

**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, 2016

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

(State or other jurisdiction of  
incorporation or organization)

200 Sidney Street - 4th Floor  
Cambridge, MA  
(Address of principal executive offices)

27-4326290

(I.R.S. Employer  
Identification Number)

02139  
(Zip Code)

(617) 945-9626

(Registrant's telephone number, including area code)

N/A

(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of May 9, 2016 there were 39,519,842 shares of Common Stock, \$0.001 par value per share, outstanding.

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## FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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 and Section 21E of the Securities Exchange Act of 1934. 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 factors described under the sections in this Quarterly Report titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” as well as 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;
- 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;
- our ability to establish our own 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 FDA 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.

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

	March 31, 2016	December 31, 2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 193,228	\$ 73,933
Investments	110,050	131,149
Prepaid expenses and other current assets	3,568	2,528
Total current assets	306,846	207,610
Property and equipment, net	16,082	7,751
Restricted cash	1,540	1,539
Total assets	<u>\$ 324,468</u>	<u>\$ 216,900</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	5,763	5,397
Accrued expenses and other current liabilities	7,059	5,523
Deferred revenue - related party	12,000	—
Total current liabilities	24,822	10,920
Lease incentive obligation	4,527	586
Deferred revenue, net of current portion - related party	105,290	—
Total liabilities	134,639	11,506
Commitments and contingencies		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at March 31, 2016 and December 31, 2015; no shares issued and outstanding at March 31, 2016 and December 31, 2015		
	—	—
Stockholders' equity:		
Common stock, \$0.001 par value; 200,000,000 shares authorized at March 31, 2016 and December 31, 2015; 39,218,702 and 39,082,017 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively		
	39	39
Additional paid-in capital	291,998	287,937
Accumulated other comprehensive income	108	30
Accumulated deficit	(102,316)	(82,612)
Total stockholders' equity	189,829	205,394
Total liabilities and stockholders' equity	<u>\$ 324,468</u>	<u>\$ 216,900</u>

*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)

	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>Revenue:</b>		
Collaboration revenue - related party	\$ 2,710	\$ —
Total revenue	2,710	—
<b>Operating expenses:</b>		
Research and development expenses	\$ 15,416	5,561
General and administrative expenses	7,210	2,606
Total operating expenses	22,626	8,167
Loss from operations	(19,916)	(8,167)
<b>Other income (expense):</b>		
Interest income	268	49
Interest expense	(56)	(66)
Revaluation of preferred stock warrant liability	—	213
Total other income, net	212	196
Net loss	\$ (19,704)	\$ (7,971)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.50)	\$ (1.15)
Weighted average common shares outstanding, basic and diluted	39,186,130	6,912,725
<b>Other comprehensive income:</b>		
Unrealized gain on investments, net of tax of \$0	78	31
Total other comprehensive income	78	31
Comprehensive loss	\$ (19,626)	\$ (7,940)

*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,	
	2016	2015
<b>Cash flows from operating activities:</b>		
Net loss	\$ (19,704)	\$ (7,971)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,904	1,327
Depreciation and amortization expense	386	92
Gain from revaluation of preferred stock warrant liability	—	(213)
Non-cash interest expense	54	30
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,040)	(710)
Deferred revenue	117,290	—
Accounts payable	1,331	(189)
Accrued expenses and other current liabilities	(806)	(706)
Net cash provided by (used in) operating activities	<u>101,415</u>	<u>(8,340)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(3,400)	(214)
Purchases of investments	(45,301)	(59,255)
Maturities of investments	66,425	—
Changes in restricted cash	(1)	—
Net cash provided by (used in) investing activities	<u>17,723</u>	<u>(59,469)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	(24)
Proceeds from exercise of stock options and common stock warrants	157	89
Repayment of notes payable	—	(300)
Payments of initial public offering costs	—	(1,096)
Net cash provided by (used in) financing activities	<u>157</u>	<u>(1,331)</u>
<b>Net increase (decrease) in cash and cash equivalents</b>	<u>119,295</u>	<u>(69,140)</u>
Cash and cash equivalents at beginning of period	73,933	114,185
Cash and cash equivalents at end of period	<u>\$ 193,228</u>	<u>\$ 45,045</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ 10	\$ 40
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Deferred offering costs included in accounts payable and accrued expenses	\$ —	\$ 162
Property and equipment purchases included in accounts payable and accrued expenses	\$ 3,395	\$ 28

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

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

**1. Nature of the Business and Basis of Presentation**

Seres Therapeutics, Inc. (the “Company”) was incorporated under the laws of the State of Delaware in October 2010 under the name Newco LS21, Inc. In October 2011, the Company changed its name to Seres Health, Inc., and in May 2015, the company changed its name to Seres Therapeutics, Inc. The Company is a microbiome therapeutics platform company developing a novel class of biological drugs, which are designed to restore health by repairing the function of a dysbiotic microbiome. The Company’s lead product candidate, SER-109, is intended to prevent further recurrences of *Clostridium difficile* infection (“CDI”), a debilitating infection of the colon, and, if approved by the FDA, could be a first-in-field drug. Using its microbiome therapeutics platform, the Company is developing additional product candidates to treat diseases where the microbiome is implicated, including SER-262 to prevent an initial recurrence of primary CDI, SER-287 to treat inflammatory bowel disease, including ulcerative colitis, SER-301, our synthetic ulcerative colitis product candidate, and SER-155 to prevent mortality following allogeneic hematopoietic stem cell transplantation (allo-HSCT) due to infections and graft-versus-host disease. The Company is also using its microbiome therapeutics platform to conduct research on metabolic diseases, such as non-alcoholic steatohepatitis (NASH); inflammatory diseases, such as Crohn’s disease, rare liver disorders such as primary sclerosing cholangitis (PSC); and immuno-oncology treatments using checkpoint inhibitors.

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, that any products 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.

**Unaudited Interim Financial Information**

The accompanying unaudited consolidated financial statements as of March 31, 2016 and the statements of operations and comprehensive loss and of cash flows for the three months ended March 31, 2016 and 2015 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 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, 2015 included in the Company’s annual report on Form 10-K for the fiscal year ended December 31, 2015, which was filed with the U.S. Securities and Exchange Commission on March 14, 2016.

The unaudited interim financial statements have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the accompanying unaudited interim consolidated financial statements contain all adjustments which are necessary for a fair statement of the Company’s financial position as of March 31, 2016 and consolidated results of operations and cash flows for the three months ended March 31, 2016. Such adjustments are of a normal and recurring nature. The results of operations for the three months ended March 31, 2016 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2016.

**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, 2015, and the notes thereto, which

are included in the Company's Annual Report on Form 10-K. During the three months ended March 31, 2016, the Company recorded revenue in connection with its collaboration agreement. See Note 9, "Collaboration Revenue," for additional information.

### Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenue and expenses, and related disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues 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.

### 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 and investments are carried at fair value, determined according to the fair value hierarchy described above. Certain cash equivalents or investments 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, 2016 and December 31, 2015 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, 2016 Using:				Total
	Level 1	Level 2	Level 3	Not Subject to Leveling (1)	
<b>Assets:</b>					
Cash Equivalents	\$ —	\$ 1,753	\$ —	\$ 27,796	\$ 29,549
<b>Investments:</b>					
Commercial Paper	\$ —	\$ 56,020	\$ —	\$ —	\$ 56,020
Corporate Bonds	—	26,972	—	—	26,972
Government Securities	—	15,044	—	—	15,044
Treasury Bonds	—	12,014	—	—	12,014
	<u>\$ —</u>	<u>\$ 111,803</u>	<u>\$ —</u>	<u>\$ 27,796</u>	<u>\$ 139,599</u>

(1) Certain cash equivalents and investments 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, 2015 Using:				
	Level 1	Level 2	Level 3	Not Subject to Leveling (1)	Total
<b>Assets:</b>					
Cash Equivalents	\$ —	\$ 11,952	\$ —	\$ 11,173	\$ 23,125
Repurchase Agreements	—	20,000	—	—	20,000
<b>Investments:</b>					
Commercial Paper	\$ —	\$ 64,820	\$ —	\$ —	\$ 64,820
Corporate Bonds	—	46,490	—	—	46,490
Government Securities	—	15,819	—	—	15,819
Treasury Bonds	—	4,020	—	—	4,020
	<u>\$ —</u>	<u>\$ 163,101</u>	<u>\$ —</u>	<u>\$ 11,173</u>	<u>\$ 174,274</u>

(1) Certain cash equivalents and investments 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, 2016, the Company's cash equivalents, which were invested in money market funds, corporate bonds and commercial paper with original maturities of less than 90 days from the date of purchase, were valued based on Level 2 inputs.

As of December 31, 2015, the Company's cash equivalents consisted of money market funds, corporate bonds, commercial paper, government securities and repurchase agreements with original maturities of less than 90 days from the date of purchase and were valued based on Level 2 inputs. Repurchase agreements are agreements with banks to repurchase notes that are collateralized by U.S. government securities.

The fair value of the Company's investments, which consisted of commercial paper, corporate bonds, government securities and treasury bonds as of March 31, 2016 and December 31, 2015 were determined using Level 2 inputs. During the three months ended March 31, 2016 there were no transfers between Level 1, Level 2 and Level 3.

### **Revenue recognition**

The Company currently generates its revenue through collaboration and license arrangements with strategic partners for the development and commercialization of product candidates.

The Company recognizes revenue in accordance with FASB ASC Topic 605, Revenue Recognition ("ASC 605"). Accordingly, revenue is recognized for each unit of accounting when all of the following criteria are met:

- Persuasive evidence of an arrangement exists
- Delivery has occurred or services have been rendered
- The seller's price to the buyer is fixed or determinable
- Collectability is reasonably assured

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the Company's consolidated balance sheets. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, current portion. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as long-term deferred revenue.

### **Collaboration revenue**

In connection with the License Agreement, the Company received an upfront, non-refundable payment of \$120,000. Other non-refundable payments to the Company under this arrangement may include: (i) payments for research and development services, (ii) payments for the supply of clinical product, (iii) payments for the supply of commercial product, (iv) payments based on the achievement of certain development, regulatory, commercial, and sales-based milestones and (v) royalties on product sales.

The Company evaluates multiple-element arrangements based on the guidance in FASB ASC Topic 605-25, Revenue Recognition-Multiple-Element Arrangements ("ASC 605-25"). Pursuant to this guidance, the Company identifies the deliverables included in the arrangement and determines: (1) whether the individual deliverables have value to the customer on a standalone basis and represent separate units of accounting or whether they must be accounted for as a combined unit of accounting; and (2) if the arrangement includes a general right of return relative to the delivered item. This evaluation requires management to make judgments about the

individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: (i) the delivered item(s) has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in the control of the Company. In assessing whether an item has standalone value, the Company considers factors such as the research, manufacturing and commercialization capabilities of the collaboration partner, the retention of any key rights by the Company, and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can use the other deliverable(s) for their intended purpose without the receipt of the remaining element(s), whether the value of the deliverable is dependent on the undelivered item(s) and whether there are other vendors that can provide the undelivered element(s).

In situations where the Company has identified multiple units of accounting, the arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. The Company determines the selling price of a unit of accounting following the hierarchy of evidence prescribed by ASC 605-25. Accordingly, the Company determines the estimated selling price for units of accounting within each arrangement using vendor-specific objective evidence (“VSOE”) of selling price, if available, third-party evidence (“TPE”) of selling price if VSOE is not available, or best estimate of selling price (“BESP”) if neither VSOE nor TPE is available.

Then, the applicable revenue recognition criteria in ASC 605-25 are applied to each of the separate units of accounting to determine the appropriate period and pattern of recognition. The Company recognizes arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in ASC 605-25 are satisfied for that particular unit of accounting. The Company will recognize as revenue, upon delivery, arrangement consideration attributed to licenses that have standalone value from the other deliverables to be provided in an arrangement. For licenses that do not have standalone value from the other deliverables to be provided in an arrangement over the Company’s estimated performance period as the arrangement would be accounted for as a single unit of accounting.

The Company recognizes arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in ASC 605-25 are satisfied for that particular unit of accounting. The Company will recognize as revenue arrangement consideration attributed to licenses that have standalone value from the other deliverables to be provided in an arrangement upon delivery. The Company will recognize as revenue arrangement consideration attributed to licenses that do not have standalone value from the other deliverables to be provided in an arrangement over the Company’s estimated performance period as the arrangement would be accounted for as a single unit of accounting.

If there is no discernible pattern of performance and/or objectively measurable performance measures do not exist, then the Company recognizes revenue under the arrangement for the single unit of accounting on a straight-line basis over the period the Company is expected to complete its performance obligations. Alternatively, if the pattern of performance in which the service is provided to the customer can be determined and objectively measurable performance measures exist, then the Company recognizes revenue under the arrangement using the proportional performance method. Revenue recognized is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line method or proportional performance method, as applicable.

At the inception of an arrangement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (i) the consideration is commensurate with either the Company’s performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company’s performance to achieve the milestone, (ii) the consideration relates solely to past performance and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone in making this assessment. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a milestone is substantive. The Company recognizes revenue associated with substantive milestones in accordance with FASB ASC Topic 605-28, Revenue Recognition-Milestone Method upon successful accomplishment of each milestone, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive would be recognized as revenue over the remaining period of performance, assuming all other revenue recognition criteria are met.

The Company will recognize royalty revenue in the period of sale of the related product(s), based on the underlying contract terms, provided that the reported sales are reliably measurable and the Company has no remaining performance obligations, assuming all other revenue recognition criteria are met.

Refer to footnote 9 for further information related to the Company’s collaboration and license agreement with Nestec, Ltd.

## 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 warrants and unvested restricted stock. The Company applied the two-class method to calculate its basic and diluted net loss per share attributable to common stockholders for the three months ended March 31, 2015, as its convertible preferred stock and common stock are participating securities. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. However, the two-class method does not impact the net loss per share of common stock as the Company was in a net loss position for the three months ended March 31, 2015 and preferred stockholders do not participate in losses.

The Company's convertible preferred stock contractually entitled the holders of such shares to participate in dividends but did not contractually require the holders of such shares to participate in losses of the Company. Similarly, restricted stock awards granted by the Company entitle the holder of such awards to dividends declared or paid by the board of directors, regardless of whether such awards are unvested, as if such shares were outstanding common shares at the time of the dividend. However, the unvested restricted stock awards 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,	
	2016	2015
Stock options to purchase common stock	5,882,186	3,989,246
Unvested restricted common stock	—	26,875
Warrants for the purchase of convertible preferred stock	—	92,127
Warrants for the purchase of common stock	—	738,635
Convertible preferred stock (as converted to common stock)	—	22,866,987
	<u>5,882,186</u>	<u>27,713,870</u>

## Recently Issued Accounting Standards

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. In March 2016, the FASB issued ASU 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations*, which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, which clarifies how a company identifies promised goods or services and clarifies whether an entity's promise to grant a license provides a customer with either a right to use the entity's intellectual property (which is satisfied at a point in time) or a right to access the entity's intellectual property (which is satisfied over time). We are currently evaluating the method of adoption and the potential impact that Topic 606 may have on our financial position and results of operations.

In May 2015, the FASB issued ASU 2015-07, *Fair Value Measurement (Topic 820): Disclosures for Investments in Certain Entities That Calculate Net Asset Value per Share (or Its Equivalent)*. The new standard removes the requirement to categorize within the fair value hierarchy all investments for which fair value is measured using the net asset value per share practical expedient. The new standard became effective for us on January 1, 2016. Refer to the Fair Value significant accounting policy for the impact of this change.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases today. ASC 842 supersedes the previous leases standard, ASC 840 Leases. The standard is effective on January 1, 2019, with early adoption permitted. The Company is in the process of evaluating the impact of this new guidance.

In March 2016, the FASB issued Accounting Standards Update (ASU) 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which amends the accounting for employee share-based payment transactions to require recognition of the tax effects resulting from the settlement of stock-based awards as income tax expense or benefit in the income statement in the reporting period in which they occur. In addition, the ASU requires that all tax-related cash flows resulting from share-based payments, including the excess tax benefits related to the settlement of stock-based awards, be classified as cash flows from operating activities in the statement of cash flows. The ASU also requires that cash paid by directly withholding shares for tax withholding purposes be classified as a financing activity in the statement of cash flows. In addition, the ASU also allows companies to make an accounting policy election to either estimate the number of awards that are expected to vest, consistent with current U.S. GAAP, or account for forfeitures when they occur. The new standard is effective for annual reporting periods beginning after December 15, 2016 with early adoption permitted. The Company is in the process of evaluating the impact of this new guidance.

## Reclassifications

Certain amounts reported in the prior year financial statements have been reclassified for comparative purposes to conform with the presentation in the current year condensed consolidated financial statements.

