applicable, that is, in each case, required by, and/or necessary or useful to, such other Party to perform the activities assigned to it under the Research Plan. For clarity, in no event shall [***] unless such [***] are not otherwise already accessible by MedImmune by way of [***] but are necessary for MedImmune to perform its obligations under the Research Plan or exercise its rights (or inform its decision as to whether to exercise such

rights), in which case Seres shall provide MedImmune access to such [***] solely for such limited purposes.

ARTICLE 3
GOVERNANCE OF THE COLLABORATION

3.1 Formation and Composition of the Joint Steering Committee. Within [***] ([***]) days after the Effective Date, MedImmune and Seres shall establish a "**Joint Steering Committee**" or "**JSC**" to serve as the overall governing body for matters within the scope of this Agreement. The JSC shall be comprised of an equal number of representatives of each Party, which number shall initially be three (3) representatives of each Party and the number of representatives may be changed upon the mutual agreement of the Parties. The JSC representatives shall be senior-level employees of the appointing Party having appropriate expertise and decision-making authority, and each Party shall designate one of its JSC representatives to serve as co-chairpersons of the JSC. Either Party may replace any or all of its representatives on the JSC at any time upon written notice to the other Party. Any member of the JSC may designate a substitute to attend and perform the functions of that member at any meeting of the JSC.

3.2 Role of JSC. The JSC shall be responsible for oversight, strategic planning, and overall management and coordination of the activities to be undertaken by the Parties with respect to the Research Plan. This will include responsibility for:

3.2.1 directing the research activities of the Parties performed pursuant to the Research Plan;

3.2.2 directing the activities of the Parties relating to Clinical Trials to be undertaken pursuant to the Research Plan (but excluding the [***] performed or to be performed by Seres and its collaborators pursuant to the [***] Collaboration or [***] Collaboration);

3.2.3 review and update the Research Plan and budget therefor pursuant to Article 4;

3.2.4 approve amendments to the Research Plan and budget therefor proposed by the Parties pursuant to Article 4;

3.2.5 review the results arising from the Research Plan;

3.2.6 establish a strategy for Publications; and

3.2.7 oversee and coordinate the Parties' efforts in preparation and submission of Regulatory Filings.

3.3 Meetings of JSC. The JSC will meet at least [***], or at such other frequency, as agreed by the JSC from time to time. The location of regularly scheduled meetings shall alternate between the offices of the Parties unless otherwise agreed by the JSC. Meetings of the JSC may also be held telephonically, by video conference or by any other media agreed to by the JSC. Members of the JSC shall have the right to participate in and vote at meetings [***]. One Party shall be responsible for appointing an individual to record the minutes of each JSC meeting, which minutes shall clearly document any decisions made by the JSC at such meeting. This responsibility shall alternate between the Parties every twelve (12) months, with Seres being responsible for the

initial twelve (12) months following the date hereof. JSC meeting minutes shall be circulated to the Parties within [***] ([***]) Business Days following the meeting for review, comment, and ratification by the Parties. Each Party shall be responsible for expenses incurred by its employees and its members of the JSC in attending or otherwise participating in JSC meetings, including travel and related costs. Any member of the JSC may invite additional representatives of the Party such member represents (including representatives from Third Parties subject to execution of a confidentiality agreement and invention assignment agreement that effectuates the principles set forth in Article 10 and Section 9.1), and who have relevant expertise, to attend JSC meetings when appropriate for the issues being addressed at the meeting with [***] ([***]) Business Days prior notice to the other Party's JSC representatives.

3.4 JSC Decision-Making. Decisions of the JSC shall be made by unanimous vote. Each of Seres and MedImmune shall be entitled to [***] on all matters coming before the JSC or any subcommittee or subgroup thereof. If the JSC does not reach unanimous agreement on any matter, [***] shall have final decision-making authority regarding such matter unless such decision would [***].

3.5 Authority. The JSC will have only the powers assigned expressly to it in this Article 3 and elsewhere in this Agreement, and will not have any power to amend, modify or waive compliance with this Agreement, the [***] Collaboration or [***] Collaboration. In furtherance thereof, each Party will retain the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion will be delegated to or vested in the JSC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing.

3.6 JSC Subcommittees. The JSC may, in its discretion, establish subcommittees or working subgroups from time to time to handle specific matters within the scope of the JSC's area of authority and responsibility. Such subcommittees or subgroups shall have such authority and responsibility as determined by the JSC from time to time, and decisions and recommendations of any such subcommittee or subgroup shall be made in accordance with Section 3.4 and Section 3.5.

ARTICLE 4
RESEARCH

4.1 General. Subject to the terms and conditions of this Agreement, the Parties will conduct a research program to investigate the role of the microbiome in cancer and cancer treatments pursuant to the Research Plan.

4.2 Research Plan. The initial Research Plan will include the elements attached hereto as Exhibit A. Promptly after the Effective Date, the Parties will agree upon a complete Research Plan. Thereafter, the JSC will review and update the Research Plan on an annual basis or at such other times as it may decide. Either Party may propose amendments or modifications to the Research Plan for consideration and approval by the JSC from time to time. The Research Plan shall set forth: (a) the research activities to be conducted by each Party and (b) the estimated timelines for such research activities, and (c) a budget (including the estimated FTE Costs to be incurred by Seres in performing its obligations thereunder). If the terms of the Research Plan contradict, or create inconsistencies or ambiguities with, the terms of this Agreement, then the terms of this Agreement shall govern.

4.3 Conduct of Research. Each Party shall use commercially reasonable efforts to perform all research activities under this Agreement in compliance with all applicable Laws (including GMP, GLP, GVP and GCP).

Research Records and Reports

. Each Party shall maintain complete, current, and accurate records of all research activities conducted by it hereunder, and all data and other information resulting from such activities. Such records shall fully and properly reflect all work done and results achieved in the performance of the research activities in good scientific manner appropriate for regulatory and patent purposes. Each Party shall keep the other Party reasonably informed as to its progress in the conduct of the research activities through meetings of the JSC or as otherwise agreed by the Parties in writing. Upon written request from the JSC, each Party shall submit to the JSC a written summary (in slide format unless otherwise agreed by the Parties) of its research activities since its prior report.

Research Costs

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4.5.1 MedImmune shall be responsible for all costs and expenses incurred by or on behalf of MedImmune in the performance of its activities under the Research Plan.

4.5.2 MedImmune will reimburse Seres for Seres R&D Costs incurred by or on behalf of Seres in the performance of its activities under the Research Plan. Promptly following the end of each Calendar Quarter during which Seres is responsible for activities under the Research Plan, but in no event later than [***] ([***]) days following the end of such Calendar Quarter, Seres will provide to MedImmune a detailed expense report with respect to the Seres R&D Costs incurred by or on behalf of Seres during such Calendar Quarter (including, [***]) together with an invoice for the same, provided that no more than [***] per Calendar Year, Seres may provide to MedImmune such detailed expense report for expedited payment of any one or more Seres R&D Costs that were incurred by Seres during the first [***] ([***]) months of any Calendar Quarter within such Calendar Year and that individually exceed $[***] (including [***]). MedImmune will reimburse Seres in U.S. dollars all undisputed amounts within such expense reports under this Section 4.5 within [***] ([***]) days following receipt of the invoice therefor.