### 3. Investments

As of March 31, 2016, the fair value of available-for-sale investments by type of security was as follows:

	March 31, 2016			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Investments:				
Commercial Paper	\$ 55,928	\$ 92	—	\$ 56,020
Corporate Bonds	26,964	8	—	26,972
Government Securities	15,037	7	—	15,044
Treasury Bonds	12,012	2	—	12,014
	<u>\$ 109,941</u>	<u>\$ 109</u>	<u>\$ —</u>	<u>\$ 110,050</u>
	December 31, 2015			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Investments:				
Commercial Paper	\$ 64,733	\$ 87	—	\$ 64,820
Corporate Bonds	46,538	—	(48)	46,490
Government Securities	15,823	—	(4)	15,819
Treasury Bonds	4,022	—	(2)	4,020
	<u>\$ 131,116</u>	<u>\$ 87</u>	<u>\$ (54)</u>	<u>\$ 131,149</u>

Investments with original maturities of less than 90 days are included in cash and cash equivalents on the consolidated balance sheets and are not included in the table above.

As of March 31, 2016 and December 31, 2015, the Company's commercial paper, corporate bonds, government securities and treasury bonds had remaining maturities of less than 12 months.

#### 4. Property and Equipment, Net

Property and equipment, net consisted of the following:

	March 31, 2016	December 31, 2015
Laboratory equipment	\$ 4,739	\$ 4,370
Computer equipment	715	408
Furniture and office equipment	498	285
Leasehold improvements	4,055	1,856
Construction in progress	7,472	1,843
	17,479	8,762
Less: Accumulated depreciation and amortization	(1,397)	(1,011)
	<u>\$ 16,082</u>	<u>\$ 7,751</u>

Construction in progress at March 31, 2016 was comprised primarily of leasehold improvements, laboratory equipment, and computer equipment purchased in connection with the build-out of office and laboratory space at our new headquarters at 200 Sidney Street in Cambridge, Massachusetts.

Depreciation and amortization expense was \$386 and \$92 for the three months ended March 31, 2016 and 2015, respectively.

#### 5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	March 31, 2016	December 31, 2015
Development and manufacturing costs	\$ 2,093	\$ 1,436
Payroll and payroll-related costs	1,187	2,756
Professional fees	498	184
Facility	3,128	1,053
Other	153	94
	<u>\$ 7,059</u>	<u>\$ 5,523</u>

#### 6. Preferred Stock Warrant Liability

In September 2013, the Company issued a warrant to purchase 92,127 shares of Series A-2 convertible preferred stock in connection with its loan and security agreement. The warrant was immediately exercisable at an exercise price of \$1.78 per share and has a contractual term of ten years from issuance. The fair value of the warrant at issuance was estimated to be \$156 and was recorded as a debt discount and as a preferred stock warrant liability.

The Company classified the warrant to purchase shares of its Series A-2 convertible preferred stock as a liability on its consolidated balance sheets and subsequently re-measured to fair value at each balance sheet date. Changes in fair value of the warrant were recognized as a component of other income (expense), net, in the consolidated statement of operations and comprehensive loss.

In connection with the automatic conversion of the Company's convertible preferred stock, which occurred upon the listing of the Company's common stock on the NASDAQ on June 26, 2015, the preferred stock warrant became a warrant to purchase common stock. The Company performed the final mark to market adjustment on the preferred stock warrant using the fair value of the underlying common shares of \$18.00 per share on June 26, 2015 and recorded the change in fair value in other income (expense), net in the consolidated statement of operations and comprehensive loss. The preferred stock warrant liability was then reclassified to additional paid-in-capital as it became a warrant to purchase common stock.

There was no balance related to the preferred stock warrant liability as of March 31, 2016 and December 31, 2015.

The Company recorded a loss \$213 for the three months ended March 31, 2015 to reflect the change in fair value of this preferred stock warrant.

The following assumptions and inputs were used in determining the fair value of the preferred stock warrant liability valued using the Black-Scholes option-pricing model:

	<u>Three Months Ended March 31, 2015</u>
Risk-free interest rate	1.83%
Expected term (in years)	8.5
Expected volatility	80.0%
Expected dividend yield	0%
Fair value of Series A-2 convertible preferred stock	\$ 14.87

## 7. Preferred Stock

On July 1, 2015, in connection with the closing of the IPO, the Company effected its Restated Certificate of Incorporation, which authorizes the Company to issue 10,000,000 shares of preferred stock, \$0.001 par value per share.

## 8. Stockholders' Equity Common Stock

On July 1, 2015, the Company completed an IPO, and issued and sold 8,545,138 shares of common stock at a public offering price of \$18.00 per share, resulting in net proceeds of approximately \$139,267 after deducting underwriting discounts and commissions and other offering expenses totaling \$3,748. The shares issued upon closing of the IPO included 1,114,583 shares of the Company's common stock, which were sold to the underwriters pursuant to the full exercise of their option to purchase additional shares of common stock. Upon the listing of the Company's common stock on the NASDAQ on June 26, 2015, all outstanding shares of the Company's convertible preferred stock automatically converted into 22,866,987 shares of the Company's common stock.

As of December 31, 2014, the Company's Amended and Restated Certificate of Incorporation, as further amended, authorized the Company to issue 38,000,000 shares of common stock, \$0.001 par value per share. On July 1, 2015, in connection with the closing of the IPO, the Company effected its Restated Certificate of Incorporation, which authorizes the Company to issue 200,000,000 shares of common stock, \$0.001 par value per share.

## Stock Options

The following table summarizes the Company's stock option activity since December 31, 2015:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term (in years)</u>	<u>Aggregate Intrinsic Value</u>
Outstanding as of December 31, 2015	5,026,246	\$ 8.01	8.70	\$ 136,945
Granted	992,625	27.52		
Exercised	(136,685)	1.15		
Forfeited	—	—		
Outstanding as of March 31, 2016	<u>5,882,186</u>	\$ 11.46	8.68	\$ 93,314
Options exercisable as of March 31, 2016	<u>1,892,915</u>	\$ 2.66	8.05	\$ 45,250
Options vested and expected to vest as of March 31, 2016	<u>5,756,568</u>	\$ 11.34	8.67	\$ 91,974

The weighted average grant-date fair value of stock options granted during the three months ended March 31, 2016 was \$19.59.

## Stock-based Compensation Expense

The Company recorded stock-based compensation expense related to stock options and restricted common stock in the following expense categories of its consolidated statements of operations and comprehensive loss:

	Three Months Ended	
	March 31,	
	2016	2015
Research and development expenses	\$ 2,186	\$ 623
General and administrative expenses	1,718	704
	<u>\$ 3,904</u>	<u>\$ 1,327</u>

## 9. Collaboration Revenue

### *Nestec Ltd.*

In January 2016 the Company entered into a Collaboration and License Agreement (the "License Agreement") with Nestec Ltd. ("NHS"), an affiliate of Nestlé Health Science US Holdings, Inc., a significant stockholder of the Company, for the development and commercialization of certain product candidates in development for the treatment and management of CDI and IBD, including ulcerative colitis and Crohn's disease. The License Agreement will support 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, or, 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, the Company's and NHS' development activities will be governed by global and regional development plans, including the conduct of additional clinical studies. The Company has agreed to manufacture and supply NHS Collaboration Products to support development and commercialization of NHS Collaboration Products in the licensed fields and in the Licensed Territory. NHS will have the right to obligate the Company to transfer technology necessary to manufacture Collaboration Products in the event that the Company materially fails to meet its supply commitments to NHS under the commercial supply agreement. The Company has also agreed to use diligent efforts to develop NHS Collaboration Products under a global development plan and to obtain approval for such NHS Collaboration Products in the European Union, or EU.

In exchange for the license, NHS agreed to pay the Company an upfront cash payment of \$120,000, which the Company received in February 2016. 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. The Company is eligible to receive up to \$295,000 in development milestone payments, \$365,000 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.

For the development of NHS Collaboration Products for IBD under a global development plan, the Company 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. For other clinical development of NHS Collaboration Products for IBD, the Company 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, the Company agreed to pay all costs of an ongoing Phase 2 clinical trial for SER-109 and of Phase 3 clinical trials for SER-109. The Company 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. The Company 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, the Company 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.

The License Agreement continues in effect until terminated by either the Company or NHS on the following bases: (i) NHS may terminate the License Agreement in the event of serious safety issues related to any of the NHS Collaboration Products; (ii) the Company may terminate the License Agreement if NHS challenges the validity or enforceability of any of our licensed patents; and (iii) either the Company or NHS may terminate the License Agreement 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 the Company will terminate, and all rights in and to the NHS Collaboration Products in the Licensed Territory will revert to the Company. If the Company commits 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.

The License Agreement contains customary representations and warranties, intellectual property protection provisions, certain indemnification rights in favor of each party and customary confidentiality provisions and limitations of liability.

At the inception of the License Agreement, the Company identified the following deliverables: (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 ("JSC"), and (iv) manufacturing services to provide clinical supply to complete future clinical trials. The Company also identified a contingent deliverable, the obligation to perform manufacturing services to provide commercial supply if commercialization occurs, which is contingent upon regulatory approval. This contingent deliverable has been excluded from the initial allocation and will be treated as a separate unit of accounting when and if delivered.

The Company concluded that none of the four deliverables identified at the inception of the License Agreement has standalone value from the other undelivered elements. Accordingly, all deliverables represent a single unit of accounting.

All consideration received relating to the four identified deliverables that comprise the single unit of accounting will be recognized over the period of performance. The period of performance will be through the completion of development services for the NHS Collaboration Products which has been estimated to be ten years. The Company will periodically review and, if necessary, revise the estimated development period.

The Company will recognize revenue utilizing a time-based proportional performance model where revenue related to each payment is recognized over the ten year performance period. As of March 31, 2016, the only consideration that is fixed and determinable is the non-refundable upfront payment of \$120,000. For additional consideration that could be received for research and development services and/or manufacturing services for clinical supply, the Company will recognize a cumulative catch-up for the amount of time that has elapsed and spread the unrecognized portion over the remaining performance period.

Development and regulatory milestones that involve substantial effort on the Company's part and the achievement of which are not considered probable at the inception of the License Agreement are considered substantive milestones, and will be recognized in their entirety in the period in which the milestone is achieved, assuming all other revenue recognition criteria are met. All commercial milestones will be recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

Royalties will be recorded as revenue in the period they are earned assuming all other revenue recognition criteria are met.

During the three months ended March 31, 2016, the Company recognized \$2,710 of related party revenue associated with the License Agreement. As of March 31, 2016, there was \$117,290 of deferred revenue related to the License Agreement, which 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 twelve months. All costs associated with the License Agreement are recorded in research and development expense in the condensed consolidated statements of operations and comprehensive loss.

## **10. Income Taxes**

The Company did not provide for any income taxes in three month periods ended March 31, 2016 or 2015.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its U.S. net deferred tax assets. As required by the provisions of ASC 740, Income Taxes, management has determined that it is more-likely-than-not that the Company will not utilize the benefits of federal and state U.S. net deferred tax assets for financial reporting purposes. Accordingly, the net deferred tax assets are subject to a valuation allowance at March 31, 2016 and December 31, 2015.

As of March 31, 2016 and December 31, 2015, the Company had no accrued interest or tax penalties recorded. The Company files income tax returns in the U.S. 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 my still be adjusted upon examination by the Internal Revenue Service or state tax authorizes to the extent it is utilized in a future period. There are no currently ongoing or pending examinations in any jurisdictions.

## **11. Commitments and Contingencies**

### **Leases**

The Company leases office and laboratory space under an operating lease agreement. The lease expires in January 2018 with no extension periods. The Company does have a right of expansion over the term as additional space becomes available but not an obligation.

On November 11, 2015, the Company entered into a non-cancelable property lease with BMR-Sidney Research Campus LLC (“BMR”) for 83,396 square feet of office, laboratory and pilot manufacturing space at 200 Sidney Street, Cambridge, Massachusetts. The lease term commenced in March 2016 and ends in November 2023. The Company has the option to extend the lease twice, each for a five-year period. The Company intends to move its corporate headquarters to this location in mid-2016. BMR will contribute a total of \$12,509 toward the cost of tenant improvements. BMR’s contribution toward the cost of tenant improvements is recorded as a lease incentive obligation on our consolidated balance sheet. The lease incentive obligation is amortized to our consolidated statement of operations as reductions to rent expense over the lease term. As of March 31, 2016, we have recorded a lease incentive obligation of \$4,527.

During the three months ended March 31, 2016 and 2015, the Company recognized \$393 and \$186, respectively, of rental expense related to office and laboratory space.

### **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 that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of March 31, 2016 or December 31, 2015.

## **12. Related Party Transactions**

In October 2010, the Company entered into a services agreement with Flagship Ventures Management, Inc., an affiliate of one of its stockholders, Flagship Venture Funds, to provide general and administrative services to the Company, including the employer portions of employee health and dental benefit plans for Seres Therapeutics employees and consulting services. The Company made payments under the agreement of \$16 and \$118 during the three months ended March 31, 2016 and 2015, respectively. There were no amounts due to Flagship Ventures Management, Inc. related to the services agreement as of March 31, 2016 and 2015.

As described in Note 9, in January 2016 the Company entered into a 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 ulcerative colitis 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, 2016, the Company recognized \$2,710 of related party revenue associated with the License Agreement. As of March 31, 2016, there was \$117,290 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, 2016. There are no amounts due from or to NHS as of March 31, 2016.

## **13. 401(k) Savings Plan**

The Company has a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Effective January 1, 2016, the Company has elected to match 50% of the first 6% of an employee’s deferral. Company contributions are expensed in the year for which they are declared.

## 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. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, 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 on Form 10-Q, 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. Our lead product candidate, SER-109, is designed to prevent further recurrences of *Clostridium difficile* infection, or CDI, a debilitating infection of the colon, 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 drug. Using our microbiome therapeutics platform, we are developing additional product candidates to treat diseases where the microbiome is implicated, including SER-262 to prevent an initial recurrence of primary CDI, SER-287 to treat inflammatory bowel disease, including ulcerative colitis, SER-301, our synthetic ulcerative colitis product candidate, and SER-155 to prevent mortality following allogeneic hematopoietic stem cell transplantation (allo-HSCT) due to infections and graft-versus-host disease. We are also using our microbiome therapeutics platform to conduct research on metabolic diseases, such as non-alcoholic steatohepatitis (NASH); inflammatory diseases, such as Crohn's disease, rare liver disorders such as primary sclerosing cholangitis (PSC); and immuno-oncology treatments using checkpoint inhibitors. Since our inception in October 2010, we have devoted substantially all of our resources to developing SER-109 and SER-287, researching SER-262 and SER-301, building our intellectual property portfolio, developing our supply chain, business planning, raising capital and providing general and administrative support for these operations. From our inception through June 30, 2015, we had financed our operations through private placements of our convertible preferred stock, the issuance of convertible promissory notes and borrowings under a loan and security agreement with Comerica Bank, or the Loan and Security Agreement. Through June 30, 2015, we had received gross proceeds of \$137.0 million from such transactions.

On July 1, 2015, we completed an initial public offering, or IPO, of our common stock, and issued and sold 8.5 million shares of common stock at a public offering price of \$18.00 per share, resulting in net proceeds of approximately \$139.3 million after deducting underwriting discounts and commissions and offering expenses. Upon the listing of our common stock on The NASDAQ Global Select Market, or NASDAQ, on June 26, 2015, all outstanding shares of our convertible preferred stock automatically converted into 22.9 million shares of our common stock. The shares issued upon closing of the IPO included 1.1 million shares of the Company's common stock, pursuant to the underwriters' full exercise of their option to purchase additional shares of common stock.

As of March 31, 2016 we had repaid all amounts of the total \$3.0 million borrowed under the Loan and Security Agreement.

All of our product candidates other than SER-109 and SER-287 are still in pre-clinical development. We expect results from our Phase 2 clinical study of SER-109 in mid-2016 and results from our Phase 1b clinical study of SER-287 in 2017. We also expect to initiate a Phase 1b clinical study of SER-262 in mid-2016. 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 \$19.7 million for three months ended March 31, 2016. As of March 31, 2016, we had an accumulated deficit of \$102.3 million.

We expect that our expenses will increase substantially in connection with our ongoing and planned activities, particularly as we:

- advance the clinical development of SER-109 for the prevention of further recurrences of CDI in patients suffering from recurrent CDI, through a Phase 2 clinical study and beyond;
- initiate clinical development of SER-262 to be used following antibiotic treatment of primary CDI to prevent an initial recurrence of CDI;
- continue the clinical development of SER-287 for the treatment of ulcerative colitis;
- conduct research and continue pre-clinical development of additional Ecobiotic microbiome therapeutics, including SER-155 to prevent mortality following allogeneic hematopoietic stem cell transplantation (allo-HSCT) due to infections and graft-versus-host disease and SER-301, our synthetic ulcerative colitis product candidate,;
- make strategic investments in manufacturing capabilities, including potentially planning and building a small-scale commercial manufacturing facility;

- maintain our current intellectual property portfolio and opportunistically acquire complementary intellectual property;
- begin to build the infrastructure necessary to support potential commercialization of our product candidates; and
- seek to obtain regulatory approvals for our product candidates.

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.

In January 2016 we entered into a Collaboration and License Agreement, or the License Agreement, with Nestec Ltd., or NHS, an affiliate of Nestlé Health Science US Holdings, Inc, for the development and commercialization of certain of our product candidates in development for the treatment and management of CDI and IBD, including ulcerative colitis and Crohn's disease. The License Agreement will support the development of our portfolio of products for CDI and IBD in markets outside of the United States and Canada, or the Licensed Territory, and is expected to provide substantial financial support for our ongoing research and development. We have retained full commercial rights to our entire portfolio of product candidates with respect to the United States and Canada, where we plan to build our own commercial organization.

Under the License Agreement, we granted to NHS an exclusive, royalty-bearing license to develop and commercialize, in the Licensed Territory, 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. We also granted to NHS a non-exclusive license, subject to the Company's right to supply NHS Collaboration Products, to export, develop and make NHS Collaboration Products in the licensed fields worldwide solely for commercialization in the licensed fields and in the Licensed Territory. Upon mutual agreement, one or more other products based on our microbiome technology for CDI or IBD may be added to the License Agreement in lieu of or in addition to the then-existing NHS Collaboration Products. NHS' exclusive license in the Licensed Territory to develop and commercialize NHS Collaboration Products extends to any indications for which the parties agree to develop such products. We also granted to NHS a non-exclusive license to export, develop and make NHS Collaboration Products in the licensed fields worldwide solely for commercialization in the licensed fields and in the Licensed Territory. Additionally, the rights to develop and commercialize a given Collaboration Product in certain non-EU countries within the Licensed Territory may revert to us if NHS either elects not to pursue commercialization of such Collaboration Product in such country, or fails to meet certain agreed upon milestones for commercialization of such Collaboration Product in such country. If the licensed rights in any country revert to us in this way, then we would pay to NHS a royalty in the mid-single digits on net sales of such Collaboration Product in such country.

In exchange for the license, NHS agreed to pay us an upfront cash payment of \$120 million, which we received in February 2016. NHS has also agreed to pay to us tiered royalties, at percentages ranging from the high single digits to high teens, of net sales of NHS Collaboration Products in the Licensed Territory. We are eligible to receive up to \$295.0 million in development milestone payments, \$365.0 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. We expect to receive a total of \$30 million in milestone payments in 2016 associated with the planned initiation of a Phase 1b study for SER-262 in CDI and the anticipated initiation of the Phase 3 clinical trial for SER-109 in CDI. 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.

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. 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 will 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 an ongoing Phase 2 clinical trial for SER-109 and of 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.

During the three months ended March 31, 2016, we recorded revenue of \$2.7 million in connection with the License Agreement.

We expect that our existing cash, cash equivalents and investments, will enable us to fund our operating expenses and capital expenditure requirements well into 2018. See “—Liquidity and Capital Resources.”

## **Financial Operations Overview**

### ***Revenue***

To date we have not generated any revenues from the sale of products. Our revenues from collaborations have been derived from the License Agreement.

### ***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, or CMOs, 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 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 SER-109, SER-287, SER-262 and SER-301. 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 and CROs in connection with our pre-clinical studies and clinical trials 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.

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Microbiome therapeutics platform	\$ 7,851	\$ 2,314
SER-109	5,489	3,185
SER-262	1,235	62
SER-287	841	—
Total research and development expenses	<u>\$ 15,416</u>	<u>\$ 5,561</u>

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-109 and SER-287 and initiate clinical trials for certain product candidates, including SER-262, continue to discover and develop additional product candidates, including SER-155, and pursue later stages of clinical development of our product candidates. For example, the European Medicines Agency, or EMA, has recently provided initial guidance regarding SER-109 Phase 3 trial design that may lead to two Phase 3 studies being conducted to support SER-109 approval in the European Union.

#### *General and Administrative Expenses*

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate and business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support the expected growth in our research and development activities and the potential commercialization of our product candidates. We also expect to 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 and SEC requirements, director and officer insurance costs and investor and public relations costs.

#### *Other Income (Expense), Net*

*Interest Income.* Interest income consists of interest earned on our cash, cash equivalents and investments.

*Interest Expense.* Interest expense consists of interest expense incurred on our debt. During the three months ended March 31, 2015, interest expense consisted of interest at the stated rate on borrowings under our loan and security agreement, amortization of deferred financing costs and interest expense related to the accretion of debt discount associated with (1) the fair value of preferred stock warrant we issued in connection with the Loan and Security Agreement and (2) a final payment due at maturity.

*Revaluation of Preferred Stock Warrant Liability.* Revaluation of preferred stock warrant liability consists of the net gain or loss associated with the change in the fair value of our preferred stock warrant liability. In connection with the Loan and Security Agreement, we issued a warrant for the purchase of our Series A-2 convertible preferred stock, which we believe is a financial instrument that may have required a transfer of assets because of the redemption feature of the underlying stock. Therefore, we classified this warrant as a liability that we re-measured to fair value at each reporting period, and we recorded the changes in the fair value as a component of other income (expense), net. Upon the listing of our common stock on the NASDAQ on June 26, 2015, the preferred stock warrant became a warrant to purchase common stock. We performed the final mark to market adjustment on the preferred stock warrant using the fair value of the underlying common shares of \$18.00 per share on June 26, 2015 and recorded the change in fair value in other income (expense), net in the consolidated statement of operations and comprehensive loss. The preferred stock warrant liability was then reclassified to additional paid-in-capital as it became a warrant to purchase common stock.

## **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 either the three-month periods ended March 31, 2016 or 2015.

## **Critical Accounting Policies and Significant Judgments and Estimates**

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States of America. The preparation of our financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. During the three months ended March 31, 2016, we have determined that as a result of the License Agreement, our accounting for collaboration revenue requires significant judgment and, accordingly, have disclosed our policy below. Our critical accounting policies, other than accounting for collaboration revenue, are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies and Significant Judgments and Estimates” in our Form 10-K filed on March 14, 2016 and the notes to the consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. We believe that of our critical accounting policies, the following accounting policies involve the most judgment and complexity:

- Accrued research and development expenses
- Stock-based compensation
- Valuation of the warrant to purchase convertible preferred stock
- Collaboration revenue

Accordingly, we believe the policies referenced above are critical to fully understanding and evaluating our financial condition and results of operations. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected.

## **Collaboration revenue**

We evaluate multiple-element arrangements based on the guidance in FASB ASC Topic 605-25, Revenue Recognition-Multiple-Element Arrangements (“ASC 605-25”). Pursuant to this guidance, we identify the deliverables included in the arrangement and determines: (1) whether the individual deliverables have value to the customer on a standalone basis and represent separate units of accounting or whether they must be accounted for as a combined unit of accounting; and (2) if the arrangement includes a general right of return relative to the delivered item. This evaluation requires us to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: (i) the delivered item(s) has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. In assessing whether an item has standalone value, we consider factors such as the research, manufacturing and commercialization capabilities of the collaboration partner, the retention of any key rights by the Company, and the availability of the associated expertise in the general marketplace. In addition, we consider whether the collaboration partner can use the other deliverable(s) for their intended purpose without the receipt of the remaining element(s), whether the value of the deliverable is dependent on the undelivered item(s) and whether there are other vendors that can provide the undelivered element(s).

In situations where we have identified multiple units of accounting, the arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. Then, the applicable revenue recognition criteria in ASC 605-25 are applied to each of the separate units of accounting in determining the appropriate period and pattern of recognition. We determine the selling price of a unit of accounting following the hierarchy of evidence prescribed by ASC 605-25. Accordingly, we determine the estimated selling price for units of accounting within each arrangement using vendor-specific objective evidence (“VSOE”) of selling price, if available, third-party evidence (“TPE”) of selling price if VSOE is not available, or best estimate of selling price (“BESP”) if neither VSOE nor TPE is available.

We recognize arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in ASC 605-25 are satisfied for that particular unit of accounting. We will recognize as revenue arrangement consideration attributed to licenses that have standalone value from the other deliverables to be provided in an arrangement upon delivery. We will recognize as revenue arrangement consideration attributed to licenses that do not have standalone value from the other deliverables to be provided in an arrangement over the estimated performance period as the arrangement would be accounted for as a single unit of accounting.

If there is no discernible pattern of performance and/or objectively measurable performance measures do not exist, then we recognize revenue under the arrangement for the single unit of accounting on a time-based proportional performance method over the period we are expected to complete our performance obligations. Alternatively, if the pattern of performance in which the service is provided to the customer can be determined and objectively measurable performance measures exist, then we recognize revenue under the arrangement using the proportional performance method. Revenue recognized is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the time-based proportional performance method or effort-based proportional performance method, as applicable.

At the inception of an arrangement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (i) the consideration is commensurate with either our performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) the consideration relates solely to past performance and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We evaluate factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone in making this assessment. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a milestone is substantive. We recognize revenue associated with substantive milestones in accordance with FASB ASC Topic 605-28, Revenue Recognition-Milestone Method upon successful accomplishment of each milestone, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive would be recognized as revenue over the remaining period of performance, assuming all other revenue recognition criteria are met.

Application of the above guidance requires significant judgment and requires the Company to make determinations based on the facts and circumstances under each arrangement.

## Results of Operations

### Comparison of Three Months Ended March 31, 2016 and 2015

The following table summarizes our results of operations for the three months ended March 31, 2016 and 2015:

	Three Months Ended March 31,		Change
	2016	2015	
	(in thousands)		
<b>Revenue:</b>			
Collaboration revenue - related party	2,710	—	2,710
Total revenue	2,710	—	2,710
<b>Operating expenses:</b>			
Research and development	\$ 15,416	\$ 5,561	\$ 9,855
General and administrative	7,210	2,606	4,604
Total operating expenses	22,626	8,167	14,459
Loss from operations	(19,916)	(8,167)	(11,749)
<b>Other income (expense):</b>			
Interest income	268	49	219
Interest expense	(56)	(66)	10
Revaluation of preferred stock warrant liability	—	213	(213)
Total other income (expense), net	212	196	16
Net loss	<u>\$ (19,704)</u>	<u>\$ (7,971)</u>	<u>\$ (11,733)</u>

## Revenue

Total revenue was \$2.7 million for the three months ended March 31, 2016. We had no revenue for the three months ended March 31, 2015. The increase was a result of revenue recorded in connection with our License Agreement with NHS, entered into during the three months ended March 31, 2016.

## Research and Development Expenses

	Three Months Ended March 31,		Change
	2016	2015	
	(in thousands)		
Microbiome therapeutics platform and pipeline	\$ 7,851	\$ 2,314	\$ 5,537
SER-109	5,489	3,185	2,304
SER-262	1,235	62	1,173
SER-287	841	-	841
Total research and development expenses	<u>\$ 15,416</u>	<u>\$ 5,561</u>	<u>\$ 9,855</u>

Research and development expenses were \$15.4 million for the three months ended March 31, 2016, compared to \$5.6 million for the three months ended March 31, 2015. The increase of \$9.9 million was due primarily to the following:

- an increase of \$5.5 million in research expenses related to our microbiome therapeutics platform, due primarily to an increase in payroll and consultant costs of \$4.8 million, which included an increase in stock-based compensation expense of \$1.6 million due primarily to an increase in employee headcount;
- an increase of \$2.3 million in expenses related to our SER-109 program, due primarily to an increase in clinical trial costs of \$1.3 million and an increase in lab consumables and supplies of \$1.0 million;
- an increase of \$1.2 million in expenses for our SER-262 program in connection with various pre-clinical and development activities related to the program; and
- an increase of \$0.8 million in expenses for our SER-287 program primarily driven by the initiation of our Phase 1b clinical trial in December 2015.

We expect that our research and development expenses will continue to increase in the foreseeable future as we advance the clinical development of SER 109 and SER-287 and initiate clinical trials for certain product candidates, including SER-262, continue to discover and develop additional product candidates, including SER-155, and pursue later stages of clinical development of our product candidates. For example, the EMA has recently provided initial guidance regarding SER-109 Phase 3 trial design that may lead to two Phase 3 studies being conducted to support SER-109 approval in the European Union.

## General and Administrative Expenses

	Three Months Ended March 31,		Change
	2016	2015	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 3,326	\$ 1,400	\$ 1,926
Professional fees	2,628	827	1,801
Facility-related and other	1,256	379	877
Total general and administrative expenses	<u>\$ 7,210</u>	<u>\$ 2,606</u>	<u>\$ 4,604</u>

General and administrative expenses were \$7.2 million for the three months ended March 31, 2016, compared to \$2.6 million for the three months ended March 31, 2015. The increase of \$4.6 million was primarily due to the following:

- an increase in personnel related costs of \$1.9 million primarily due to hiring of additional employees from March 31, 2015 to March 31, 2016 to support corporate operations and business development activities, including an increase of \$1.0 million in stock-based compensation;
- an increase in professional fees of \$1.8 million due to an increase in accounting, audit and legal fees as a result of ongoing business activities; and



an increase in facility costs of \$0.9 million primarily due to an increase in office-related expenses, insurance cost and depreciation charges, including an increase of \$0.2 million in insurance costs in connection with operating as a public company.

#### *Other Income (Expense), Net*

Other income (expense), net for each of the three months ended March 31, 2016 and March 31, 2015 was \$0.2 million. The \$0.2 million of other income (expense), net for the three months ended March 31, 2015 was primarily due to the revaluing of the preferred stock warrant liability in connection with the automatic conversion of our convertible preferred stock, which occurred upon the listing of our common stock on the NASDAQ on June 26, 2015. The preferred stock warrant liability was remeasured at fair value and reclassified to additional paid-in capital. The \$0.2 million of other income (expense), net for the three months ended March 31, 2016 was 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. We expect that our research and development and general and administrative expenses will 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.

From our inception through June 30, 2015, we had financed our operations through private placements of our convertible preferred stock, the issuance of convertible promissory notes and borrowings under the Loan and Security Agreement. Through June 30, 2015, we had received gross proceeds of \$137.0 million from such transactions and we had repaid \$1.0 million of the total \$3.0 million borrowed under the Loan and Security Agreement.

On July 1, 2015, we completed the IPO and issued and sold 8.5 million shares of our common stock at a public offering price of \$18.00 per share, resulting in net proceeds of approximately \$139.3 million after deducting underwriting discounts and commissions and offering expenses. The shares issued upon closing of the IPO included 1.1 million shares of our common stock, which were sold pursuant to the underwriters' full exercise of their option to purchase additional shares of our common stock. Upon the listing of our common stock on NASDAQ on June 26, 2015, all outstanding shares of our convertible preferred stock automatically converted into 22.9 million shares of our common stock.

On September 17, 2015, we made a payment of \$1.8 million to Comerica to satisfy all amounts owed under the Loan and Security Agreement. The extinguishment amount was comprised of \$1.7 million of outstanding principal and \$0.1 million of final payment fees and accrued interest. Upon payment, Comerica released us of all security interests held in our assets, except for the cash collateral securing our corporate cards and standby letters of credit, and terminated all loan documents related to the loan and security agreement (other than any indemnification obligations and other provisions which survive termination).

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 ulcerative colitis and Crohn's disease. In exchange for the license, NHS agreed to pay us an upfront cash payment of \$120 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 NHS Collaboration Products in the Licensed Territory. We are eligible to receive up to \$295.0 million in development milestone payments, \$365.0 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. We expect to receive a total of \$30 million in milestone payments in 2016 associated with the planned initiation of a Phase 1b study for SER-262 and the anticipated initiation of the Phase 3 clinical trial for SER-109. The full potential value of the upfront payment and milestone payments payable by NHS is over \$1.9 billion, assuming all products receive regulatory approval and are successfully commercialized.

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. 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 an ongoing Phase 2 clinical trial 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.

As of March 31, 2016, we had cash, cash equivalents and investments totaling \$303.3 million and an accumulated deficit of \$102.3 million.

### Cash Flows

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

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Cash provided by (used in) operating activities	\$ 101,415	\$ (8,340)
Cash provided by (used in) investing activities	\$ 17,723	(59,469)
Cash provided by financing activities	\$ 157	(1,331)
Net increase (decrease) in cash and cash equivalents	<u>\$ 119,295</u>	<u>\$ (69,140)</u>

*Operating Activities.* During the three months ended March 31, 2016, operating activities provided \$101.4 million of cash, primarily due to upfront cash received of \$120.0 million in connection with the License Agreement. The increase was partially offset by a net loss of \$19.7 million, cash used from changes in our operating assets and liabilities of \$0.5 million and by non-cash charges of \$4.3 million. Net cash used for changes in our operating assets and liabilities during the three months ended March 31, 2016 consisted of a \$1.0 million increase in prepaid expenses and other current assets, a \$0.8 million decrease in accrued expenses and other current liabilities, offset in part by an increase in accounts payable of \$1.3 million. The increase in our accounts payable was due to the timing of payments. The increase in prepaid expenses and other current assets was due primarily to prepayments made for clinical trial activities and insurance premiums.