4.5.3 Audit. MedImmune shall have the right to examine and audit Seres' relevant books and records pursuant to Section 4.4 to verify the Seres R&D Costs to be reimbursed pursuant to Section 4.5.2 reported hereunder. Any such audit shall be on at least [***] ([***]) days' prior written notice. MedImmune's rights to perform an audit under this Section 4.5.3 shall be limited to not more than [***] ([***]) such audit in any Calendar Year and shall be limited to the pertinent books and records for any Calendar Year ending not more than [***] ([***]) months before the date of the request. The audit shall be performed at MedImmune's sole expense by an independent certified public accounting firm of internationally recognized standing that is selected by MedImmune and reasonably acceptable to Seres. The accounting firm may be required to enter into a reasonable and customary confidentiality agreement with Seres to protect the confidentiality of its books and records. Seres 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 Seres' and/or its Affiliates' 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 of the Seres R&D Costs are correct, and the specific details concerning any discrepancies. The accounting firm shall not provide MedImmune with any additional information or access to Seres' confidential information. If any audit pursuant to this Section 4.5.3 reveals a discrepancy in the Seres R&D Costs and, on the basis thereof, an additional net amount is owed to Seres based on the provisions of this Section 4.5, such additional amount shall be paid to Seres within [***] ([***]) Business Days of the date that the Parties receive such accountant's written report. In the event that the total amount of any underpayments by MedImmune to Seres for the audited period exceeds [***] percent ([***]%) of the aggregate total amount that was properly due and payable by MedImmune pursuant to this Section 4.5.3 for the audited period, then MedImmune shall also reimburse Seres for the documented, reasonable out of pocket expenses incurred in conducting the audit. If any audit pursuant to this Section 4.5.3 reveals a discrepancy in the Seres R&D Costs and, on the basis thereof, it is found that MedImmune has been incorrectly charged an additional net amount by Seres, such additional amount shall be repaid to MedImmune within [***] ([***]) Business Days of the date that the Parties receive such accountant's written report. In the event that the total amount of any overpayments by MedImmune to Seres for the audited period exceeds [***] percent ([***]%) of the aggregate total amount that was properly due and payable by MedImmune pursuant to this Section 4.5.3 for the audited period, Seres shall also reimburse MedImmune for the documented, reasonable out of pocket expenses incurred in conducting the audit and such audit shall not count towards the [***] ([***]) permitted audit for such Calendar Year.

4.6 Regulatory Matters. MedImmune shall have the sole right and responsibility for making Regulatory Filings for the MedImmune Study Products (including for the use of MedImmune Study Products in combination with the Microbiome Oncology Products as provided for under the Research Plan) and shall have the right to control interactions with Regulatory Authorities with respect to Research Plan activities. Seres will provide reasonable support for such Regulatory Filings and interactions with Regulatory Authorities as related to Microbiome Oncology Products that are used for Research Plan activities in combination with the MedImmune Study Products. Seres will have the right to attend all [***] meetings and conferences with Regulatory Authorities in which Microbiome Oncology Products will be discussed. Seres grants MedImmune a right to reference the drug master files ("**DMFs**") for the Microbiome Oncology Products solely as and to the extent needed for MedImmune to make Regulatory Filings for the MedImmune Study Products [***]. In the event that MedImmune deems it necessary to make Regulatory Filings in territories that do not support the referencing of DMFs, then Seres and MedImmune shall discuss such filings in good faith and agree an alternative arrangement, which may include [***]. Additionally, notwithstanding any other provision of this Agreement (including Article 10 hereunder), with respect to all data, results, analyses, and information which result from activities conducted under the Research Plan ("**Research Plan Data**"), (i) Seres may use the Research Plan Data in connection with filing, obtaining, and maintaining Regulatory Approvals for Microbiome Products (and for clarity subject to Section 2.2) and (ii) MedImmune may use the Research Plan Data in connection with filing, obtaining, and maintaining Regulatory Approvals for MedImmune Study Products.

4.7 Subcontracting. Either Party may perform any specific activities for which it is responsible in connection with the research activities allocated to it under the Research Plan through subcontracting to an Affiliate or a Third Party contractor (including a contract service organization or contract research organization). The subcontracting Party shall: (i) ensure that any Third Party subcontractor to whom a Party discloses Confidential Information of the other Party

is bound by an appropriate written agreement obligating such Third Party to obligations of confidentiality and restrictions on use of the other Party's Confidential Information that are no less restrictive than the obligations in this Agreement; (ii) ensure that such Affiliate or Third Party is bound in writing to assign or license (with the right to grant sublicenses) to such Party any inventions (and Patents and other intellectual property rights covering such inventions) made by such Third Party or its employees or agents in performing such services for such Party so as to enable such Party to comply with the terms of this Agreement; and (iii) at all times be responsible for and liable under this Agreement with respect to the performance or non-performance of such subcontractor.

ARTICLE 5
COMPLIANCE; OTHER REGULATORY MATTERS

5.1 Compliance. During the Term, each Party shall maintain in full force and effect all necessary licenses, permits, and other authorizations required by applicable Law to carry out its obligations under this Agreement. In addition, each Party shall be responsible for ensuring that all activities for which it is responsible under this Agreement are performed in accordance with all applicable Laws.

5.2 Debarred Persons. Without limiting Section 5.1, in the course of activities performed under this Agreement, neither Party shall use any employee, consultant or contractor:

5.2.1 who has been debarred under 21 U.S.C. § 335(a)-(b) or pursuant to the analogous applicable Laws of any Regulatory Authority;

5.2.2 who, to such Party's Knowledge, has 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 otherwise pursuant to the analogous applicable Laws of any Regulatory Authority, or is proposed for exclusion, or the subject of exclusion or debarment proceedings by a Regulatory Authority, during the employee's or consultant's employment or contract term with such Party; and

5.2.3 who is excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any U.S. or non-U.S. healthcare programs (or who has been convicted of a criminal offense that falls within the scope of 42 U.S.C. §1320a-7 but has not yet been 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.

Each Party shall notify the other Party promptly, but in no event later than [***] ([***]) Business Days, upon becoming aware that any of its employees or consultants has been excluded, debarred, suspended or is otherwise ineligible, or is the subject of exclusion, debarment or suspension proceedings by any Regulatory Authority.

5.3 Notifications Regarding Regulatory Matters. Each Party shall promptly (but in any event within [***] ([***]) Business Days) notify the other Party in writing upon the occurrence of any of the following:

5.3.1 receiving any communication from Regulatory Authorities with

respect to any CMC, safety or efficacy issue with respect to Microbiome Oncology Products or MedImmune Study Products in connection with the conduct of Research Plan activities.

5.3.2 In addition, if either Party determines that it is required to communicate with any Regulatory Authority regarding Microbiome Oncology Products or MedImmune Study Products in connection with the conduct of Research Plan activities, then it shall (x) so advise the other Party promptly, but in any event in less than [***] ([***]) Business Days, and (y) except to the extent prohibited by applicable Laws provide the other Party in advance with a copy of any proposed written communication with such Regulatory Authority. For purposes of clarity it is acknowledged that nothing herein shall be construed as limiting a Party's right to communicate with any Regulatory Authority or take such other immediate action related to Microbiome Oncology Products or MedImmune Study Products in connection with the conduct of Research Plan activities as is it reasonably deems necessary in order to comply with applicable Law; provided that notification to the other Party is provided as soon as practicable thereafter.

5.4 Safety Issues. The Parties will enter into a pharmacovigilance agreement ("**Pharmacovigilance Agreement**"), at a mutually agreed date, at least [***] ([***]) days prior to [***]. The Pharmacovigilance Agreement will govern the procedure for the mutual exchange of safety information within appropriate timeframes and in an appropriate format to enable the Parties to comply with any local and international regulatory reporting obligations and to facilitate appropriate safety reviews.

5.5 Each Party shall use any such information provided by the other Party pursuant to Section 5.4 solely to conduct the activities under the Research Plan and evaluate the safety of the MedImmune Study Products and Microbiome Oncology Products, and to comply with safety reporting requirements in accordance with applicable Laws. The Parties agree that such information provided to one another pursuant to Section 5.4 may be disclosed, to the extent required to be disclosed pursuant to the Pharmacovigilance Agreement. Such information may also be disclosed by a Party, to the extent required, to a Third Party in the event that such Party enters into a licensing, partnership, collaboration or acquisition agreement with such Third Party that involves MedImmune Study Products (as to a transaction to which MedImmune is a party) or Microbiome Oncology Products (as to a transaction to which Seres is a party), provided that the Third Party recipient of such information shall be bound by an obligation of confidentiality consistent with the obligations contained herein.

5.6 The Party that is the sponsor of a Clinical Trial conducted pursuant to the Research Plan shall be responsible for all safety reporting requirements to the appropriate Regulatory Authority and the investigators of such Clinical Trials.

5.7 The Party that is the sponsor of a Clinical Trial conducted pursuant to the Research Plan shall comply with all safety reporting requirements required under applicable Laws, including GVP, as well as insuring all appropriate consents have been obtained, and compliance with applicable Laws concerning privacy.

5.8 MedImmune shall report to Seres on any safety information related to its MedImmune Study Products and Seres shall report to MedImmune on any safety information related to its Microbiome Oncology Products in each case that [***], in each case where a Party

reasonably needs to know such safety information [***] in the conduct of the Clinical Trials conducted pursuant to the Research Plan.

5.9 In the event either Party has a material concern about a safety issue related to Microbiome Oncology Products in the Territory, such Party will present such safety issue to the JSC and the Parties will take the steps reasonable and necessary to review, address and resolve such safety concerns.

5.10 [***] will have the final decision rights regarding safety governance pertaining to the reference safety information of [***], should the Parties disagree, including [***].

ARTICLE 6
OPTION

6.1 Options. Subject to the terms and conditions in this Agreement, Seres hereby grants to MedImmune an exclusive option to obtain either (i) a worldwide, sublicensable (through multiple tiers) exclusive license under the Seres Patents, Seres Know-How and Seres Excluded [***] Know How) to make, use, sell, offer to sell, or import any and all Microbiome Oncology Products in the Field in the Territory (the "**Microbiome Oncology Collaboration Option**"), or (ii) a worldwide, sublicensable (through multiple tiers) exclusive license under the Seres Patents, Seres Know-How and Seres Excluded [***] Know How to make, use, sell, offer to sell, or import one (1) or more specific Microbiome Oncology Products in the Field in the Territory (the "**Individual Program Option**") and/or (iii) subject to Section 14.3.1(c), a worldwide, sublicensable (through multiple tiers) non-exclusive or exclusive (at MedImmune's sole discretion [***]) license under one or more items of (A) [***], (B) [***] and/or (C) [***] to make, use, sell, offer to sell, or import the MedImmune Study Products in the Territory ("**Non-Product Option**") (the Microbiome Oncology Collaboration Option, Individual Program Option and Non-Product Option, together, the "**Options**").

6.2 Option Exercise Period. At any time prior to ninety (90) days after the end of the Exclusivity Period (the "**Option Period**"), MedImmune shall have the one-time right to exercise the Microbiome Oncology Collaboration Option or the Individual Program Option and the additional right to exercise the Non-Product Option (whether alone or in conjunction with the exercise of the Microbiome Oncology Collaboration Option or the Individual Program Option) by delivering to Seres a license option exercise notice(s) (a "**License Option Exercise Notice**").

6.3 Option Negotiation.

6.3.1 Upon delivery by MedImmune of a License Option Exercise Notice pursuant to Section 6.2, the Parties shall, in good faith, negotiate exclusively for a period of six (6) months (or such longer period as the Parties may agree in writing) (the "**Exclusive Option Negotiation Period**") to put in place a definitive agreement providing for the rights to be granted as described above in Section 6.1, the rights to be granted as further described in this Section 6.3.1, financial terms, and any other matters that would customarily be included in a definitive licensing and collaboration agreement, including without limitation, [***]. Any such definitive agreement shall include:

(i) with respect to a definitive agreement executed pursuant to the Microbiome Oncology Collaboration Option, (a) [***]; (b) any additional research or development

activities in the Field on which the Parties may elect to collaborate and the financial terms associated therewith; (c) [***], upon MedImmune's request and (d) terms necessary to protect Seres' interests in the Seres Excluded [***] Know How such as, by way of example only, [***]; or

(ii) with respect to a definitive agreement executed pursuant to the Individual Program Option, (a) a provision that each Party, itself or with or through any Affiliate or Third Party, [***], including [***]; (b) [***], upon MedImmune's request and (c) terms necessary to protect Seres' interests in the Seres Excluded [***] Know How such as, by way of example only, [***]; and/or

(iii) with respect to a definitive agreement executed pursuant to the Non-Product Option, [***].

6.3.2 If during the Exclusive Option Negotiation Period the Parties are unable to execute a definitive agreement consistent with Section 6.3.1, then Seres shall be free to license and/or further develop or otherwise exploit the Seres Patents, Seres Know-How, and Joint Intellectual Property Rights without further obligation to MedImmune, except that during a period of one (1) year following the expiration of the Exclusive Option Negotiation Period:

(i) Seres shall not [***] rights to a Third Party with respect to the [***] (a "**Grant**") upon [***] terms [***] than the last such terms offered to MedImmune, without first offering such [***] terms to MedImmune; and

(ii) [***].

6.4 Termination of Options. If upon the expiration of the Option Period MedImmune has not delivered a License Option Exercise Notice pursuant to Section 6.2, Seres shall be free to license and/or further develop or otherwise exploit the Seres Patents and Seres Know-How and Joint Intellectual Property Rights without further obligation to MedImmune.

ARTICLE 7
FINANCIAL TERMS

7.1 Payment. Subject to the terms and conditions of this Agreement and receipt of an invoice from Seres, MedImmune shall pay to Seres twenty million dollars ($20,000,000), payable in three (3) non-cancellable (subject to Section 12.3.3) installments as follows:

Payment Date	**Payment**
Within thirty (30) Business Days of the Effective Date	$6,666,666.67 (six million six hundred and sixty-six thousand dollars and sixty-seven cents)
January 2, 2020	$6,666,666.67 (six million six hundred and sixty-six thousand dollars and sixty-seven cents)

January 4, 2021	$6,666,666.66 (six million six hundred and sixty-six thousand dollars and sixty-six cents)

7.2 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.

7.3 Interest on Late Payments. 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 [***] ([***]) percentage points above the U.S. prime interest rate, as reported by The Wall Street Journal (New York edition) for the first Business Day of such month. Such interest shall be accrued daily.

7.4 Taxes and Withholding. The amounts payable under this Agreement shall not be reduced on account of any taxes [***]. If any applicable Law requires the deduction or withholding of any taxes from any payment to Seres under this Agreement (i) MedImmune shall give advance notice to Seres [***], (ii) MedImmune shall [***], and (iii) MedImmune shall [***]. The Parties agree to cooperate with each other in a commercially reasonable manner in obtaining all legally available exemptions from or reductions of any such taxes and in timely providing each other with any applicable documents necessary to obtain any such exemptions or reductions. Any such amounts deducted by MedImmune in respect of such withholding or similar tax [***]. Notwithstanding the foregoing, if (a) [***], (b) [***], and (c) [***]. Solely for purposes of this Section 7.4, [***]. Notwithstanding anything to the contrary in this Section 7.4, the Parties acknowledge and agree that MedImmune [***]. For the avoidance of doubt, except as otherwise provided herein, (i) [***]; and (ii) [***].

7.5 Indirect Taxes. All payments under this Agreement are stated exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any payments due to Seres under this Agreement, MedImmune 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 in the appropriate form by Seres in respect of those payments.

ARTICLE 8
REPRESENTATIONS AND WARRANTIES

8.1 Mutual Representations and Warranties. Seres and MedImmune each represents and warrants to the other, as of the Effective Date, as follows:

8.1.1 Organization. It is duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

8.1.2 Authorization. The execution and delivery of this Agreement and the performance by it of its obligations contemplated hereby have been duly authorized by all necessary corporate action, and do not violate (i) such Party's charter documents, bylaws, or

other organizational documents, (ii) in any material respect, any agreement, instrument, or contractual obligation to which such Party is bound, (iii) any requirement of any applicable Law, or (iv) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party.

8.1.3 Binding Agreement. This Agreement is a legal, valid, and binding obligation of such Party enforceable against it in accordance with its terms and conditions, 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).

8.1.4 Consents and Approvals. No consent, approval, waiver, order or authorization of, or registration, declaration or filing with, any Third Party or any Governmental Authority is required in connection with the execution, delivery, and performance of this Agreement by such Party or the performance by such Party of its obligations contemplated hereby or thereby.

8.1.5 No Conflict. The execution and delivery of this Agreement, the performance of such Party's obligations hereunder and the licenses and sublicenses to be granted pursuant to this Agreement (i) do not and will not conflict with or violate any requirement of applicable Law; (ii) do not and will not conflict with or violate the certificate of incorporation, by-laws or other organizational documents of such Party; and (iii) do not and will not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates.

8.1.6 No Consents. No authorization, consent, approval of a Third Party, nor any license, permit, exemption of or filing or registration with or notification to any court or Governmental Authority is or will be necessary (i) for the valid execution, delivery or performance of this Agreement by such Party; or (ii) for the consummation by such Party of the transactions contemplated hereby.