During the three months ended March 31, 2015, operating activities used \$8.3 million of cash, primarily resulting from our net loss of \$8.0 million and cash used from changes in our operating assets and liabilities of \$1.6 million, partially offset by non-cash charges of \$1.2 million. Net cash used for changes in our operating assets and liabilities during the three months ended March 31, 2015 consisted of a \$0.7 million increase in prepaid expenses and other current assets, a \$0.2 million decrease in accounts payable and a \$0.7 million decrease in accrued expenses and other current liabilities. The decreases in our accounts payable and accrued expenses were due to the timing of payments and a decrease in amounts accrued for clinical trial and contracted manufacturing expenses. The increase in prepaid expenses and other current assets was due primarily to prepayments made for clinical trial activities.

*Investing Activities.* During the three months ended March 31, 2016, net cash provided by investing activities was \$17.7 million, consisting of purchases of investments of \$45.3 million and purchases of property and equipment of \$3.4 million. The decrease was partially offset by maturities of investments of \$66.4 million.

During the three months ended March 31, 2015, we used \$59.5 million of cash in investing activities, consisting of purchases of investments of \$59.3 million and purchases of property and equipment of \$0.2 million.

*Financing Activities.* During the three months ended March 31, 2016, net cash provided by financing activities was \$0.2 million in connection with the exercise of options and warrants to purchase our common stock.

During the three months ended March 31, 2015, net cash used in financing activities was \$1.3 million as a result of principal repayments of \$0.3 million of borrowings under our Loan and Security Agreement and payments of initial public offering costs of \$1.1 million, both of which were partially offset by proceeds from the exercise of stock options of \$0.1 million.

## **Funding Requirements**

We expect our expenses to increase substantially in connection with our ongoing development activities related to SER-109 and SER-287, which are in clinical development, and our follow-on therapeutics and other programs. 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:

- conduct our Phase 2 clinical study of SER-109, our lead product candidate, and potentially advance to Phase 3 clinical studies;
- conduct our Phase 1 clinical study of SER-287;
- continue the research and development of our other product candidates, including commencing clinical trials for SER-262;
- seek to enhance our microbiome therapeutics platform and discover and develop additional product candidates, including SER-155 and SER-301;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- potentially establish a sale, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our transition to a public company;
- 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; and
- perform our obligations under the collaboration agreement with Nestlé.

We expect that our existing cash, cash equivalents and investments will enable us to fund our operating expenses and capital expenditure requirements well into 2018. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of SER-109, SER-287 or our follow-on programs, 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 for SER-109, SER-287 or our other programs will depend on many factors, including:

- the progress and results of our Phase 2 clinical study of SER-109;
- the progress and results of our Phase 1 clinical study of SER-287;
- the cost of manufacturing clinical supplies of 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-262, SER-155 and SER-301;
- 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, although, aside from the License Agreement, we currently have no commitments or agreements to complete any such transactions.

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, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. 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 your ownership interest.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, in addition to the License Agreement, 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 the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015. There have been no material changes from the contractual commitments and obligations previously disclosed in our 2015 Annual Report on Form 10-K.

### **Off-Balance Sheet Arrangements**

As of March 31, 2016, we did not have any off-balance sheet arrangements as defined in the rules and regulations of the Securities and Exchange Commission.

## **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, 2016, our cash, cash equivalents and investments consisted of cash, money market accounts and investments in corporate bonds, commercial paper and government securities with remaining maturities of less than one year. 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 Chief Financial 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 Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2016.

### **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, 2016 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.

We are not party to any material legal proceedings.

### 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.***

Since inception, we have incurred significant operating losses. Our net loss was \$16.7 million for the year ended December 31, 2014, \$54.8 million for the year ended December 31, 2015 and \$19.7 million for the 3 months ended March 31, 2016. As of March 31, 2016, we had an accumulated deficit of \$102.3 million. To date, we have financed our operations through the initial public offering of our common stock, private placements of our preferred stock, and the issuance of convertible promissory notes and borrowings under a loan and security agreement with Comerica Bank, or the loan and security agreement. We have devoted substantially all of our financial resources and efforts to developing our microbiome therapeutics platform, identifying potential product candidates and conducting pre-clinical studies and clinical trials. We are in the early stages of development of our product candidates, which we call Ecobiotic microbiome therapeutics, and we have not completed development of any 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 will increase substantially as we:

- conduct our Phase 2 clinical study of SER-109, our lead product candidate, and potentially advance to Phase 3 clinical studies;
- conduct our Phase 1b clinical study of SER-287;
- continue the research and development of our other product candidates, including completing pre-clinical studies and commencing clinical trials for SER-262 and SER-155;
- seek to enhance our microbiome therapeutics platform and discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- potentially establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our operation as a public company; 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 pre-clinical 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 only in the preliminary stages of most 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. If we are required by the U.S. Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA, or other regulatory

authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase and revenue could be further delayed.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations.

***We will need additional funding in order to complete development of our product candidates and commercialize our products, if approved. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.***

We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our Phase 2 clinical study of SER-109 and our Phase 1b clinical study of SER-287, and continue to research, develop and initiate clinical trials of SER-262 and SER-155 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 expect that our existing cash, cash equivalents and investments will enable us to fund our operating expenses and capital expenditure requirements well into 2018. 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 Phase 2 clinical study of SER-109 and our Phase 1b clinical study of SER-287, as well as future clinical studies for these candidates;
- the cost of manufacturing clinical supplies of 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-262 and SER-155;
- the costs, timing and outcome of regulatory review of our product candidates;
- 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

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. 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 for you 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 SER-109 and SER-287, researching SER-262, building our intellectual property portfolio, developing our supply chain, planning our business, raising capital and providing general and administrative support for these operations. All but two of our product candidates, SER-109 and SER-287, are still in pre-clinical development. We have completed our Phase 1b/2 clinical study of SER-109, our lead product candidate, but have not completed any other clinical trials for this or any other product candidate. We have not yet demonstrated our ability to successfully complete any Phase 2 clinical study or any Phase 3 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 you make 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**

***We are very 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, with an initial focus on developing SER-109 for the prevention of further recurrences of CDI in patients suffering from recurrent CDI and SER-287 for the treatment of ulcerative colitis. While we believe our pre-clinical and Phase 1b/2 clinical data to date has validated our platform to a degree, 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 non-*Clostridium difficile* infection and to treat inflammatory and metabolic diseases. We may have problems applying our technologies to these other areas, and our new product candidates may not be as effective in preventing infection and disease as our initial product candidates. Even if we are successful in identifying additional product candidates, they 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 pre-clinical 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 pre-clinical 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 the 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 based upon our technological approach, 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 therapy, a therapeutic approach that is designed to 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 a therapeutic based on this approach. We cannot be certain that our approach will lead to the development of approvable or marketable products. 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 raw materials or products, which could delay the development or commercialization of our product.

***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.***

We dosed the first patient in a Phase 2 clinical study of our lead product, SER-109, in May 2015. In December 2015, we initiated a Phase 1b clinical trial evaluating SER-287 in mild-to-moderate ulcerative colitis. Our other product candidates are in pre-clinical development. It is impossible 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 pre-clinical 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 pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. For example, in anticipation of our Phase 2 clinical study of SER-109, we have refined the formulation of the inner capsule and changed the manufacturing process that we expect to use for commercial production. This formulation has not previously been clinically tested. The Phase 2 clinical study is the first clinical trial using this formulation and we cannot assure you that the results of this new formulation will be consistent with those experienced in the Phase 1b/2 clinical study of SER-109. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks.

In addition, we cannot be certain as to what type and how many clinical trials the FDA, or other regulators, will require us to conduct before we may successfully gain approval to market SER-109 or 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. In the course of our discussions with the FDA, the FDA has indicated that we may be required to conduct more than one Phase 3 clinical trial of SER-109 in order to gain approval. Additional clinical trials could cause us to incur significant development costs, delay or prevent the commercialization of SER-109 or otherwise adversely affect our business.

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;
- we may experience delays in reaching, or fail to reach, 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.

We completed our Phase 1b/2 clinical study of SER-109 in 2014 and dosed the first patient in a Phase 2 clinical study for this product candidate in May 2015. Although most clinical research performed in the United States must be authorized in advance by the FDA under its investigational new drug application, or IND, regulations, we did not conduct our Phase 1b/2 clinical study under an IND pursuant to the FDA's exercise of enforcement discretion with regard to IND requirements for use of fecal microbiota for transplantation to treat CDI not responsive to standard therapies. Although the FDA provided confirmation that it intends to exercise enforcement discretion with respect to our Phase 1b/2 clinical study of SER-109, it stated that continued clinical evaluation of SER-109 will require an IND. In April 2015, the FDA authorized the conduct of our Phase 2 clinical study of SER-109 under an IND. We intend to conduct all future clinical studies of SER-109 under this IND. Unlike with SER-109, we expect that the FDA will require an IND before we initiate clinical testing of our other product candidates and may also require us to conduct more extensive pre-clinical tests prior to the start of clinical trials than were required for SER-109.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our pre-clinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant pre-clinical 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 our lead product candidate, SER-109, to prevent further recurrences of CDI in patients suffering from recurrent CDI. We estimate the addressable population of patients with recurrent CDI to be between 85,000 and 110,000 patients per year in the United States, and accordingly, 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;
- 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 would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may 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.

***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 pre-clinical 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 pre-clinical 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 as deficient. In addition, varying interpretations of the data obtained from pre-clinical 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. Upon the FDA's review of data from any pivotal trial, it may request that the sponsor conduct additional analyses of the 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 therapeutic 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 therapeutic candidates. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of our therapeutic 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. Fast Track designation provides increased opportunities for sponsor meetings with the FDA during pre-clinical 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 a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive 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 availability of Breakthrough Therapy designation was established recently with the passage of the Food and Drug Administration Safety and Innovation Act of 2012, and the FDA has only recently released additional guidance as to the criteria it uses in designating drugs as breakthrough therapies. As a result, we cannot be sure that our evaluation of our product candidates as qualifying for Breakthrough Therapy designation will meet the FDA's expectations. In any event, 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 for SER-109 for recurrent *C. difficile* infection 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 annually 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.

### **Risks Related to our Dependence on Third Parties and Manufacturing**

***The Collaboration and License Agreement, or the License Agreement, with Nestec Ltd., or 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 and SER-287, 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, including SER-109 and SER-287, 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, including SER-109 and SER-287, 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 the manufacture of our product candidates for pre-clinical 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 the manufacture of our product candidates for pre-clinical 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 manufacturing agreements by the third-party manufacturers;
- failure to manufacture our product according to our specifications;
- failure to manufacture our 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 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 manufacturer we rely on to produce SER-109 and SER-287 has never produced a FDA-approved therapeutic. If our contract manufacturer is unable to comply with cGMP regulation or if the FDA does 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 a backup facility in California, we do not currently have arrangements in place for redundant supply or a second source for required raw materials used in the manufacture of our product candidates or for the manufacture of finished SER-109 product. If our current contract 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 if we decide to establish our own manufacturing facility, 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 a pilot manufacturing facility at our Cambridge location 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 do not have any manufacturing facilities that meet the FDA's cGMP requirements for the production of any product candidates used in humans.

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. We expect our new headquarters in Cambridge, MA to expand our existing clinical supply manufacturing capabilities. 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.

#### **Risks Related to Commercialization of Our Product Candidates and Other Legal Compliance 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 fecal microbiota transplantation, or FMT, and physicians may continue to rely on these treatments. 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
- inability of certain types of patients to take our product.

***We currently have a limited sales organization. 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 limited sales or marketing infrastructure and 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 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 the prevention of 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 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 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, pre-clinical 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 \$3.0 million in product liability insurance coverage in the aggregate, with a per occurrence limit of \$3.0 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 BCPIA, 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 BCPIA, 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 new 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. In each of his proposed budgets for fiscal years 2013 through 2015, President Obama has proposed to cut this 12-year period of exclusivity down to seven years. He also proposed to prohibit additional periods of exclusivity due to minor changes in product formulations, a practice often referred to as “evergreening.” It is possible that Congress may take these or other measures to reduce or eliminate periods of exclusivity. The BCPIA is complex and only beginning 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 BCPIA in March

2015. However, several issues still remain unclear with respect to the FDA's final implementation of the BCPIA, 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, or REMS, 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. 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. 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.

***Our relationships with customers, physicians and third-party payors 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 future arrangements with third-party payors, physicians and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain 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 federal False Claims Act imposes criminal and civil penalties, including 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 or 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 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 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 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 a healthcare company 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 regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, 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 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The MMA expanded Medicare coverage for outpatient drug purchases by those covered by Medicare under a new Part D and introduced a new reimbursement methodology based on average sales prices for Medicare Part B physician-administered drugs. In addition, the MMA authorized Medicare Part D prescription drug plans to limit the number of drugs that will be covered in any therapeutic class in their formularies. The MMA's cost reduction initiatives and other provisions could decrease the coverage and price that we receive for any approved products. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in Medicare reimbursement may result in a similar reduction in payments from private payors. Similar regulations or reimbursement policies may be enacted in international markets which could similarly impact our business.

More recently, in 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act, 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 Affordable Care Act 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;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% 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;
- new requirements to report financial arrangements with physicians and teaching hospitals;
- 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.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes 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 2025 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, including hospitals. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain.

We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria 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 products.

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.

***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.

### **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, and we are just beginning to reach the statutory deadlines for deciding whether and where to initiate prosecution in specific foreign jurisdictions by filing national state applications based on our Patent Cooperation Treaty, or PCT, applications. As those deadlines come due, we will have to decide whether and where to pursue patent protection for the various inventions claimed in our patent portfolio, and we will only have the opportunity to obtain patents in those jurisdictions where we pursue protection. 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.

If, in the future, we obtain licenses from third parties, 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.

Our patent portfolio is in the early stages of prosecution. We currently have four issued U.S. patents. Although we have numerous patent applications pending, substantive prosecution has begun in only a small number of those applications. 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. 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 a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, 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. 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 on 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, recent 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 recently 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 patents 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, recent United States 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 U.S. Supreme Court, other federal courts, the United States 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 recent 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) or *Myriad; Alice Corp. v. CLS Bank International*, 573 U.S. 13-298 (2014); and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, or *Prometheus*, 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. The *Myriad* decision, issued on June 13, 2013, is the most recent Supreme Court decision to address patent eligibility of 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. In *Myriad*, the Court held that claims to isolated genomic DNA are not patentable, but claims to complementary DNA, or cDNA, molecules, which are not genomic sequences, may be patent eligible because they are not a natural product. The effect of the decision on patents for other isolated natural products is uncertain. However, on March 4, 2014, the USPTO issued a memorandum to patent examiners providing guidance for examining claims that recite laws of nature, natural phenomena or natural products under the *Myriad* and *Prometheus* decisions. The guidance did not limit the application of *Myriad* to DNA but, rather, applied the decision broadly to other natural products, which may include our product candidates. The March 4, 2014 memorandum and the USPTO's interpretation of the cases and announced examination rubric received widespread criticism from stakeholders during a public comment period and was superseded by interim guidance published on December 15, 2014. Additional guidance was published in July 2015 (July 2015 Update: Subject Matter Eligibility). 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 a third-party patent family that includes issued and allowed patents, including in the United States, with claims that, if valid and enforceable, could be construed to cover some of our product candidates or their methods of use.

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 all of the patent families in our portfolio, including the families that may provide coverage for our lead product candidates, the relevant statutory deadlines have not yet expired. Therefore, for each of the patent families that we believe provide coverage for our lead product candidates, we will need to 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 Employee Matters and Managing Growth and Other Risks Related to Our Business**

#### ***Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.***

We are highly dependent on Roger Pomerantz, our President and Chief Executive Officer and Chairman of the Board of Directors, as well as the other principal members of our management, scientific and clinical team, including Eric Shaff, our Chief Financial Officer and Executive Vice President, David Cook, our Chief Scientific Officer and Executive Vice President of Research & Development, John Aunins, our Chief Technology Officer and Executive Vice President of Bioprocess & Manufacturing, Michele Trucksis, our Chief Medical Officer and Executive Vice President, Wael Hashad, our Chief Commercial Officer, and Executive Vice President, and Matthew Henn, our Head of Drug Discovery & Bioinformatics and Senior Vice President. 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 expect to expand our operational capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We expect to 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 our anticipated 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 anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

We currently have limited international operations, but our business strategy incorporates potentially expanding internationally if any of our product candidates receive regulatory approval. We currently 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, or FCPA, 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 those of our current and future contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, 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 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;
- 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.