8.2 Representations and Warranties of Seres. Seres represents and warrants to MedImmune as follows as of the Effective Date:

8.2.1 the Seres Patents, insofar as they have been granted, have been maintained, and, to Seres' knowledge are not invalid or unenforceable, in whole or in part;

8.2.2 there are no claims, judgments or settlements against or owed by Seres and, to the knowledge of Seres, no pending or threatened claims or litigation, relating to any Seres Patents, Seres Know-How, or Microbiome Oncology Product;

8.2.3 neither it nor its applicable Affiliates have previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in Seres Patents or Seres Know-How in a manner that would prevent it and its Affiliates from fulfilling any of their respective obligations hereunder, or otherwise conflict with the rights of MedImmune. hereunder;

8.2.4 neither Seres nor any of its Affiliates are subject to any payment obligations to Third Parties as a result of the execution of this Agreement;

8.2.5 Seres (and its Affiliates) is not aware of any material adverse information with respect to the safety or efficacy of any Microbiome Product that has not been disclosed to MedImmune as of the Effective Date;

8.3 Covenants of Seres. At all times during the Term, Seres shall comply with the following:

8.3.1 neither Seres nor its Affiliates shall enter into any agreement, whether written or oral, with respect to, or otherwise assign, transfer, license, or convey its right, title or interest in or to, the Seres Patents, Seres Know-How, Seres Arising Inventions and Information or Microbiome Oncology Products (including by granting any covenant not to sue with respect thereto) that is in conflict with the rights granted to MedImmune under this Agreement; and

8.3.1 Seres (and its Affiliates) (a) shall not breach and shall maintain in full force and effect each of the [***] Collaboration and [***] Collaboration, and keep MedImmune fully informed of any material development pertaining thereto, (b) shall faithfully and timely perform and discharge its obligations under each of the [***] Collaboration and [***] Collaboration (c) to the extent within Seres' (or its Affiliate's) reasonable control, not take any action or allow any event to occur that would [***] without the written consent of MedImmune, and (d) shall not exercise any right itself (or through its Affiliate) to terminate, or enter into any amendment or modification of, or waive any material right under the [***] Collaboration (including [***]) or [***] Collaboration (including [***]) without the prior written consent of MedImmune.

ARTICLE 9
INTELLECTUAL PROPERTY

9.1 Ownership of Inventions and Intellectual Property.

9.1.1 Seres Inventions. As between the Parties, Seres shall solely own all Seres Arising Inventions and Information, and all Patents and other intellectual property rights therein. MedImmune hereby assigns to Seres all of its right, title, and interest in, to, and under the Seres Arising Inventions and Information, and all Patents and other intellectual property rights therein.

9.1.2 MedImmune Inventions. As between the Parties, MedImmune shall solely own all MedImmune Arising Inventions and Information, and all Patents and other intellectual property rights therein. Seres hereby assigns to MedImmune all of its right, title, and interest in, to, and under the MedImmune Arising Inventions and Information, and all Patents and other intellectual property rights therein.

9.1.3 Joint Inventions. Except for the Seres Arising Inventions and Information and the MedImmune Arising Inventions and Information, as between the Parties,

each Party shall each own an equal, undivided interest in all Inventions and Information that are conceived, discovered, or otherwise made by or on behalf of such Parties (or their Affiliates or sublicensees), whether solely or jointly, in the course of performing activities contemplated in this Agreement, whether or not patented or patentable, and any and all Patents ("**Joint Patents**") and other intellectual property rights therein (the "**Joint Intellectual Property Rights**"). Jointly owned Inventions and Information include without limitation Inventions and Information that [***]. 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 such Inventions and Information. Subject to the licenses and covenants granted under Article 2, each Party may, and may permit, through sublicenses or otherwise, others to, freely use, practice, and otherwise exploit the Joint Intellectual Property Rights without a duty of seeking consent or accounting to the other Party.

9.1.4 United States Law. The determination of whether Information and Inventions are conceived, discovered or otherwise made by a Party, shall, for purposes of this Agreement, be made in accordance with applicable Law in the United States.

9.1.5 Assignment Obligation. Each Party shall cause all Persons who perform activities for such Party under this Agreement to assign their rights in any Inventions resulting therefrom to such Party.

9.2 Maintenance and Prosecution of Patents in the Territory.

9.2.1 Prosecution of Seres Patents. Seres shall (i) using outside legal counsel of its choice, have the sole right, but not the obligation, to file, prosecute (including any opposition or post-grant proceedings at the patent offices, inter partes proceedings or supplementary protection certificates or the like, in each case in respect of the Seres Patents), and maintain the Seres Patents in the Territory.

9.2.2 Prosecution of MedImmune Patents. MedImmune shall (i) using legal counsel of its choice, have the sole right, but not the obligation, to file, prosecute (including any opposition or post-grant proceedings at the patent offices, inter partes proceedings or supplementary protection certificates or the like, in each case in respect of the MedImmune Patents), and maintain the MedImmune Patents in the Territory.

9.2.3 Prosecution of Joint Patents.

(i) [***] shall, using legal counsel of its choice that is reasonably acceptable to [***], have the first right, but not the obligation, to obtain, prosecute (including any oppositions, post-grant reviews, inter partes proceedings or supplementary protection certificates, in each case in respect of Joint Patents), and maintaining a Joint Patent throughout the world. If [***] declines, or otherwise fails, to initiate any such requested action with respect to a Joint Patent within [***] ([***]) days after notice of the applicable Invention or Information (or, if after initiating any requested action, [***] at any time thereafter fails to [***]), in each case [***] shall have the right to take such action with respect to such Joint Patent. The Parties shall, and shall cause their respective Affiliates, as applicable, to assist and cooperate with one another in, and share equally the cost and expense of, filing, prosecuting and maintaining the Joint Patents. Notwithstanding the above, either Party may decline to pay its share of the costs and expenses for filing,

prosecuting and maintaining any Joint Patent in a particular country or particular countries, in which case the declining Party shall assign, and shall cause its Affiliates to assign, to the other Party all of their rights, title, and interest in and to any such Joint Patent in the relevant country or countries whereupon such Joint Patent shall become a Patent owned solely by the relevant Party assignee in such country or countries, as the case may be.

(ii) In connection with the activities set forth in this Section 9.2.3: (a) each Party prosecuting rights under Section 9.2.3 shall consult with the other as to the strategy and prosecution of applications for such Joint Patents and the maintenance or extension of such Joint Patents; (b) each prosecuting Party shall regularly provide the other Party with copies of all Joint Patent applications filed hereunder for such Joint Patents and other material submissions and correspondence with the patent offices in such jurisdictions for such Joint Patents to allow reasonable time to allow for review and comment by the other Party, and in any event at least [***] ([***]) days in advance of the due date of any payment or other administrative action that is required to obtain or maintain such Joint Patent ([***]); (c) such prosecuting Party shall provide the other Party and its patent counsel with an opportunity to consult with the filing Party and its patent counsel regarding the filing and contents of any such application, amendment, submission, or response; and (d) such prosecuting Party shall notify the other Party as early as reasonably practicable, and in any event at least [***] ([***]) days in advance of all meetings and [***] communications with any patent authorities concerning such Joint Patents ([***]) and shall permit the other Party to participate in such meetings, and the advice and suggestions of the other Party and its patent counsel shall be taken into consideration in good faith by such Party and its patent counsel in connection with such filing.

9.3 Enforcement of Patents. In the event that either Party has cause to believe that a Third Party may be infringing: (i) any of the Seres Patents or MedImmune Patents, in each case, in the Field in the Territory, or (ii) any of the Joint Patents worldwide, it shall promptly notify the other Party in writing, identifying the alleged infringer and the alleged infringement complained of, and furnishing the information upon which such determination is based.

9.3.1 Seres Patents. Seres, using counsel of its choice, shall have the sole right, but not the obligation, to stop such infringement of the Seres Patents by such Third Party in the Field and outside the Field worldwide.

9.3.2 MedImmune Patents. MedImmune, using counsel of its choice, shall have the sole right, but not the obligation, to stop such infringement of the MedImmune Patents by such Third Party in the Field and outside the Field worldwide.

9.3.3 Joint Patents. In consultation with [***], [***], using counsel reasonably acceptable to [***], shall have the first right to stop such infringement of the Joint Patents by such Third Party. If [***] fails to take action within [***] ([***]) days following its receipt of a notice of such infringement, then [***] shall have the right to take action to stop such infringement. Upon reasonable request by the Party enforcing a Joint Patent (the "**Enforcing Party**"), the other Party (the "**Non-Enforcing Party**") shall give the Enforcing Party all reasonable information and assistance, including allowing the Enforcing Party access to the Non-Enforcing Party's files and documents and to the Non-Enforcing Party's personnel who may have possession of relevant information and, if necessary or desirable for the Enforcing Party to prosecute any legal action, joining in the legal action as a party using counsel

of its own choosing. Any such assistance provided by a Non-Enforcing Party shall be rendered at the Enforcing Party's cost and expense and the Enforcing Party shall reimburse the Non-Enforcing Party for its reasonable and documented costs and expenses upon the Non-Enforcing Party's request.

9.3.4 Settlement of an Enforcement Claim.

(i) Seres shall have the right to control settlement of any claims that a Third Party may be infringing any Seres Patent.

(ii) MedImmune shall have the right to control settlement of any claims that a Third Party may be infringing any MedImmune Patent.

(iii) The Enforcing Party shall have the right to control settlement of any claims that a Third Party may be infringing any Joint Patent; provided, however, that if such settlement could reasonably be deemed to have a material adverse effect on the Non-Enforcing Party, the Enforcing Party shall not enter into any such settlement without the prior written consent of the Non-Enforcing Party.

9.3.5 Expenses and Recovery.

(i) As between the Parties, Seres shall bear all costs and expenses (including any costs or expenses incurred that exceed the amounts recovered by Seres pursuing any action under this Section 9.3) and payments awarded against or agreed to be paid by Seres with respect to enforcement claims related to the Seres Patents.

(ii) As between the Parties, MedImmune shall bear all costs and expenses (including any costs or expenses incurred that exceed the amounts recovered by MedImmune pursuing any action under this Section 9.3) and payments awarded against or agreed to be paid by MedImmune with respect to enforcement claims related to the MedImmune Patents.

(iii) As between the Parties, the Enforcing Party shall bear all costs and expenses (including any costs or expenses incurred that exceed the amounts recovered by the Enforcing Party pursuing any action under this Section 9.3) and payments awarded against or agreed to be paid by the Enforcing Party with respect to enforcement claims related to the Joint Patents. Any amounts recovered by either Party pursuant to Section 9.3, whether by settlement or judgment, shall be allocated in accordance with the following: (a) such amounts first shall be used to reimburse the Parties for their reasonable costs and expenses in making such recovery and, if insufficient to cover the totality of such costs and expenses, shall be allocated between the Parties in proportion to their respective costs and expenses; and (b) such remainder shall be allocated [***] percent ([***]%) to the Enforcing Party and [***] percent ([***]%) to the other Party.

ARTICLE 10
CONFIDENTIAL INFORMATION; PUBLICATIONS

10.1 Nondisclosure. Each Party agrees that during the Term and for a period of [***] ([***]) years thereafter, a Party (the "**Receiving Party**") receiving Confidential Information of

the other Party (the "**Disclosing Party**") (or that has received any such Confidential Information from the other Party prior to the date hereof) shall (i) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own proprietary industrial information of similar kind and value, which shall be no less than a reasonable degree of care, (ii) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below, and (iii) not use such Confidential Information for any purpose except those permitted by this Agreement (it being understood that this clause (iii) shall not create or imply any rights or licenses not expressly granted under Article 2 hereof). Each Party will promptly notify the other Party upon gaining Knowledge of any material use or disclosure of Confidential Information of the other Party not permitted pursuant to this Article 10. The Parties agree that any "Confidential Information" (within the meaning of the Prior CDA) disclosed by the Parties or their Affiliates pursuant to the Prior CDA shall be Confidential Information within the meaning of, and shall be subject to, this Article 10.

10.1.1 Exceptions. The obligations in Section 10.1 shall not apply with respect to any portion of the Confidential Information that the Receiving Party to the extent that such information:

(i) is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party hereunder;

(ii) was known to the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party, and such prior knowledge can be properly documented by the Receiving Party;

(iii) is subsequently disclosed to the Receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof and without any obligation to keep it confidential or any restriction on its use;

(iv) is published by a Third Party or otherwise becomes publicly available or enters the public domain, either before or after it is disclosed to the Receiving Party without the fault or cause of the Receiving Party; or

(v) is independently developed by employees or contractors of the Receiving Party or any of its Affiliates without the aid, application or use of Confidential Information of the Disclosing Party, and such independent development can be properly documented by the Receiving Party.

10.2 Authorized Disclosure. The Receiving Party may disclose Confidential Information belonging to the Disclosing Party only to the extent such disclosure is reasonably necessary in the following instances:

(i) to any relevant patent office in preparing, filing, prosecuting, and maintaining patents in accordance with the provisions of Article 9;

(ii) prosecuting or defending litigation or in establishing rights (whether through declaratory actions or other legal proceedings) or enforcing obligations under this

Agreement;

(iii) to Regulatory Authorities as and to the extent permitted by Section 4.6;

(iv) subject to Section 10.4, complying with applicable Laws and regulations (including, without limitation, the rules and regulations of the Securities and Exchange Commission or any national securities exchange) and with judicial process, if in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance;

(v) disclosure to its Affiliates, and to its (actual or potential) permitted sublicensees, acquirers, or assignees under Sections 5.5 and 14.3 and subcontractors (and their advisors) and to investment bankers, investors, lenders, accountants, and legal advisors and each of the Parties' respective directors, employees, contractors, and agents, each of whom prior to disclosure must be bound by written obligations of confidentiality and non-use no less restrictive than the obligations set forth in this Article 10; provided, however, that the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 10.2(v) to treat such Confidential Information as required under this Article 10; and

(vi) to relevant academics or healthcare professionals who are deemed to be "opinion leaders" in order to promote, or raise awareness of, any Microbiome Oncology Product; provided, however, that the JSC 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.

If and whenever any Confidential Information is disclosed in accordance with this Section 10.2, such disclosure shall not cause any such information to cease to be Confidential Information, except to the extent that such disclosure results in a public disclosure of such information (otherwise than by breach of this Agreement). Where reasonably possible and subject to Section 10.4 and other than pursuant to Section 10.2 (ii)-(iv), the Receiving Party shall:

(1) give the Disclosing Party reasonable advance notice of the Receiving Party's intent to make such disclosure pursuant to this Section 10.2, to the extent practicable; and

(2) provide reasonable cooperation to the Disclosing Party regarding the timing and content of such disclosure and regarding any action which the Disclosing Party may deem appropriate to protect the confidentiality of the information by appropriate legal means.

10.3 Terms of this Agreement. The Parties acknowledge that the terms of this Agreement shall be treated as Confidential Information of both Parties.

10.4 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

intention. 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 [***] ([***]) Business Days (or such shorter period of time as may be required, under the circumstances, to comply with applicable Laws, but in no event less than [***] ([***]) Business Days) 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. The Party required to file shall use commercially reasonable efforts to obtain confidential treatment of the terms and conditions of this Agreement that such other Party requests be kept confidential and shall only disclose Confidential Information which it is advised by legal counsel is legally required to be disclosed in order to comply. No such notice shall be required under this Section 10.4 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.

10.5 Publications. Each Party recognizes that the publication of papers regarding results of and other information regarding activities under this Agreement may be beneficial to the potential of the research undertaken pursuant to this Agreement. All publications, and other forms of public disclosure such as abstracts and presentations, of results of studies carried out under this Agreement (each of the foregoing, a "**Publication**") will comply with the strategy established by the JSC and will not contain the Confidential Information of the other Party without the other Party's advance written consent. Neither Party nor their Affiliates may submit for publication, publish or present a Publication without the opportunity for prior review by the other Party, except to the extent required by applicable Laws. A Party seeking, or whose Affiliate is seeking, to submit, publish, or present a Publication shall provide the other Party the opportunity to review and comment on the proposed Publication at least [***] ([***]) Business Days prior to its intended submission for publication or presentation. The other Party shall provide the Party seeking, or whose Affiliate is seeking, to publish or present with its comments in writing, if any, within [***] ([***]) days after receipt of such proposed Publication. The Party seeking, or whose Affiliate is seeking, to publish, or present shall consider in good faith any comments thereto provided by the other Party and shall comply with the other Party's request to remove any and all of such other Party's Confidential Information from the proposed Publication. In addition, the Party seeking, or whose Affiliate is seeking, to publish, or present shall delay the submission for a period of up to an additional [***] ([***]) days in the event that the other Party can demonstrate reasonable need for such delay in order to prepare and file a patent application for which it has prosecution control pursuant to this Agreement. If the other Party fails to provide its comments to the Party seeking, or whose Affiliate is seeking, to publish or present within such [***] ([***])-day period, such other Party shall be deemed not to have any comments, and the Party seeking, or whose Affiliate is seeking, to publish or present shall be free to submit for publication or present in accordance with this Section 10.5 after the [***] ([***])-Business Day period has elapsed. The Party seeking, or whose Affiliate is seeking, to publish or present shall provide the other Party a copy of the manuscript, abstract or presentation at the time of the submission or presentation, as applicable. Each Party agrees to acknowledge the contributions of the other Party and its Affiliates and their employees in all publications, as scientifically appropriate.