## 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. 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, you may not be able to sell your common stock at or above the price you paid for your 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 partners 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 70.2% 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. Approximately 30.5 million shares of our common stock recently became eligible to be sold into the market, unless held by one of our affiliates, in which case the resale of those securities is subject to volume limitations under Rule 144 of the Securities Act. Moreover, holders of an aggregate of approximately 22.9 million shares of our common stock as of the completion of the initial public offering of our common stock on July 1, 2015 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 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 \$1.0 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:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- 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.

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.

***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, and particularly after we are no longer an emerging growth company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private 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 will be 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. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

***If securities or industry analysts issue an adverse or misleading opinion regarding our stock, our 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 you might otherwise receive a premium for your 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:

- 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 your sole source of gain.***

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 your sole source of gain for the foreseeable future.

***We could be subject to securities class action litigation.***

In the past, 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. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

### ***Use of Proceeds from Registered Securities***

On July 1, 2015, we completed the initial public offering of our common stock and issued and sold 8,545,138 shares of our common stock at a public offering price of \$18.00 per share, including 1,114,583 pursuant to the underwriters' full exercise of their option to purchase additional shares of our common stock.

The offer and sale of all of the shares in the offering was registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-204484), which was declared effective by the SEC on June 25, 2015, and a registration statement on Form S-1MEF (File No. 333-205238), which was automatically effective upon filing with the SEC on June 25, 2015. On September 17, 2015, we made a payment of \$1.8 million to Comerica to satisfy all amounts owed under our loan and security agreement. The payoff amount was comprised of \$1.7 million of outstanding principal under the loan and security agreement and \$0.1 million of final payment fees and accrued interest. There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on June 26, 2015.

### **Item 3. Defaults Upon Senior Securities.**

None.

### **Item 4. Mine Safety Disclosures.**

None.

### **Item 5. Other Information.**

None.

### **Item 6. Exhibits.**

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

**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 16, 2016

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

**EXHIBIT INDEX**

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Restated Certificate of Incorporation, filed on July 1, 2015	8-K	001-37465	3.1	7/1/15	
3.2	Amended and Restated Bylaws	8-K	001-37465	3.2	7/1/15	
10.1^	Collaboration and License Agreement, dated January 9, 2016, by and between the Registrant and Nestec Ltd.					*
10.2	First Amendment to Employment Agreement, dated February 3, 2016 by and between the Registrant and Roger J. Pomerantz	8-K	001-37465	10.1	2/4/16	
10.3	Employment Agreement, dated December 11, 2015, by and between the Registrant and Wael Hashad					*
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer					*
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer					*
32.1	Section 1350 Certification of Chief Executive Officer					**
32.2	Section 1350 Certification of Chief Financial Officer					**
101.INS	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.

^ Confidential treatment has been requested with respect to redacted portions of this exhibit. Redacted portions of this exhibit have been filed separately with the SEC.

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**COLLABORATION AND LICENSE AGREEMENT**

**between**

**NESTEC LTD.**

**and**

**SERES THERAPEUTICS, INC.**

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**Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4), 200.83 and 240.24b-2** **Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4), 200.83 and 240.24b-2**

**Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4), 200.83 and 240.24b-2**

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## COLLABORATION AND LICENSE AGREEMENT

This COLLABORATION AND LICENSE AGREEMENT (the “**Agreement**”) is made as of January 9, 2016 (the “**Effective Date**”), by and between NESTEC LTD., a limited company organized and existing under the laws of Switzerland, having an office located at Avenue Nestlé 55, 1800 Vevey, Switzerland (“**NHSc**”), and Seres Therapeutics, Inc., a corporation incorporated and existing under the laws of the State of Delaware, having an office located at 215 First Street, Cambridge, MA 02142, USA (“**Seres**”). NHSc 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 a new class of 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 further development of such products for use in treating and managing inflammatory bowel disease and treating and preventing the recurrence of *C. difficile* infections; and

WHEREAS, NHSc wishes to obtain, and Seres is willing to grant to NHSc, certain licenses under intellectual property controlled by Seres in connection with such products for such uses, including an exclusive license thereunder to enable NHSc and its Affiliates and sublicensees to exploit such products for such uses outside of the United States and Canada, 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.

“**Additional Collaboration Products**” has the meaning set forth in Section 4.3.

“**Additional Development**” has the meaning set forth in Section 4.5(a).

“**Affected Products**” means, in the event that NHSc has the right to terminate this Agreement pursuant to Section 13.2.3 due to material breach by Seres, but NHSc does not terminate this Agreement and instead invokes its rights under Section 13.5, those Collaboration Products to which the applicable material breach relates.

“**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.

“**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 Day**” means a day other than Saturday, Sunday or any day on which commercial banks located in New York, New York or Geneva, Switzerland, 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.

“**C Difficile Field**” means (i) the treatment of a *C. difficile* infection and the prevention of [\*\*\*] *C. difficile* infections and associated complications, as well as (ii) any other indications for which a given C Difficile Product may be Developed pursuant to this Agreement by mutual agreement of the Parties; provided that such other indication(s) shall only be included in the C Difficile Field for the specific C Difficile Product that the Parties agree to Develop for such other indication.

“**C Difficile Product**” means the First C Difficile Product and the Second C Difficile Product, and any Additional Collaboration Products Developed primarily for the treatment of a *C. difficile* infection and the prevention of [\*\*\*] *C. difficile* infections and associated complications.

“**C Difficile Royalty Period**” means the period beginning with the First Commercial Sale of a C Difficile Product in the C Difficile Field in the Territory and ending, on the later to occur of (i) the [\*\*\*] anniversary of the date of such First Commercial Sale of such Collaboration Product, and (ii) January 1<sup>st</sup> of the Calendar Year during the Term following any Calendar Year in which Net Sales of C Difficile Products in the C Difficile Field in the Territory are below [\*\*\*]. For the sake of clarity, if Net Sales of C Difficile Products for the final Calendar Year

ending prior to such [\*\*\*] anniversary are less than [\*\*\*], then the C Difficile Royalty Period shall end on such [\*\*\*] anniversary.

“**Challenge Proceeding**” has the meaning set forth in Section 10.4.3.

“**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 Collaboration Product. Clinical Trials shall include Phase I Clinical Trials, Phase II Clinical Trials, Phase III Clinical Trials.

“**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.

“**COGS**” means with respect to any Collaboration Product supplied under the Development Supply Agreement or the Commercial Supply Agreement: the fully absorbed manufacturing costs attributable to the manufacture of Collaboration Products calculated in accordance with U.S. generally accepted accounting principles (“**GAAP**”), consistently applied, and otherwise calculated in a manner consistent with Seres’ past practice and internal accounting practices and policies. For clarity, subject to the preceding sentence, COGS includes, [\*\*\*], in each case, to the extent directly allocable to the applicable Collaboration Product.

“**Collaboration Products**” means (i) the First C Difficile Product, (ii) the Second C Difficile Product, (iii) the First IBD Product, (iv) the Second IBD Product and (v) each Additional Collaboration Product that becomes a Collaboration Product pursuant to Section 4.3.

“**Combination Product**” means a therapeutic preparation containing a Collaboration Product and one or more active ingredients or active compounds that are not Collaboration Products (an “**Other Product**”) sold for a single invoiced price.

“**Commercial Supply Agreement**” has the meaning set forth in Section 5.3.

“**Commercialization**” means any and all activities relating specifically to the preparation for sale of, offering for sale of, or sale of a product, including activities related to launching, marketing, promoting, distributing, detailing, importing, pricing, reimbursement, and advertising such product, and interacting with Regulatory Authorities regarding any of the foregoing, but excluding any activities relating to Manufacture. When used as a verb, “**to Commercialize**” and “**Commercializing**” means to engage in Commercialization, and “**Commercialized**” has a corresponding meaning.

“**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 Collaboration Product, any Exploitation of any Collaboration 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. Joint Know-How 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, or (2) misappropriating the material, know-how or information of a Third Party.

“**Core Countries**” means those countries in which Seres shall be obligated to file, prosecute and maintain Licensed Patents, as set forth in Exhibit G, or as otherwise agreed by the Parties in writing from time to time.

“**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.

“**Crohn’s**” means Crohn’s disease.

“**Decision Country**” has the meaning set forth in Section 4.1.2.

“**Development**” means non-clinical and clinical drug development activities reasonably related to the development and submission of information to a Regulatory Authority or otherwise to the research, identification, testing and validation of a therapeutic agent, including, without limitation, toxicology, pharmacology and other discovery and pre-clinical efforts, test method development and stability testing, manufacturing process and CMC development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical trials (including, without limitation, pre- and post-approval studies), whether for purposes of label expansion or otherwise. Development shall include post-approval Development activities. When used as a verb, “**Develop**” means to engage in Development.

“**Development Budget**” means, with respect to each approved Development Plan, an itemized budget of the estimated Shared Development Costs expected to be incurred during each Calendar Quarter in connection with the performance of the applicable specific Development activities set forth in such Development Plan.

“**Development Costs**” means any and all costs and expenses incurred by or on behalf of the Parties in connection with the Development of Collaboration Products in the Field, including without limitation costs of each Party’s employees supporting such efforts (calculated using the FTE Costs), as well as all out-of-pocket costs of procuring services, products or materials used in the Development of Collaboration Products in the Field, and any amounts paid to clinical research organizations engaged to conduct Development activities and amounts paid to Third Party contractors to supply Collaboration Product for Development, in each case, to the extent

such costs or expenses do not comprise COGS for purposes of the price paid for any Collaboration Products supplied under the Development Supply Agreement and are not otherwise reimbursed under the Development Supply Agreement. Development Costs shall include without limitation all costs of CMC process development, development and validation of methods and facilities for Manufacturing Collaboration Products, development of quality assurance and quality control procedures and protocols, formulation development and other nonclinical and preclinical studies for Collaboration Products.

**“Development Plan”** means collectively or individually, as the context requires, the Global Development Plan and any Regional Development Plan(s) and any other development plan that the Parties may mutually agree to in relation to an Additional Collaboration Product, as contemplated in Section 4.3.

**“Development Supply Agreement”** has the meaning set forth in Section 5.2.

**“Diligent Efforts”** means efforts that are consistent with the type and scope of efforts that a similarly-situated company within the biopharmaceutical industry would devote to a product of similar risk profile and profit potential, [\*\*\*]. Without limiting the foregoing, in relation to Development activities, including for purposes of obtaining Regulatory Approval of a product, Diligent Efforts require that such Party: (i) assign responsibility for the relevant activities to specific employees who are responsible for progress and monitor such progress on a regular basis; (ii) set and consistently seek to achieve specific and meaningful objectives and timelines for carrying out such activities; and (iii) consistently make and implement decisions and allocate resources consistent with the efforts described above. Without limiting the foregoing, in relation to Commercialization activities, Diligent Efforts shall be determined on a country-by-country basis.

**“Dispute”** has the meaning set forth in Section 14.1.

**“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 10.3.1.

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

**“Exploit”** shall mean to make, have made, import, use, sell or offer for sale, including to Develop, Commercialize, Manufacture and have Manufactured.

**“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, as applicable (i) in relation to the IBD Products, the IBD Field, (ii) in relation to the C Difficile Products, the C Difficile Field, and (iii) in relation to any Additional Collaboration Product, such field as is mutually agreed by the Parties in writing as provided in Section 4.3 and, solely with respect to any Additional Collaboration Product, any other indication for which such Additional Collaboration Product may be Developed pursuant to this Agreement, subject to and in accordance with Section 4.5 or by mutual agreement of the Parties.

“**First C Difficile Product**” means the Collaboration Product currently being Developed by Series and identified as SER-109, as further described on Exhibit A.

“**First Commercial Sale**” means, with respect to any Collaboration Product in a particular country and a particular Field, the first commercial sale, transfer or other disposition by the applicable Party or an Affiliate or sublicensee in such country of such Collaboration Product in such Field following the receipt of the requisite Product Approval for such Collaboration Product in such country in exchange for cash or some other consideration.

“**First IBD Product**” means (i) the Collaboration Product candidate currently being Developed by Series and identified as SER-287, as further described on Exhibit C, or (ii) such other Collaboration Product candidate that the Parties agree in writing shall be substituted for such Collaboration Product described in clause (i), other than the Second IBD Product.

“**FTE Costs**” of an activity within a period of time means the number of hours actually spent directly and specifically 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) any person’s hours to the extent the person works a number of hours that, when annualized, is more than [\*\*\*] (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 [\*\*\*], subject to [\*\*\*].

“**Generic Product**” means any version of a Collaboration Product that is approved through an abbreviated application referencing the applications for approval of such Collaboration Product and Commercialized by a Third Party in the Field that is not a licensee or sublicensee of NHSc, or its Affiliates or sublicensees.

“**Global Development Plan**” means a comprehensive, multi-year plan specifying the details of all clinical and non-clinical Development activities (and corresponding Development Budget) planned to be undertaken for the Collaboration Products to be Developed hereunder in connection with obtaining Regulatory Approvals for such Collaboration Products in the United States and the European Union, as amended or otherwise modified in accordance with this Agreement. The initial version of the Global Development Plan will contain the elements attached as Exhibit E hereto, and will be completed and updated as provided in Section 4.2.1.

“**Global Registration Dossier**” means, in respect of a particular Collaboration Product, a core set of regulatory documents to be included in the BLA for Collaboration Product in the Field in the Territory and the Retained Territory, as defined by the JSC.

**“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 or the Retained 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 or the Retained 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.

**“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).

**“IBD Field”** means (i) the treatment or management of Inflammatory Bowel Disease, defined specifically as UC and Crohn’s, as well as (ii) any other indications for which any IBD Product may be Developed pursuant to this Agreement by mutual agreement of the Parties; provided that such other indication(s) shall only be included in the IBD Field for the specific IBD Product that the Parties agree to Develop for such other indication, but in each of (i) and (ii), excluding any application that is solely diagnostic or monitoring in nature.

**“IBD Product”** means the First IBD Product and the Second IBD Product and any Additional Collaboration Products Developed for the treatment or management of Inflammatory Bowel Disease as provided in Section 4.3, including UC and Crohn’s, but excluding any application that is solely diagnostic or monitoring in nature.

**“IBD Royalty Period”** means the period beginning with the First Commercial Sale of an IBD Product in the IBD Field in the Territory and ending, on the later to occur of (i) [\*\*\*] anniversary of the date of such First Commercial Sale of such Collaboration Product, and (ii) January 1st of the Calendar Year during the Term following any Calendar Year in which Net Sales of the IBD Products in the IBD Field in the Territory are below [\*\*\*]. For the sake of clarity, if Net Sales of IBD Products for the final Calendar Year ending prior to such [\*\*\*] anniversary are less than [\*\*\*], then the IBD Royalty Period shall end on such [\*\*\*] anniversary.

“**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.

“**IFRS**” means the current International Financial Reporting Standards, as published by the International Accounting Standards Board.

“**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 12.3.1.

“**Indemnifying Party**” has the meaning set forth in Section 12.3.1.

“**Induction**” means, with respect to IBD Products, that such IBD Product is being Developed to induce remission of Crohn’s or UC.

“**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 Development, Manufacture or Commercialization of Collaboration Products in the Field pursuant to this Agreement.

“**Joint Intellectual Property Rights**” has the meaning set forth in Section 10.1.2.

“**Joint Invention**” means any Invention that is jointly invented (as determined in accordance with United States patent Laws governing inventorship) by (i) one or more employees, consultants or contractors of Seres or its Affiliates, and (ii) one or more employees, consultants or contractors of NHSc or its Affiliates.

“**Joint Know-How**” has the meaning set forth in Section 10.1.2.

“**Joint Patents**” means any and all Patents based upon or otherwise arising from patent applications filed during or after the Term to claim one or more Joint Inventions.

“**Joint Steering Committee**” or “**JSC**” means the Joint Steering Committee to be established by Seres and NHSc in accordance with 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.

“**Licensed 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 Exploitation of Licensed Products in the Field.

“**Licensed Patents**” means all 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, and (ii) either (a) claim or cover any Licensed Product or the Exploitation thereof in the Field, or (b) claim or cover inventions, the practice of which are otherwise necessary or reasonably useful for the Exploitation of Licensed Products in the Field. Licensed Patents shall include the Patents listed in Exhibit F hereto.

“**Licensed Products**” means any and all therapeutic products or therapeutic product candidates, that are clinically Developed, approved or Commercialized for either (i) the treatment of a *C. difficile* infection or the prevention of a [\*\*\*] *C. difficile* infection and associated complications, or (ii) the treatment or management of Inflammatory Bowel Disease, defined specifically as Crohn’s and UC, in each of (i) and (ii) the Exploitation of which utilizes or utilized, or is or was covered by, the Microbiome Technology. For the sake of clarity, the Licensed Products include the Collaboration Products.

“**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.

“**Maintenance**” means, with respect to IBD Products, treatments designed to maintain remission of Crohn’s or UC.

“**Major Milestone Countries**” means, collectively, [\*\*\*] and “**Major Milestone Country**” means any of the foregoing.