10.6 Return of Confidential Information. Upon termination of this Agreement, any and all Confidential Information possessed in a tangible form by a Receiving Party, its Affiliates, sublicensees, or subcontractors and belonging to a Disclosing Party shall, upon written request, be returned or destroyed to the extent practicable, except to the extent necessary to practice rights and

licenses surviving such termination, with written confirmation of such destruction, provided, however, that a Party may retain one (1) copy of any Confidential Information solely for archival purposes. Notwithstanding the Receiving Party's return or destruction of Confidential Information, the Receiving Party shall continue to be bound by its obligations of confidentiality and non-use under this Agreement.

10.7 Publicity. Upon execution of this Agreement, the Parties shall issue a press release announcing the existence of this Agreement in a form, and containing substance, to be agreed in good faith between the Parties (such agreement not to be unreasonably withheld or delayed by either Party). Subject to Section 10.4, each Party agrees not to issue any other press release or other public statement disclosing other information relating to this Agreement or the transactions contemplated hereby without the prior written consent of the other Party. Each Party shall use all reasonable efforts to provide to the other Party a copy of any public announcement regarding this Agreement or the subject matter hereof as soon as reasonably practicable under the circumstances prior to its scheduled release (but in no event less than [***] ([***]) Business Days prior to its scheduled release, unless a shorter period is required to comply with applicable Law under the circumstances). Each Party shall have the right to expeditiously review and recommend changes to any such announcement and the Party whose announcement has been reviewed shall remove any Confidential Information of the reviewing Party that the reviewing Party reasonably deems to be inappropriate for disclosure except to the extent such disclosure is required by applicable Law or rules of a securities exchange or the Securities and Exchange Commission or the securities regulators of any state or other jurisdiction. The contents of any announcement or similar publicity, which has been reviewed and approved by the reviewing Party, (including the press release referred to at the beginning of this Section 10.7) can be re-released by either Party without a requirement for re-approval.

ARTICLE 11
INDEMNIFICATION

11.1 Indemnification of MedImmune. Subject to Section 11.3, Seres shall indemnify, defend, and hold harmless MedImmune and its Affiliates and each of their officers, directors, shareholders, employees, successors, and permitted assigns from and against all Third Party Claims, and pay all associated Losses, arising out of (i) Seres' or its Affiliate's or its or their sublicensee's, distributor's, subcontractor's or its or their respective director's, officer's, employee's or agent's gross negligence, willful misconduct, or violation of applicable Law in performing any of its obligations under this Agreement or (ii) any breach by Seres of this Agreement, including any of its representations, warranties, or covenants hereunder. Notwithstanding the preceding sentence, Seres shall have no obligation with respect to Third Party Claims or associated Losses to the extent they are subject to MedImmune's indemnification obligations pursuant to Section 11.2.

11.2 Indemnification of Seres. Subject to Section 11.3, MedImmune shall indemnify, defend, and hold harmless Seres and its Affiliates and each of their officers, directors, shareholders, employee's, successors, and permitted assigns from and against all Third Party Claims, and pay all associated Losses, to the extent arising out of (i) MedImmune's or its Affiliate's or its or their sublicensee's, distributor's, subcontractor's or its or their respective director's, officer's, employee's or agent's gross negligence, willful misconduct, or violation of applicable Law in performing any of its obligations under this Agreement or (ii) any breach by MedImmune of this Agreement, including any of its representations, warranties, or covenants hereunder.

Notwithstanding the preceding sentence, MedImmune shall have no obligation with respect to Third Party Claims or associated Losses to the extent they are subject to Seres' indemnification obligations pursuant to Section 11.1.

11.3 Procedure for Indemnification.

11.3.1 Notice. Each Party ("**Indemnified Party**") will notify promptly the other Party ("**Indemnifying Party**") in writing if it becomes aware of a Claim (actual or potential) by any Third Party or any proceeding commenced by a Third Party (including any investigation by a Governmental Authority) (any of the foregoing, a "**Third Party Claim**") for which indemnification may be sought and will give such related information as the Indemnifying Party shall reasonably request; provided, however, that no failure or delay in giving such notice shall limit the Indemnified Party's right to indemnification hereunder except to the extent that the Indemnifying Party is prejudiced thereby.

11.3.2 Defense of Claim. The Indemnifying Party shall defend or control the defense of Third Party Claims. [***]. The Indemnifying Party shall retain counsel reasonably acceptable to the Indemnified Party (such acceptance not to be unreasonably withheld, refused, conditioned, or delayed) to represent the Indemnified Party and [***]. In any such proceeding, the Indemnified Party shall have the right to participate in, but not control, the defense of such proceeding [***] and shall have the right to retain its own counsel, [***]. Neither Party shall [***]. The Indemnified Party shall cooperate in all reasonable respects in the defense of such Third Party Claim, as requested by the Indemnifying Party. The Indemnifying Party shall not, [***], effect any settlement of any such Third Party Claim, unless such settlement [***]. Notwithstanding the foregoing, if the Indemnifying Party notifies the Indemnified Party 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 [***] ([***]) Business Days before any deadline the passing of which could adversely affect the outcome without responsive action by or on behalf of the Indemnified Party (or, if the Indemnifying Party receives less than [***] ([***]) Business Days' notice of such deadline, if it fails to assume such defense as soon as practicable following receipt of notice), the Indemnified Party shall have the right to assume and control such defense and shall have the right to settle or compromise the same without the Indemnifying Party's consent, and [***] by the Indemnified Party in connection therewith, including [***], will be [***].

11.4 Insurance. During the Term of this Agreement, the Parties shall obtain and maintain at their sole cost and expense, an adequate liability insurance or self-insurance program (including product liability insurance) to protect against potential liabilities and risk arising out of the research activities performed pursuant to this Agreement (including coverages, deductible limits, and self-insured retentions) as are customary in the biopharmaceutical industry in such Party's territory. The 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.

ARTICLE 12
TERM AND TERMINATION

12.1 Effectiveness; Term. This Agreement is binding and effective as of the Effective

Date and shall continue in force from and after the date hereof until terminated in accordance with the terms hereof or by mutual written agreement of the Parties (the "**Term**").

12.2 Termination Rights.

12.2.1 Insolvency. Either Party shall have the right to terminate this Agreement in its entirety upon immediate written notice if the other Party (i) files for protection under bankruptcy or insolvency laws, (ii) makes an assignment for the benefit of creditors, (iii) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within ninety (90) days after such filing, (iv) proposes a written agreement of composition or extension of its debts, (v) proposes or is a party to any dissolution or liquidation, (vi) files a petition under any bankruptcy or insolvency act relating to bankruptcy, insolvency, reorganization, winding-up, or composition or readjustment of debts or has any such petition filed against that is not discharged within sixty (60) days of the filing thereof, (vii) commences a voluntary case under the Bankruptcy Code of any country, (viii) fails to controvert in a timely and appropriate manner, or acquiesce in writing to, any petition filed against it in any involuntary case under the Bankruptcy Code of any country, (ix) takes any corporate action for the purpose of effecting any of the foregoing, (x) has a proceeding or case commenced against it in any court of competent jurisdiction, seeking (A) its liquidation, reorganization, dissolution or winding-up, or the composition or readjustment of its debts, (B) the appointment of a trustee, receiver, custodian, liquidator or the like of all or any substantial part of its assets, or (C) similar relief under the Bankruptcy Code of any country, or an order, judgment or decree approving any of the foregoing is entered and continues unstayed for a period of sixty (60) days, or (xi) has an order for relief against it entered in an involuntary case under the Bankruptcy Code of any country.

12.2.2 Termination for Material Breach.

(i) Breach. Subject to Section 12.2.2(ii) below, a Party shall have the right to terminate this Agreement in such Party's sole discretion, upon delivery of written notice to the other Party in the event of any material breach by such other Party of this Agreement, provided that such breach has not been cured within sixty (60) days after written notice thereof is given by the terminating Party specifying the nature of the alleged material breach in reasonable detail. Notwithstanding the foregoing, if such material breach, by its nature cannot be cured within the foregoing cure period or is incurable, but the consequences of such breach can be reasonably alleviated but not within the foregoing cure period, then such cure period shall be extended if, prior to the end of the initial sixty (60) day cure period, the non-terminating Party provides a reasonable written plan for curing or reasonably alleviating the consequences of such material breach and thereafter uses diligent efforts to cure or alleviate such material breach in accordance with such written plan; provided that no such extension shall exceed ninety (90) days after the end of the initial sixty (60) day cure period without the consent of the terminating Party.

(ii) Disputed Breach. If a Party disputes in good faith (a) the existence or materiality of a material breach specified in a notice provided by the other Party pursuant to Section 12.2.2(i), (b) any assertion by the other Party that such Party has failed to cure or reasonably alleviate any such material breach, or (c) any assertion by the other Party that such Party has failed to use its diligent efforts to cure or reasonably alleviate any such material breach in accordance with any relevant written plan, and, in each case, such Party provides notice to the other Party of such dispute within the applicable cure period, the other Party shall not have the right to terminate this Agreement, unless and until the existence of such material breach or failure by such Party has been determined in accordance with Sections 13.1 and 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.

12.2.3 Termination by MedImmune Without Cause. MedImmune shall have the right to terminate this Agreement in its entirety without cause upon one hundred and twenty (120) days written notice to Seres.

12.3 Effect of Termination. Upon the effectiveness of any termination of this Agreement in its entirety:

12.3.1 All rights and licenses granted to MedImmune in Article 2 shall terminate, all rights of MedImmune under the Seres Patents and Seres Know-How shall revert to Seres, and MedImmune shall cease all use of the Seres Patents and Seres Know-How;

12.3.2 All rights and licenses granted to Seres in Article 2 shall terminate, all rights of Seres under the MedImmune Patents and MedImmune Know-How shall revert to MedImmune, and Seres shall cease all use of the MedImmune Patents and MedImmune Know-How; and

12.3.3 All amounts due or payable to a Party that were accrued, or that arise out of acts or events occurring, prior to the date of termination or expiration, or acts taken to

wind down activities being conducted under this Agreement in connection with termination hereof, shall be or remain due and payable; additionally, any amounts payable but not yet paid by MedImmune to Seres under Section 7.1 shall continue to be payable by MedImmune to Seres on the terms and conditions set forth therein solely in the event of termination by MedImmune pursuant to Sections 12.2.3 or by Seres pursuant to Section 12.2.1 or 12.2.2; but (except as otherwise expressly provided herein) no additional amounts shall be payable based on events occurring after the effective date of such termination or expiration.

12.3.4 Further Effects of Termination. If this Agreement is terminated as provided in Section 12.2, this Agreement shall thereafter become void and have no effect, provided that (i) the following provisions hereof shall survive any such termination and remain in full force and effect in accordance with the terms thereof: Articles 1, 5 (solely with respect to activities conducted during the Term), 10, 11 (solely with respect to activities conducted during the Term and except for Section 11.4), 13 and 14 (except that Section 14.3.1 shall not apply unless it becomes applicable during the Term), and Sections 2.3, 7.1 (subject to Section 12.3.3), 7.2, 7.3, 7.4, 7.5, 9.1, 9.3.5 (solely to the extent amounts become payable during the Term), and 12.3; (ii) such termination shall not relieve either Party of any obligation, or deprive either Party from any benefit, accruing prior thereto, and (iii) such termination shall be without prejudice to the rights and remedies of any party with respect to any antecedent breach of the provisions of this Agreement.

12.4 Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Seres or MedImmune are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code of the United States (or the corresponding provision of any applicable bankruptcy laws of any other country or competent Governmental Authority, as applicable), licenses of right to "intellectual property" as defined under Section 101 of the Bankruptcy Code of the United States (or the corresponding provision of any applicable bankruptcy laws of any other country or competent Governmental Authority, as applicable). The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the Bankruptcy Code, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under (i) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

ARTICLE 13
DISPUTE RESOLUTION

13.1 Elevation of Issues for Resolution. In the event the Parties or their representatives are unable to agree upon any matter coming before the JSC or any subcommittee or subgroup thereof (except for those matters within the purview of the JSC for which MedImmune has final decision-making authority for pursuant to Section 3.4) or in the event of any other dispute or disagreement between the Parties arising from or in connection with this Agreement, the construction hereof, or the rights, duties or liabilities of either Party hereunder (each, a "**Dispute**"),

the Parties shall endeavor to resolve such Dispute in accordance with the terms of this Section 13.1. Upon the receipt of a written notice from one Party to the other Party of the Dispute (the "**Notice of Dispute**"), authorized representatives of the Parties, each with authority to settle the Dispute, shall endeavor to discuss their respective positions and attempt to resolve the Dispute. In connection with such discussion, the Parties may agree to confer with one or more mutually acceptable independent Third Party experts having expertise in the relevant subject matter and both Parties shall consider in good faith the views of such Third Party(ies). If for any reason a written agreement signed by both Parties is not reached within [***] ([***]) Business Days of the Notice of Dispute, the Parties shall promptly refer the Dispute to, as appropriate, Seres' and MedImmune's respective [***] (the "**Senior Officers**"), depending on the subject matter of the Dispute, which Senior Officers will have authority to settle the Dispute and shall be charged with resolving such Dispute. If for any reason a written agreement signed by both Parties has not been reached within [***] ([***]) Business Days after submission to the Senior Officers of such Dispute, the Parties shall promptly refer such Dispute to the respective Chief Executive Officers of Seres and MedImmune for resolution.

13.2 Governing Law. This Agreement shall be governed by and construed and enforced under the substantive laws of the State of Delaware, excluding any conflicts or choice of law rule or principle that might otherwise make this Agreement subject to the substantive law of another jurisdiction; provided that any dispute relating to the inventorship, scope, validity, enforceability or infringement of any patent right shall be governed by and construed and enforced in accordance with the patent laws of the applicable jurisdiction.

ARTICLE 14
MISCELLANEOUS

14.1 Severability. If and to the extent that any provision (or any part thereof) of this Agreement is held to be invalid, illegal or unenforceable, in any respect in any jurisdiction, the provision (or the relevant part thereof) shall be considered severed from this Agreement and shall not serve to invalidate the remainder of such provision or any other provisions hereof. The Parties shall make a good faith effort to replace any invalid, illegal or unenforceable provision (or any part thereof) with a valid, legal, and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

14.2 Notices. Any notice required or permitted to be given by the Parties pursuant to this Agreement shall be in writing and shall be (i) delivered by hand, (ii) delivered by overnight courier with tracking capabilities, (iii) mailed postage prepaid by first class, registered, or certified mail, or (iv) transmitted by facsimile or electronic mail, with confirmation copy by mail as provided in (iii), and in each case addressed to the recipient Party as set forth below, unless changed by notice so given:

If to MedImmune:

MedImmune, LLC
One MedImmune Way
Gaithersburg, MD 20878

Attention: [***]

with a copy to:

[***]

[***]

If to Seres:

Seres Therapeutics, Inc.
200 Sidney Street
Cambridge, MA 02139
Attention: [***]

with a copy to:

Latham & Watkins LLP
140 Scott Dr.
Menlo Park, CA 94025
Attention: [***]

(a) with respect to any notice delivered pursuant to clauses (i) or (iv), such notice shall be deemed effective upon submission to such other Party, (b) with respect to any notice delivered pursuant to clause (ii), such notice shall be deemed effective the Business Day following the date of submission to the carrier, and (c) with respect to any notice delivered pursuant to clause (iii), such notice shall be deemed effective [***] ([***]) Business Days after the date of submission of such facsimile or electronic mail, as applicable. A Party may add, delete, or change the person or address to whom notices should be sent at any time upon written notice delivered to the other Party in accordance with this Section 14.2.