**“Manufacture”** and **“Manufacturing”** means all activities related to the production, manufacture, processing, formulation, filling, finishing, packaging, labeling, shipping and holding of a product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control.

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

**“Microbiome Technology”** means all Information, whether or not patented or patentable, Controlled by Seres and its Affiliates as of the date hereof and from time to time during the Term, comprising or relating to the use of [\*\*\*], in any formulation or composition, for (a) [\*\*\*], (b) [\*\*\*], and/or (c) [\*\*\*], as well as methods for, and compositions for use in, manufacturing any of the foregoing compositions, but excluding [\*\*\*].

**“Milestone Event”** means an event or occurrence described under the heading “Milestone Event” in Section 8.2.1, Section 8.3.1, Section 8.3.2 or Section 8.4.

**“Milestone License Payment”** means an amount identified under the heading “Milestone License Payment” in Section 8.2.1, Section 8.3.1, Section 8.3.2 or Section 8.4 to be paid upon the occurrence of the Milestone Event corresponding thereto.

**“Net Sales”** means the gross amounts invoiced [\*\*\*] by NHSc, its Affiliates or NHSc’s sublicensees for sales of Collaboration Products to Third Party purchasers of such Collaboration Products, less the following deductions with respect to such sales to the extent that such amounts are either included in the billing as a line item as part of the gross amount invoiced, or otherwise documented to be specifically attributable to actual sales of such Collaboration Products:

- (a) trade discounts, including trade, cash and quantity discounts or rebates, credits or refunds (including inventory management fees, discounts or credits);
- (b) allowances or credits actually granted upon claims, returns or rejections of Collaboration Products, including recalls, regardless of the Party requesting such recall;
- (c) [\*\*\*]; provided that the amount of any [\*\*\*] deducted pursuant to this exception and actually collected in a subsequent Calendar Quarter shall be included in Net Sales for such subsequent Calendar Quarter;
- (d) charges included in the gross sales price for freight, insurance, transportation, postage, handling and any other charges directly relating to the sale, transportation, delivery or return of such Collaboration Product;

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

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

All of the foregoing deductions from the gross invoiced sales prices of Collaboration Products will be determined in accordance with IFRS or GAAP, or such other accounting standard utilized by NHSc or its Affiliate or sublicensee, as consistently applied by NHSc or its Affiliate or sublicensee, as applicable, with respect to external reporting. In the event that NHSc, its Affiliates or any of its sublicensees makes any adjustments to such deductions after the associated Net Sales have been reported pursuant to this Agreement, the adjustments will be reported and reconciled in the next report and payment of any royalties due.

For clarification, sale of Collaboration Products by NHSc, its Affiliates or any of its sublicensees to another of such Persons for resale by such entity to a Third Party shall not be deemed a sale for purposes of this definition of “Net Sales” unless such Person is the end customer of the Collaboration Product sold. Further, use, supply or donation of Collaboration Products by NHSc, its Affiliates or any of its sublicensees for no profit [\*\*\*] shall not, in each case, be deemed sales of such Collaboration Products for purposes of this definition of “Net Sales.”

“**NHSc Election Notice**” has the meaning set forth in Section 13.5.

“**NHSc Expenses**” has the meaning set forth in Section 10.6.

“**Non-Enforcing Party**” has the meaning set forth in Section 10.3.1.

“**Notice of Dispute**” has the meaning set forth in Section 14.1.

“**Other Product**” has the meaning set forth in the definition of “Combination Product”.

“**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 extensions or restorations by existing or future extension or restoration mechanisms, including 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) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

“**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.

“**Phase I Clinical Trial**” means a Clinical Trial that provides for the first introduction into humans of a product with the primary purpose of determining safety, metabolism and pharmacokinetic properties and clinical pharmacology of such product, in a manner that is generally consistent with 21 C.F.R. § 312.21(a), as amended (or its successor regulation).

“**Phase II Clinical Trial**” means a Clinical Trial, the principal purpose of which is to make a preliminary determination as to whether a product is safe for its intended use and to obtain sufficient information about such product’s efficacy, in a manner that is generally consistent with 21 C.F.R. § 312.21(b), as amended (or its successor regulation), to permit the design of further Clinical Trials.

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

“**Pricing Approval**” means the governmental approval, agreement, determination or decision establishing prices for a Collaboration 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.

“[\*\*\*]” means, with respect to C Difficile Products, that such C Difficile Product is being Developed in connection with an episode of *C. difficile* infection in a patient who has [\*\*\*], with the goal of preventing a [\*\*\*] *C. difficile* infection.

“**Prior CDA**” has the meaning set forth in Section 15.11.

“**Product Approval**” means, with respect to a particular Collaboration Product in a given country in the Territory, the grant or issuance of all Regulatory Approvals and Pricing Approvals necessary to import, distribute, market, promote, offer for sale and sell such Collaboration Product in such country in accordance with applicable Laws and in a commercially reasonable fashion.

“**Product Literature**” means, with respect to a given country, any promotional, medical, informative and other information intended for distribution or use by sales representatives in connection with the detailing and promotion of Collaboration Products in such country (whether in the form of written, printed, graphic, electronic, audio or video materials), and shall include, without limitation, all related sales representative training materials.

“**Promotional Materials**” means any and all promotional, advertising, communication and educational materials relating to Collaboration Products which are developed by or on behalf

of the Parties for use in connection with the marketing, promotion and sale of any Collaboration Product, and shall include, without limitation, Product Literature, journal advertisements, sales aids, formulary binders, publication reprints, direct mail, direct-to-consumer advertising, Internet postings, broadcast advertisements and sales reminder aids.

**“Prosecuting Party”** has the meaning set forth in Section 10.2.2(b).

**“[\*\*\*]”** means, with respect to [\*\*\*], that such [\*\*\*] is being Developed to treat [\*\*\*] in a patient who has [\*\*\*] within [\*\*\*].

**“Regional Development Plan”** a comprehensive, multi-year plan specifying the details of any clinical and non-clinical Development activities planned to be undertaken for the Collaboration Products in connection with obtaining and maintaining Regulatory Approvals for such Collaboration Products in countries in the Territory outside the EU, as amended or otherwise modified from time to time in accordance with this Agreement.

**“Regulatory Approval”** means, with respect to any Collaboration 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 the Collaboration 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 Documentation”** means all (i) Regulatory Filings and other registrations, licenses, authorizations, and approvals of or with Regulatory Authorities (including Regulatory Approvals); (ii) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files; and (iii) clinical and other data contained or relied upon in any of the foregoing, in each case ((i), (ii), and (iii)) relating to the Development, Manufacture, or Commercialization of a Collaboration Product in a particular country or jurisdiction.

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

**“Retained Territory”** means the United States and Canada, and their territories and possessions.



**“Royalty Period”** means, collectively or individually, as the context requires, the IBD Royalty Period, the C Difficile Royalty Period and any other royalty period agreed upon by the Parties in writing with respect to an Additional Collaboration Product.

**“Rules”** has the meaning set forth in Section 14.3.

**“Second C Difficile Product”** means (i) the Collaboration Product currently being Developed by Series and identified as SER-262, as further described on Exhibit B, or (ii) such other Collaboration Product that the Parties agree in writing shall be substituted for such Collaboration Product described in clause (i) as set forth in Section 4.3, other than the First C Difficile Product.

**“Second IBD Product”** means (i) the Collaboration Product currently being Developed by Series and identified as SER-301, as further described on Exhibit D, or (ii) such other Collaboration Product that the Parties agree in writing shall be substituted for such Collaboration Product described in clause (i) as set forth in Section 4.3, other than the First IBD Product.

**“Senior Officers”** has the meaning set forth in Section 14.1.

**“Shared Development Costs”** means any and all Development Costs that are to be shared by the Parties in accordance with Section 4.8.

**“Term”** has the meaning set forth in Section 13.1.

**“Territory”** means the entire world, excluding the Retained Territory.

**“Third Party”** means any entity other than NHSc, Seres and their respective Affiliates.

**“Third Party Claims”** has the meaning set forth in Section 12.3.1.

**“Trademark”** means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo or business symbol, whether or not registered.

**“Trademark License Agreement”** has the meaning set forth in Section 2.6.

**“Transition Working Group”** and **“TWG”** have the meaning set forth in Section 13.5.4.

**“[\*\*\*]”** has the meaning set forth in Section 4.1.2.

**“UC”** means ulcerative colitis.

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

**ARTICLE 2**  
**GRANT OF LICENSE AND RIGHTS**

2.1 Licenses Granted.

2.1.1 Exclusive License to NHSc. Subject to the terms and conditions of this Agreement, including without limitation Section 2.1.4 hereof, Seres hereby grants to NHSc, and NHSc accepts, an exclusive (including as to Seres and its Affiliates), perpetual, royalty-bearing license, with the right to grant sublicenses (through multiple tiers of sublicensees), under the Licensed Patents and the Licensed Know-How, to use, register, sell, offer for sale, import, export, Develop and Commercialize (i) Licensed Products in the Field in the Territory and (ii) Collaboration Products in any field or indication in the Territory, except, in each case, that Seres retains the right to Develop and Manufacture, itself or through Third Parties, Licensed Products in the Field in the Territory solely for Commercialization in the Retained Territory and to perform its obligations under this Agreement, the Development Supply Agreement and the Commercial Supply Agreement. For clarity, subject to the final sentence of Section 2.1.4, Seres retains all rights not expressly licensed to NHSc pursuant to this Agreement, including without limitation the right to grant licenses under the Licensed Patents to Third Parties outside the Field for products other than Collaboration Products.

2.1.2 Non-Exclusive License to NHSc. Subject to the terms and conditions of this Agreement, including Section 2.1.4 hereof, Seres hereby grants to NHSc, and NHSc accepts, a non-exclusive, perpetual license, with the right to grant sublicenses (through multiple tiers of sublicensees), under the Licensed Patents and the Licensed Know-How, to export and Develop Collaboration Products in the Field in the Retained Territory, and to make and have made Collaboration Products in the Field anywhere in the world, in each case solely for Commercialization in the Territory.

2.1.3 Sublicensing by NHSc. NHSc shall have the right to grant sublicenses of the rights granted to it by Seres under Sections 2.1.1 and 2.1.2 to [\*\*\*]; provided, however, that NHSc shall ensure that the terms of any sublicense granted pursuant to this Section 2.1.3 are not inconsistent with the terms and conditions of this Agreement. NHSc 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 sublicenses.

2.1.4 Certain Limitations. Anything to the contrary notwithstanding, but without limiting the exclusive nature of the license contemplated in Section 2.1.1, [\*\*\*]. Seres shall not, and shall not permit any of its Affiliates or any Third Party licensee or sublicensee of Seres or its Affiliates to, clinically Develop or Commercialize in the Territory any Microbiome Products for use in either subsection (i) of the C Difficile Field or subsection (i) of the IBD Field, outside the scope of this Agreement.

2.1.5 License to Seres. Subject to the terms and conditions of this Agreement, NHSc hereby grants to Seres, and Seres accepts, [\*\*\*] license, [\*\*\*] under [\*\*\*] Controlled by NHSc that claim or cover [\*\*\*], that absent the license granted in this Section 2.1.5, would be infringed by the sale of any Collaboration Products in the Field in any country in the Retained

Territory, to make, have made, use, import, sell and offer for sale and otherwise Develop and Commercialize Collaboration Products in the Field in the Retained Territory, and to make, have made, export, Develop and Manufacture Collaboration Products in the Field in the Territory, solely for Commercialization in the Retained Territory and to perform its obligations under this Agreement, the Development Supply Agreement and the Commercial Supply Agreement.

2.1.6 Sublicensing by Seres. Seres shall have the right to grant sublicenses of the rights granted to it by Seres under Sections 2.1.5 to its Affiliates and to Third Parties; provided, however, that Seres shall ensure that the terms of any sublicense granted pursuant to this Section 2.1.6 are not inconsistent 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 sublicenses.

2.2 [\*\*\*]. NHSc [\*\*\*] that neither NHSc nor its Affiliates, licensees or sublicensees shall [\*\*\*] or the performance of Seres' obligations under this Agreement, the Development Supply Agreement and the Commercial Supply Agreement. Upon any termination of this Agreement, the foregoing [\*\*\*] shall survive such termination and shall be expanded to include all Exploitation of Collaboration Products in the Field in the Territory.

2.3 Right of Reference. Each Party shall have the right to (i) cross-reference the other Party's and such other Party's Affiliates' and licensees' Regulatory Approvals and Regulatory Documentation related to Collaboration Products, (ii) access such Regulatory Approvals and Regulatory Documentation and any Information therein, and (iii) use such Information, in each case in connection with the performance of its obligations and exercise of its rights under this Agreement. Each Party hereby grants to the other Party a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) in the United States, or an equivalent right of access/reference in any other jurisdiction, to any data, including any Party's and such Party's Affiliates' Regulatory Approvals and Regulatory Documentation, that relate to a Collaboration Product for use by the other Party to Develop Collaboration Products for Commercialization in the Territory or the Retained Territory, as applicable, pursuant to this Agreement. Each Party shall, or shall cause its Affiliates to, provide a signed statement to this effect, if requested by the other Party, in accordance with 21 C.F.R. § 314.50(g)(3) or the equivalent as required in any other jurisdiction or otherwise provide appropriate notification of such right to the applicable Regulatory Authority.

2.4 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.

2.5 Transfer of Know-How. [\*\*\*], Seres shall provide NHSc with copies of and/or reasonable access to all existing material Licensed Know-How with respect to the Collaboration Products and their use in the Field that is reasonably required by or useful to NHSc for the Development and Commercialization of Collaboration Products in the Field and in the Territory under this Agreement, except to the extent that such Licensed Know-How has previously been provided to NHSc and except to the extent such Licensed Know-How is specific to the Manufacture of the Collaboration Products. Such Licensed Know-How may be provided and/or

made accessible to NHSc 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, Seres will provide NHSc with copies of or reasonable access to any additional material Licensed Know-How obtained or generated by or on behalf of Seres or its Affiliates with respect to the Collaboration Products and/or their use in the Field that is required by or reasonably useful to NHSc for the Development or Commercialization of Collaboration Products in the Field and in the Territory under this Agreement.

2.6 Trademark License Agreement. [\*\*\*], the Parties shall enter into a Trademark License Agreement (such agreement, as amended from time to time, the “**Trademark License Agreement**”), pursuant to which, among other things, Seres shall grant NHSc and its Affiliates an exclusive, perpetual, fully paid-up, royalty-free license to use in the Territory, in connection with the Commercialization of Collaboration Products, such Trademarks, Product Literature and Promotional Materials that have been used, or are contemplated to be used, by Seres or its Affiliates in connection with the Commercialization of Collaboration Products in the Retained Territory from time to time.

### ARTICLE 3 GOVERNANCE OF THE COLLABORATION

3.1 Formation and Composition of the Joint Steering Committee. [\*\*\*], NHSc 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) senior-level representatives of each Party and 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 Development of the Collaboration Products. This will include responsibility for:

- (a) strategic oversight of the Development of Collaboration Products for the Field, including approval of a global regulatory strategy for Collaboration Products in the Field;
- (b) approval of all Development Plans (and the related Development Budgets) for Collaboration Products, and any material amendments to such plans, including agreeing at the appropriate time on the respective target product profiles for the various Collaboration Products as part of the Global Development Plan;
- (c) monitoring and coordinating the Parties’ performance of Development Plans;

(d) approval of any proposed increase of a previously agreed Development Budget by an amount greater than [\*\*\*]; and

(e) monitoring the status of and coordinating Manufacturing of Collaboration Products for Development and Commercialization purposes;

(f) review and approval of protocols for all pre-clinical studies and Clinical Trials and any post-marketing clinical studies, risk evaluation and mitigation strategies (“REMS”) or other post-marketing commitments or requirements imposed by Regulatory Authorities involving Collaboration Products in the Field to be undertaken by or on behalf of the Parties;

(g) periodic review of the results arising from Development of Collaboration Products in the Field;

(h) monitoring and coordinating the performance by each Party of the regulatory activities in respect of the Collaboration Products in the Field for which it is responsible;

(i) establishment of the contents of the Global Registration Dossier to be used by the Parties to prepare BLAs for the Collaboration Products in the Field in the Territory and the Retained Territory, and allocation of responsibility between the Parties for completing each section of such Global Registration Dossier;

(j) review of Regulatory Filings for Collaboration Products in the Field prior to their submission to Regulatory Authorities; and

(k) facilitating the exchange between the Parties of data and information regarding Development and regulatory activities for Collaboration Products.

3.3 Meetings of JSC. The JSC will meet at least [\*\*\*], or more frequently, as agreed by the JSC. 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 [\*\*\*] 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, and who have relevant expertise, to attend JSC meetings when appropriate for the issues being addressed at the meeting with [\*\*\*] 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 NHSc shall be entitled to [\*\*\*] on all matters coming before the JSC or any subcommittee or subgroup thereof. If the JSC is incapable of reaching [\*\*\*], such matter shall be resolved in accordance with Section 14.1 and/or Section 14.2.