14.3 Assignment. Neither this Agreement nor any of the rights or obligations hereunder may be assigned or transferred by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld, refused, conditioned or delayed; provided, however, that (i) either Party may, without the other Party's consent, but with written notice to the other Party, assign or transfer all of its rights and obligations hereunder to any Affiliate or to a Third Party with whom it completes a Business Combination or to whom it sells substantially all of such Party's assets relating to this Agreement, and (ii) this Section 14.3 shall not limit the rights of a Party to subcontract its obligations or sublicense its rights as otherwise permitted under this Agreement. The assigning Party shall in any event remain responsible for and liable hereunder with respect to the acts and omissions of the assignee in the performance of this Agreement. This Agreement shall inure to the benefit of and be binding on the Parties' successors and assigns. Any assignment or transfer in violation of the foregoing shall be null and void and wholly invalid, the assignee or transferee in any such assignment or transfer shall acquire no rights whatsoever, and the non-assigning non-transferring Party shall not recognize, nor shall it be required to recognize, such assignment or transfer. Notwithstanding anything to the contrary in this Agreement, with respect to any intellectual property rights controlled by the acquiring Third Party or its Affiliates (if other than one of the Parties to this Agreement) involved in any Business Combination of either Party, or by a permitted Third Party assignee of a Party, [***]. For purposes of this Section 14.3, "**Business Combination**" means, with respect to a Party, any of the following events: (a) any Third Party (or group of Third Parties acting in concert) acquires, directly or indirectly, shares of such Party representing at least a majority of the voting power (where voting refers to being entitled to vote for the election of directors) then outstanding of such Party; (b) such Party consolidates with or merges into another corporation or entity which is a Third Party, or any corporation or

entity which is a Third Party consolidates with or merges into such Party, in either event pursuant to a transaction in which at least a majority of the voting power of the acquiring or resulting entity outstanding immediately after such consolidation or merger is not held by the holders of the outstanding voting power of such Party immediately preceding such consolidation or merger; or (c) such Party conveys, transfers, licenses, and/or leases all or substantially all of its assets to a Third Party (the resulting entity following the consummation of a Business Combination of a Party, the "**Resultant Entity**").

14.3.1 Notwithstanding anything to the contrary in this Agreement, if Seres consummates a Business Combination after the Effective Date, then with respect to any products, technologies, methods, information or processes, and intellectual property rights therein, controlled by the Third Party or its affiliates consummating such Business Combination immediately prior to such Business Combination (the "**Relevant Third Party Assets and Intellectual Property Rights**"), (a) [***] of the Relevant Third Party Assets and Intellectual Property Rights; (b) [***] with respect to such Relevant Third Party Assets and Intellectual Property Rights, provided that in each case of (a) and (b), the Resultant Entity [***] such Relevant Third Party Assets and Intellectual Property Rights and [***] such Relevant Third Party Assets and Intellectual Property Rights [***]; (c) [***]; and (d) [***]) (but [***]).

14.4 Performance by Affiliates. At a Party's election, any rights of such Party under this Agreement may be exercised, and any obligations of such Party under this Agreement may be performed, by one or more of its Affiliates; provided, however, that such Party shall at all times remain responsible and liable for the performance or non-performance of its Affiliates as though such performance or non-performance were of the Party itself.

14.5 Further Assurances. Each Party agrees, at its own expense, to do, or procure the doing of, all such further acts and things and shall execute and deliver such other agreements, certificates, instruments, and documents as are reasonably necessary in order to give full effect to this Agreement.

14.6 Waivers and Modifications. No waiver, modification, release or amendment of any obligation under or provision of this Agreement shall be valid or effective unless in writing and signed by all Parties hereto. The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any provision hereunder or of any breach of any provision hereof shall not be deemed to be a continuing waiver or a waiver of any other breach of such provision (or any other provision) on such occasion or any succeeding occasion.

14.7 Choice of Law. This Agreement (and any claims or disputes arising out of or relating hereto or to the transactions contemplated hereby or to the inducement of any Party to enter herein or therein, whether for breach of contract, tortious conduct, or otherwise and whether predicated on common law, statute, or otherwise) shall be governed by, enforced, and shall be construed in accordance with the laws of the Delaware without regard to its conflicts of law provisions. The Parties hereby expressly disclaim the application of the United Nations Convention on the International Sale of Goods to this Agreement.

14.8 Injunctive Relief. Notwithstanding anything herein to the contrary, each party shall be entitled to seek injunctive relief and specific performance (including but not limited to any relief or recovery under this Agreement) in any court of competent jurisdiction in the world.

14.9 Relationship of the Parties. Each Party is an independent contractor under this Agreement. Nothing herein is intended or is to be construed so as to constitute Seres and MedImmune as partners, agents, employees or joint venturers. Neither Party 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. There are no express or implied third party beneficiaries hereunder.

14.10 Entire Agreement. The Parties agree that this Agreement and the attached Exhibits constitutes the entire agreement between the Parties as to the subject matter of this Agreement, and hereby supersedes all prior negotiations, representations, agreements, and understandings (whether written or verbal) regarding the same, including the Mutual Confidentiality Agreement by and between Seres and MedImmune effective as of [***] (the "**Prior CDA**"). Each Party acknowledges that in entering into this Agreement it has not relied on, nor shall it be entitled to rely upon, any representation, warranty, collateral contract or other assurances made by or on behalf of the other Party except for those which are expressly set forth in this Agreement.

14.11 Counterparts. This Agreement may be executed in two or more counterparts, including counterparts delivered by facsimile or other electronic transmission, with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together, and shall together constitute one and the same instrument.

14.12 Exports. Each Party agrees not to export or re-export, directly or indirectly, any information, technical data, the direct product of such data, samples or equipment received or generated under this Agreement in violation of any applicable export control Laws.

14.13 Amendments. Any amendment of this Agreement shall not be binding on the Parties unless set out in writing, expressed to amend this Agreement, and signed by authorized representatives of each of the Parties.

14.14 Interpretation. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including," "include," or "includes" as used herein shall mean including, without limiting the generality of any description preceding such term. Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (ii) any reference to any applicable Laws herein will be construed as referring to such Laws as from time to time enacted, repealed or amended, (iii) any reference herein to any person will be construed to include the person's successors and permitted assigns, (iv) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (v) any reference herein to the words "mutually agree" or "mutual written agreement" will not impose any obligation on either Party to agree to any terms relating thereto relating to such terms except as such Party may determine in such Party's sole discretion, (vi) all references herein to Sections or Exhibits will be construed to refer to Sections and Exhibits to this Agreement, (vii) the word "days" means calendar days unless otherwise specified,

(viii) except as otherwise expressly provided herein all references to "$" or "dollars" refer to the lawful money of the U.S., and (ix) the words "copy" and "copies" and words of similar import when used in this Agreement include, to the extent available, electronic copies, files or databases containing the information, files, items, documents or materials to which such words apply. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions. The language in this Agreement is to be construed in all cases according to its fair meaning.

[*Signature page follows*]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized officers.

SERES THERAPEUTICS, INC.

By:/s/ Eric Shaff
(Signature)

Name:Eric Shaff

Title:President, CEO

Date:2/27/19

MEDIMMUNE, LLC

By: [***]
(Signature)

Name: [***]

Title: [***]

Date: 11 March 2019

Exhibit A

Research Plan

Omitted pursuant to Regulation S-K, Item 601(a)(5)

Exhibit 31.1

CERTIFICATIONS

I, Eric D. Shaff, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 2, 2019

By: /s/ Eric D. Shaff
Eric D. Shaff
President, Chief Executive Officer and Director

Exhibit 31.2

CERTIFICATIONS

I, Marcus Chapman, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 2, 2019

By: /s/ Marcus Chapman
Marcus Chapman
Vice President, Finance and 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

(1) 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:

(2) The Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

May 2, 2019

/s/ Eric D. Shaff
Eric D. Shaff
President and Chief 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, Marcus Chapman, Vice President, Finance and Principal Financial and Accounting Officer of Seres Therapeutics, Inc. (the "Company"), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

May 2, 2019

/s/ Marcus Chapman
Marcus Chapman
Vice President, Finance and Principal Financial and Accounting Officer