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. 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.

3.7 JSC Membership Following Development. Notwithstanding anything to the contrary herein, following the completion of the Development of all Collaboration Products and the completion of all activities set out in any then current Development Plan, each Party shall have the right, but not the obligation, to terminate its membership in and cause the dissolution of the JSC in accordance with this Section 3.7. If either Party exercises its right to withdraw from membership in, and cause the dissolution of, the JSC in accordance with the foregoing, it shall provide the other Party with thirty (30) days' prior written notice, and such withdrawal and dissolution shall be effective upon the expiration of such thirty (30) day period. Following the dissolution of the JSC in accordance with this Section 3.7, (i) each Party shall have the right to continue to receive the information it would otherwise be entitled to receive under this Agreement and (ii) any matter that this Agreement contemplates will be determined by the JSC will be made by the mutual written agreement of the Parties, unless a Party has the right to decide such matter pursuant to Section 14.2, in which case the Parties shall discuss such matter, but such decision shall ultimately be made by such Party having such right pursuant to Section 14.2.

#### **ARTICLE 4 DEVELOPMENT AND REGULATORY MATTERS**

##### 4.1 Commitment to Develop Collaboration Products.

4.1.1 Subject to the terms and conditions of this Agreement, Seres will use Diligent Efforts to (i) Develop each Collaboration Product contemplated in the Global Development Plan from time to time in the Field and (ii) obtain approval of a BLA for each such Collaboration Product in the European Union. Subject to and in accordance with the terms, conditions and limitations of this Agreement and the Global Development Plans, and to Seres' performance of its obligations under this Agreement that relate to Development of the Collaboration Products and obtaining Regulatory Approval for the Collaboration Products in the

EU, NHSc will use Diligent Efforts to (x) conduct Development activities allocated to NHSc for each Collaboration Product with respect to the EU, as contemplated in the Global Development Plan in the Field, and (y) make such applications and filings as are necessary to obtain Regulatory Approval in the EU for each Collaboration Product in the Field [\*\*\*].

4.1.2 Without limiting NHSc's obligations under Section 4.1.1, with respect to each of the Second C Difficile Product and the Second IBD Product and any Additional Collaboration Product [\*\*\*], no later than the date that is [\*\*\*], NHSc shall notify Seres in writing whether or not it wishes to retain rights to such Collaboration Product in any or all of [\*\*\*] (each, a "**Decision Country**"). If NHSc notifies Seres that it does not wish to retain rights to the applicable Collaboration Product in a particular Decision Country, Section 4.1.3 will apply with respect to such Collaboration Product in such Decision Country. For each Decision Country for which NHSc notifies Seres that it does wish to retain rights, then NHSc shall either (a) submit a Regional Development Plan covering such Collaboration Product in such Decision Country to the JSC for consideration as soon as practicable but in no event later than the [\*\*\*] anniversary of [\*\*\*], and shall thereafter use Diligent Efforts to conduct the Development activities allocated to NHSc under the Regional Development for such Collaboration Product in such Decision Country and use Diligent Efforts to achieve First Commercial Sale of such Collaboration Product [\*\*\*] or (b) notify the JSC that NHSc wishes to delay using Diligent Efforts, as contemplated in the preceding clause (a), and the reasons therefor; provided, however, that if Seres does not agree that such delay, or a different commitment on NHSc's part, is warranted in respect of such Collaboration Product in such Decision Country for legitimate business, legal or technical reasons, then clause (a) of this Section 4.1.2 shall apply with respect to such Collaboration Product in such Decision Country. Without limitation, to the extent that clause (a) applies with respect to a particular Collaboration Product in a particular Decision Country, such obligation to use Diligent Efforts may be performed through NHSc's sublicensees or distributors, and shall be deemed satisfied if, prior [\*\*\*], the First Commercial Sale of such Collaboration Product occurs in such Decision Country. Anything to the contrary notwithstanding, [\*\*\*].

4.1.3 If NHSc notifies Seres that it does not intend to pursue Commercialization of any Collaboration Product in any Decision Country, Seres may elect, [\*\*\*], to notify NHSc in writing that it wishes to take control of Exploitation of such Collaboration Product in such Decision Country, in which event, the following shall apply:

(a) The Territory, solely with respect to such Collaboration Product, shall cease to include such Decision Country and the Retained Territory shall thereupon include such Decision Country solely with respect to such Collaboration Product;

(b) In the event that NHSc has commenced any Development activities solely in respect of such Collaboration Product and such Decision Country, it shall use Diligent Efforts to transition such Development activities to Seres or its designee as soon as practicable and in a manner determined by the JSC;

(c) In the event that NHSc has theretofore made any Regulatory Filings in respect to of such Collaboration Product in such Decision Country, it shall transfer such Regulatory Filings to Seres or its designee as soon as practicable; and

(d) Seres shall pay NHSc a royalty of [\*\*\*] of all Net Sales of such Collaboration Product in such Decision Country and Sections 8.7, 8.8, 8.9, 8.10, 8.11 and 8.12 shall apply to Seres with respect to such royalties owing by Seres, *mutatis mutandis*, except that all references in the definition of Net Sales to NHSc shall be deemed to refer to Seres and only to Net Sales in such Decision Country.

4.1.4 Anything to the contrary notwithstanding, if NHSc, in accordance with Section 4.1.2, does not elect to retain rights to the relevant Collaboration Product in a particular Decision Country and Seres elects to have such rights revert to Seres in accordance with Section 4.1.3, NHSc's obligations under Section 4.1 shall terminate with respect to such Collaboration Product in such Decision Country. [\*\*\*]. Anything to the contrary notwithstanding, in no event will [\*\*\*].

#### 4.2 Development Plans.

4.2.1 Global Development Plan. The initial Global Development Plan will include the elements attached hereto as Exhibit E. Within [\*\*\*] after the Effective Date, the Parties, working through the JSC will agree upon a complete Global Development Plan. The JSC will review and update the Global Development Plan on an annual basis. [\*\*\*] may propose amendments or modifications to the Global Development Plan for consideration and approval by the JSC from time to time.

4.2.2 Regional Development Plans. In the event that NHSc elects, in its sole discretion to undertake any Development activities with respect to Collaboration Products in respect of the Territory that are outside the scope of the Global Development Plan, it shall prepare one or more Regional Development Plans and submit the same to the JSC for review and approval. [\*\*\*] may propose amendments or modifications to such Regional Development Plan(s) for consideration and approval by the JSC from time to time.

4.2.3 Content of Development Plans. Each JSC approved Development Plan will clearly identify the Collaboration Products covered thereby (including any required or anticipated label elements) and shall typically include, to the extent available, details of: [\*\*\*]. All Development Plans will also include clearly indicate which Party will be responsible for performing each Development activity set forth therein, and shall also include, respectively, the corresponding Development Budget.

4.3 Additional Collaboration Products. As of the Effective Date of this Agreement, the Collaboration Products to be Developed pursuant to this Agreement and the Global Development Plan include the First IBD Product, the Second IBD Product, the First C Difficile Product and the Second C Difficile Product. From time to time during the Term, the Parties may mutually agree to pursue the Development in the Field of one or more other products based on Microbiome Technology in lieu of or in addition to the then-existing Collaboration Products. Any such other Collaboration Product is referred to herein as an "**Additional Collaboration Product**". Any such agreement with respect to an Additional Collaboration Product shall be set forth in writing and signed by both the Parties. In connection with the Parties' agreement to pursue Development of an Additional Collaboration Product, the Parties will agree on, among other things [\*\*\*]. In addition, except upon the mutual written agreement of the Parties, the



Global Development Plan shall not be modified so as to remove any Collaboration Product from the scope thereof or to provide for the abandonment of Development of any Collaboration Product.

4.4 Responsibility for Development Work. Subject to Section 4.8 and except as may otherwise be specified in the applicable Development Plan or separately agreed in writing by the Parties, (i) Seres shall be responsible for the performance of all Development activities contemplated in the Global Development Plan, and for any other Development activities conducted solely with respect to the Retained Territory, [\*\*\*] for Collaboration Products in the Field, and (ii) NHSc shall be responsible for the performance of all Development activities contemplated in any Regional Development Plan. All material Development activities in subsections (i) and (ii) shall be discussed and approved by the JSC, and responsibility for performance of any other Development activities to be undertaken during the Term for the Collaboration Products in the Field shall be allocated between the Parties as set forth, as applicable, in the relevant JSC-approved Development Plan. Either Party may request that [the other Party provide assistance in certain aspects of Development activities for which it is otherwise responsible under subsections (i) and (ii). When making such request, the requesting Party shall provide to the other Party information reasonably necessary for such other Party to evaluate such request]. Such other Party shall reasonably consider and discuss with the requesting Party the nature and scope of such activities and shall respond to any such request within ten (10) Business Days follow such request. Each Party shall perform the Development activities for which it is responsible in compliance with: (A) the terms of this Agreement, (B) the relevant Development Plan, and (C) all applicable Laws, including without limitation [\*\*\*].

4.5 Additional Development.

(a) If (i) NHSc wishes to [\*\*\*], or (ii) Seres wishes to [\*\*\*] (any of the foregoing contemplated in clause (i) or (ii), an “**Additional Development**”), then such Party may so notify the other Party and present the proposed design and projected costs of such Additional Development to the JSC. If the other Party through its members of the JSC agrees to conduct such co-development and co-fund such Additional Development, the Parties would amend the Global Development Plan to include such Additional Development and the associated costs would be included in Development Costs and shared by the Parties subject to and in accordance with Section 4.8, in which case all resulting data would be available for use by NHSc in connection with exercising its rights under this Agreement with respect to the Collaboration Products in the Field and in the Territory and for use by Seres in the Retained Territory in connection with the Collaboration Product.

(b) If the non-proposing Party does not wish to co-fund such proposed Additional Development, [\*\*\*], the proposing Party may proceed with such Additional Development outside of the Global Development Plan (but if NHSc is the proposing Party, such Additional Development would be conducted pursuant to a Regional Development Plan approved by the JSC) and would be solely responsible for the conduct and costs of such study. In such case, [\*\*\*] would have [\*\*\*], except with respect to [\*\*\*] required to be filed with the [\*\*\*] as set forth below, in any filings with [\*\*\*] in its territory (for NHSc, in the Territory and for Seres, in the Retained Territory).

Notwithstanding the foregoing, [\*\*\*] right to conduct any proposed Clinical Trial as part of any Additional Development that is not required to obtain initial Regulatory Approval of a Product in the Field and in the Territory unilaterally would not apply until [\*\*\*].

(c) Notwithstanding the foregoing, if the non-proposing Party [\*\*\*], such non-proposing Party would have the right to refer such matter to [\*\*\*] for resolution of whether such proposed Additional Development would have the effect that is concerning the non-proposing Party. If the matter is not resolved by [\*\*\*], it shall be submitted for discussion and resolution in accordance with Article 14.

(d) [\*\*\*] right to conduct unilaterally an Additional Development as described above would not include the right to conduct such study in [\*\*\*]. [\*\*\*] right to conduct unilaterally an Additional Development would not include the right to conduct such study [\*\*\*].

(e) Notwithstanding the foregoing, the non-proposing Party would have the right to “**Buy In**” to co-fund any Additional Development for the Collaboration Product for which the non-proposing Party declined previously to co-fund by (i) reimbursing the proposing Party an amount equal to the Relevant Percentage of the costs the proposing Party incurred to conduct such Additional Development prior to the Buy In, plus a premium of [\*\*\*] of such amount; and (ii) sharing the Relevant Percentage of all costs incurred by the proposing Party to conduct such Additional Development after such Buy In, to the extent applicable. The “**Relevant Percentage**” for NHSc as the non-proposing Party is [\*\*\*] and the “**Relevant Percentage**” for Seres as the non-proposing Party is [\*\*\*].

4.6 Development Reports. Each Party will keep the other Party reasonably informed with respect to the progress and results of the various Development activities for which it is responsible, including without limitation by providing regular updates at each meeting of the JSC. In addition, the JSC will compile written [\*\*\*] Development reports within [\*\*\*] following the end of the [\*\*\*] presenting a meaningful summary of progress against each Development Plan and activities accomplished by the Parties in relation thereto through the end of such [\*\*\*] period, which summary will include, to the extent applicable, a summary of significant results, adverse event reports, information and data generated, Manufacturing developments, significant challenges anticipated and updates regarding significant intellectual property and supply chain matters, with respect to each Collaboration Product in the Field. The Parties will agree on an appropriate format for such [\*\*\*] reports, which may consist of a compilation of separate subject matter reports (or excerpts therefrom) that are generated in the ordinary course by or on behalf of the Party responsible for the relevant Development activities.

4.7 Development Records. Each Party shall maintain, and require its Affiliates and Third Party subcontractors to maintain, complete and accurate records of (i) all work conducted by it or on its behalf in furtherance of the Development of the Collaboration Products in the Field, and (ii) all results, data, Inventions and other developments generated in connection with conducting such activities. Such records shall be complete and accurate and shall fully and properly reflect all such work done and results achieved in sufficient detail and in good scientific manner appropriate for business, patent and regulatory purposes. Such records shall be

Confidential Information of the applicable Party and shall be maintained and treated as such in accordance with the terms of Article 11.

4.8 Development Costs. The Parties agree to share certain Development Costs incurred by or on behalf of the Parties during the Term in respect of Clinical Trials, as provided in this Section 4.8. [\*\*\*]. Shared Development Costs shall include only those Development Costs incurred in accordance with [\*\*\*], including [\*\*\*] contained therein. For clarity, Shared Development Costs are specifically limited to [\*\*\*], not to exceed [\*\*\*] for any one Collaboration Product. Each Party shall promptly notify the other Party in writing in the event it determines that the Shared Development Costs for one or more Development activities for which it is responsible are expected to exceed the amounts budgeted in the relevant Development Budget for such activities.

4.8.1 Development Costs for IBD Products in the IBD Field. Subject to Section 4.5, the Parties shall pay and be responsible for Development Costs relating to the Development of Collaboration Products in the IBD Field as follows:

(a) Seres shall pay for all Development Costs for each IBD Product in the IBD Field up to and including the Phase II Clinical Trial for such IBD Product; and

(b) With respect to the Development Costs in respect of Phase III Clinical Trials for IBD Products in the IBD Field, and all Development Costs in respect of any other Clinical Trials of IBD Products for the IBD Field that are set forth in the Global Development Plan, Seres shall pay 67% and NHSc shall pay 33%;

(c) Seres shall pay for all Development Costs associated with conducting activities associated with IBD Products in the IBD Field that are not included in a Development Plan and that are conducted in respect of the Retained Territory; and

(d) NHSc shall pay for all Development Costs associated with conducting activities associated with IBD Products in the IBD Field under any Regional Development Plan, in each case, to the extent not contemplated in clause (a) or clause (b) of this Section 4.8.1.

4.8.2 Development Costs for C Difficile Products in the C Difficile Field. The Parties shall pay and be responsible for Development Costs for C Difficile Products in the C Difficile Field as follows:

(a) Seres shall pay for all Development Costs in respect of the ongoing Phase II Clinical Trial, and, subject to Section 4.5, for any Phase III Clinical Trial set forth in the Global Development Plan, for the First C Difficile Product in the C Difficile Field;

(b) Seres shall pay for all Development Costs in respect of any Phase I Clinical Trial or Phase II Clinical Trial for the Second C Difficile Product or any Additional Collaboration Product in the C Difficile Field;

(c) With respect to the Development Costs in respect of any Phase III Clinical Trials (other than those contemplated by clause (a) or (b) of this Section 4.8.2) for C

Difficile Products in the C Difficile Field set forth in the Global Development Plan, Seres shall pay 67% and NHSc shall pay 33% thereof;

(d) Seres shall pay for all Development Costs associated with conducting activities associated with C Difficile Products in the C Difficile Field that are not included in a Development Plan and that are conducted in the Retained Territory; and

(e) NHSc shall pay for all Development Costs of conducting activities associated with C Difficile Products in the C Difficile Field under any Regional Development Plan, in each case, to the extent not contemplated in clauses (a), (b) or (c) of this Section 4.8.2.

4.8.3 Reporting and Reconciliation of Shared Development Costs. During the Term, each of Seres and NHSc shall generate and maintain accurate and complete books and records of all Shared Development Costs actually incurred by it or its Affiliates in a manner consistent with its internal policies and in sufficient detail to enable the tracking of such Shared Development Costs on a Collaboration Product-by-Collaboration Product and country-by-country basis. Within [\*\*\*] after the end of each Calendar Quarter during the Term, each Party shall submit to the other Party a written report of all Shared Development Costs incurred by or on its behalf during such Calendar Quarter in performance of the specific Development activities for which it was responsible under the Development Plans. As promptly as practicable thereafter, the Parties shall determine, based on such reports, the amount required to be paid by one Party to the other in order to give effect to the allocation of Shared Development Costs set forth in this Section 4.8. Each such reconciliation payment will be due and payable within [\*\*\*] of such notice and shall be made by wire transfer of immediately available funds to such account and in accordance with such instructions as the payee shall specify.

4.8.4 Audit. Each Party shall have the right to examine and audit the other Party's relevant books and records to verify the other Party's Shared Development Costs or costs to be reimbursed to a Party pursuant to Section 4.5 reported hereunder. Any such audit shall be on at least thirty (30) days' prior written notice. A Party's rights to perform an audit under this Section 4.8.4 shall be limited to not more than one (1) such audit in any Calendar Year and shall be limited to the pertinent books and records for any Calendar Year ending not more than thirty-six (36) months before the date of the request. The audit shall be performed at the requesting Party's sole expense by an independent certified public accounting firm of internationally recognized standing that is selected by the auditing Party and reasonably acceptable to the audited Party. The accounting firm may be required to enter into a reasonable and customary confidentiality agreement with the audited Party to protect the confidentiality of its books and records. The Party being audited shall make the relevant books and records reasonably available during normal business hours for examination by the accounting firm. Except as may otherwise be agreed, the accounting firm shall be provided access to such books and records at the audited Party's and/or its Affiliates' 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 its Shared Development Costs or costs to be reimbursed to a Party pursuant to Section 4.5 are correct, and the specific details concerning any discrepancies. The accounting firm shall not provide the requesting Party with any additional information or access to the audited Party's confidential information. If any audit pursuant to this Section 4.8.4

reveals a discrepancy in one or both Parties' Shared Development Costs or costs to be reimbursed to a Party pursuant to Section 4.5 and, on the basis thereof, an additional net amount is owed to a Party based on the provisions of this Section 4.8, such additional amount shall be paid to such Party [\*\*\*] of the date that the Parties receive such accountant's written report. In the event that the total amount of any underpayments by the audited Party to the other Party for the audited period exceeds [\*\*\*] of the aggregate total amount that was properly due and payable to such other Party pursuant to this Section 4.8.4 for the audited period, then the audited Party shall also reimburse such Party for the documented, reasonable out of pocket expenses incurred in conducting the audit, except to the extent that such underpayment was due to any inaccurate or incomplete information provided to the audited Party by such Party. Any audit of NHSc's Shared Development Costs pursuant to this Section 4.8.4 or costs to be reimbursed to NHSc pursuant to Section 4.5 shall be conducted concurrently with any audit conducted by Seres pursuant to Section 8.12.

#### 4.9 Regulatory Matters.

##### 4.9.1 Regulatory Filings and Regulatory Approvals.

(a) In accordance with the Global Development Plan, [Seres] shall be responsible for [\*\*\*].

(b) [\*\*\*] and [\*\*\*] shall have [\*\*\*] for regulatory matters in countries in [\*\*\*], subject to the terms and conditions of this Agreement, (ii) subject to clause (c) below, [\*\*\*] or sublicensees shall own all Regulatory Filings and Regulatory Approvals in respect of [\*\*\*] and [\*\*\*] shall have [\*\*\*] for regulatory matters in countries in [\*\*\*], subject to the terms and conditions of this Agreement.

(c) All Regulatory Filings in the European Union shall [\*\*\*]; provided, however, that until such time as Regulatory Approval for a particular Collaboration Product is received in the European Union, [\*\*\*]. [\*\*\*] shall pay directly or reimburse [\*\*\*].

(d) It is anticipated that, in most cases, BLAs or other similar Regulatory Filings by the Parties to obtain Regulatory Approval for a given indication will be based upon a Global Registration Dossier to be prepared by the Parties and which is generally intended to comply with applicable United States, Canadian and EU Laws. The specific Regulatory Filings to be made in each country or jurisdiction [\*\*\*], as modified and/or supplemented to comply with applicable Laws in such country. Such Party's responsibilities will also include: (i) [\*\*\*]; (ii) [\*\*\*]; and (iii) [\*\*\*]. All such activities shall be undertaken and performed in accordance with the applicable Development Plan and the global regulatory strategy [\*\*\*].

4.9.2 Review and Comment. [\*\*\*] shall serve as a forum to oversee and coordinate the Parties' efforts in preparing and submission of Regulatory Filings for the Collaboration Products, and shall be responsible for review and approval of such Regulatory Filings. The foregoing shall include the allocation of responsibility for preparing the various sections and related supporting documentation for the Global Registration Dossier to be used for

such Regulatory Filings, it being understood that, except as may otherwise be agreed in writing by the Parties, Seres shall be responsible for preparing the CMC sections. Each of Seres and NHSc shall, [\*\*\*]. Anything to the contrary notwithstanding, [\*\*\*].

4.9.3 Data Sharing. Subject to Section 4.5, each Party shall [\*\*\*], relating to or intended to support any Regulatory Filing for the Collaboration Products in the Field. In addition, the Party [\*\*\*] shall provide the other Party with copies of [\*\*\*] with respect to the Collaboration Products. All [\*\*\*] exchanged by the Parties pursuant to this Section 4.9.3 shall be treated by the Parties as Confidential Information in accordance with Article 11.

4.9.4 Communications and Participation in Meetings with Regulatory Authorities. Each Party shall provide the other Party with notice of all [\*\*\*] concerning Regulatory Filings and/or Regulatory Approval relating to Collaboration Products within [\*\*\*] after such Party [\*\*\*]. At all such [\*\*\*], the non-filing Party shall have the right to [\*\*\*] applicable Regulatory Authority. Subject to the foregoing, the filing Party shall [\*\*\*] the relevant Regulatory Authority. However, if attendance [\*\*\*] with a Regulatory Authority is [\*\*\*], attendance shall be based on [\*\*\*] Collaboration Product; provided that each Party shall in any event be entitled to [\*\*\*] at any such [\*\*\*].

4.9.5 Regulatory Expenses. Except as otherwise provided in Section 4.8, [\*\*\*] for all costs and expenses relating to obtaining and maintaining Collaboration Product Approvals [\*\*\*].

4.10 Subcontracting. Either Party may perform any specific activities for which it is responsible in connection with the Development of the Collaboration Products through subcontracting to [\*\*\*]. The subcontracting Party shall: (i) [\*\*\*]; (ii) [\*\*\*]; 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 MANUFACTURE AND SUPPLY

5.1 Responsibility for Manufacturing for Development. Except as may otherwise be agreed in writing by the Parties, Seres and/or its designated Affiliates shall be responsible for Manufacturing or having Manufactured Collaboration Products for Development in the Field. [\*\*\*]. Seres shall perform or cause to be performed all of its and its Affiliates' and subcontractors' obligations under the Development Supply Agreement and the Commercial Supply Agreement in accordance with their respective terms. Seres shall perform its responsibilities under this Section 5.1 [\*\*\*] in accordance with the terms of Sections 5.2 and 5.3.

5.2 Supply of Collaboration Product for Development. Except as may otherwise be agreed by the Parties in writing, Seres shall be responsible for supplying and/or procuring the supply of all of the Parties' respective requirements for Collaboration Products for use in Development of the Collaboration Products the Field in accordance with a development supply agreement to be entered into by the Parties [\*\*\*] after the Effective Date (such agreement, as amended from time to time, the "**Development Supply Agreement**"). [\*\*\*] and shall [\*\*\*] in respect of all such Collaboration Product supplied to NHSc for such purposes, [\*\*\*].

5.3 Commercial Supply. Not later than [\*\*\*], the Parties shall negotiate in good faith the terms of a supply agreement for the commercial supply by Seres of Collaboration Products to NHSc (such agreement, as amended from time to time, the “**Commercial Supply Agreement**”). The Parties shall enter into the Commercial Supply Agreement [\*\*\*]. Such Commercial Supply Agreement will contemplate [\*\*\*].

5.4 Manufacturing Compliance. Each of the Development Supply Agreement and the Commercial Supply Agreement shall require Seres to Manufacture or have Manufactured and supply Collaboration Products for Development or Commercialization, as applicable, in the Field and in the Territory [\*\*\*]. The foregoing shall include without limitation establishing and maintaining proper quality assurance and quality control policies and procedures in connection with such Manufacturing activities. Each of the Development Supply Agreement and the Commercial Supply Agreement shall also require Seres to Manufacture or have Manufactured Collaboration Product using Manufacturing facilities (including those of its Affiliates’ or Third Party contractors) that have been properly validated and comply with GMPs and all applicable Laws, including without limitation, local health, safety and environmental Laws. Each of the Development Supply Agreement and the Commercial Supply Agreement shall require [\*\*\*].

5.5 Technology Transfer. The Commercial Supply Agreement shall provide that if Seres fails to supply all of NHSc’s requirements of Collaboration Products thereunder in any material respect [\*\*\*], Seres shall [\*\*\*] transfer or require its Third Party contractors to transfer (to the extent Seres has the right to do so) all Manufacturing technologies used in the Manufacture of any Collaboration Product in the Field as are reasonably necessary to enable the Third Party Manufacturer to Manufacture Collaboration Products, including providing [\*\*\*]. Such technology transfer may be implemented by means of [\*\*\*]. The Commercial Supply Agreement shall require that [\*\*\*]. Recognizing the importance of [\*\*\*]. The Commercial Supply Agreement shall provide that [\*\*\*].

## ARTICLE 6 COMMERCIALIZATION

6.1 Commercialization Generally. As between the Parties and subject to the terms and conditions of this Agreement (i) NHSc shall be solely responsible for Commercializing the Collaboration Products in the Field in the Territory, either directly or through its Affiliates, sublicensees or distributors, and (ii) Seres shall be solely responsible for Commercializing the Collaboration Products in the Retained Territory, either directly or through its Affiliates, sublicensees or distributors. Each Party shall ensure that all Commercialization activities it undertakes, directly or indirectly, shall be undertaken in accordance with all applicable Laws.

### 6.2 NHSc Diligence Obligation.

6.2.1 NHSc shall use Diligent Efforts to achieve First Commercial Sale of each Collaboration Product in the Field in at least [\*\*\*] Major Milestone Countries in the European Union within [\*\*\*]. In addition, NHSc shall use Diligent Efforts to Commercialize each Collaboration Product in the Field in the European Union following [\*\*\*].

6.2.2 Unless rights to a particular Collaboration Product in the Field in a particular Decision Country have reverted to Seres in accordance with Section 4.1.3, with respect to each Collaboration Product and each Decision Country, NHSc shall use Diligent Efforts to Commercialize such Collaboration Product in the Field in such Decision Country following [\*\*\*].

6.2.3 The Parties recognize that the application of Diligent Efforts could result in the determination that it is not commercially viable or economically feasible to Commercialize a Collaboration Product in a particular country or countries. In addition, [\*\*\*].

6.2.4 Except as set forth in this Section 6.2 and subject to the express terms of this Agreement, any Commercialization of Collaboration Product in the Territory shall be in NHSc's sole and absolute discretion. Without limiting the foregoing, [\*\*\*].

## **ARTICLE 7 COMPLIANCE, PHARMACOVIGILANCE AND OTHER REGULATORY MATTERS**

7.1 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 related to the Development, Manufacture and/or Commercialization of Collaboration Products are performed in accordance with all applicable Laws.

7.2 Debarred Persons. Without limiting Section 7.1, in the course of the Development, Manufacture and Commercialization of a Collaboration Products, neither Party shall use any employee, consultant or contractor:

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

7.2.2 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)(1)-(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

7.2.3 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 nonprocurement programs.

Each Party shall notify the other Party promptly, but in no event later than five (5) 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.



7.3 Notifications Regarding Regulatory Matters. Each Party shall promptly [\*\*\*] notify the other Party in writing upon the occurrence of any of the following:

7.3.1 receiving any communication from Regulatory Authorities with respect to any CMC, safety or efficacy issue with respect to any Collaboration Product, or any advertising or promotional claims with respect to a Collaboration Product; or

7.3.2 receiving information concerning the initiation of any investigation, review or inquiry regarding any Collaboration Product (including with respect to its Manufacture or supply) by any Regulatory Authority, including but not limited to (1) the need for a remedial action related to one or more batches of any Collaboration Product (including a recall or withdrawal), (2) possible detention, seizure of, or injunction against distribution of any Collaboration Product, (3) the facilities used in conjunction with the Manufacture or distribution of any Collaboration Product, (4) the receipt of a report concerning any bacteriological contamination, significant chemical, physical, or other change or deterioration in any Collaboration Product or (5) the receipt of any complaint concerning suspected or actual tampering, contamination, misbranding or other similar issues related to any Collaboration Product.

In addition, if either Party determines that it is required to communicate with any Regulatory Authority regarding any Collaboration Product, then it shall (x) so advise the other Party promptly, [\*\*\*] 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 any Collaboration Product 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.

7.4 Pharmacovigilance. At least [\*\*\*] prior to [\*\*\*], the Parties shall enter into an agreement to initiate a process for the exchange of adverse event safety data (including post-marketing spontaneous reports received by each Party and its Affiliates) and any other risk management activities and related data required for the Collaboration Products in a mutually agreed format in order to monitor the safety of the Collaboration Products and to meet reporting requirements of any applicable Regulatory Authority.

7.5 Safety Issues. In the event either Party has a material concern about a safety issue related to a Collaboration Product prior to the First Commercial Sale 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.

7.6 Product Complaints. Each Party shall maintain a record of all non-medical and medical product-related complaints it receives with respect to the Collaboration Products. Each Party shall promptly notify the other Party of any such complaint received by it in sufficient detail and in accordance with the timeframes and procedures for reporting to be mutually established by the Parties in writing within thirty (30) days of the date hereof. Seres shall investigate and respond to all such complaints with respect to the Collaboration Products arising

in the Retained Territory as soon as reasonably practicable and provide a copy of all such responses to NHSc promptly. NHSc shall investigate and respond to all such complaints with respect to the Collaboration Products arising in the Territory as soon as reasonably practicable and provide a copy of all such responses to Seres promptly.

7.7 Product Recalls. During the Term, Seres and NHSc shall promptly consult with one another in good faith as to all decisions concerning any potential recall, field correction or withdrawal of a Collaboration Product from the market in any country or region in the Territory (each such event, a “**Recall**”), including, but not limited to, [\*\*\*] any Recall. Without limiting the foregoing, each Party shall keep the other Party promptly and fully informed of any notification or other information, whether received directly or indirectly, which might affect the marketability, safety or effectiveness of any Collaboration Product or which might result in a Recall. Notwithstanding anything herein to the contrary, the ultimate decision as to whether or not any Recall shall be made and the timing and scope thereof shall [\*\*\*]. If the applicable Party having discretion with respect to a particular Recall decision elects to conduct any Recall, such Party shall have sole discretion and control with respect to [\*\*\*].

**ARTICLE 8  
FINANCIAL TERMS**

8.1 Upfront Payment. Subject to the terms and conditions of this Agreement, within [\*\*\*] after the date hereof, NHSc shall pay to Seres a one-time, non-refundable, license fee of one hundred twenty million US dollars (\$120,000,000).

8.2 Payments Relating to IBD Products.

8.2.1 Development and Approval Milestone License Payments for IBD Products. Subject to the terms of this Agreement, within [\*\*\*] after the achievement of a Milestone Event set forth below, NHSc shall make a one-time, non-refundable Milestone License Payment to Seres in the amount below corresponding to such Milestone Event (which Milestone License Payments contemplated by this Section 8.2.1 shall not exceed, in the aggregate, four hundred ninety million US dollars (\$490,000,000)). For purposes of this Article 8 (i) [\*\*\*].

<u>Milestone Event</u>	<u>Milestone License Payment</u>
<b>First IBD Product</b>	
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

<u>Milestone Event</u>	<u>Milestone License Payment</u>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
<b>Second IBD Product</b>	
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

8.2.2 IBD Product Royalties. Subject to the terms of this Agreement, including Section 8.6, during the IBD Royalty Period, NHSc shall make tiered royalty payments to Seres in respect of Net Sales of IBD Products in the Territory during each Calendar Year, as set forth below.

<u>Annual Net Sales</u>	<u>Royalties</u>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

8.3 C Difficile Field Payments.

8.3.1 Development and Approval Milestone License Payments for C Difficile Products. Subject to the terms of this Agreement, within [\*\*\*] after the achievement of a Milestone Event set forth below, NHSc shall make a one-time, non-refundable Milestone License Payment to Seres in the amount below corresponding to such Milestone Event (which Milestone License Payments pursuant to this Section 8.3.1 shall not exceed, in the aggregate, (i) with respect to the First C Difficile Product, [\*\*\*] and (ii) with respect to the Second C Difficile Product, [\*\*\*]):

<u>Milestone Event</u>	<u>Milestone License Payment</u>
<b>First C Difficile Product</b>	
Commencement of a Phase III Clinical Trial in accordance with the Global Development Plan in respect of the First C Difficile Product for [***] C Difficile.	\$20,000,000
[***]	[***]
[***]	[***]
[***]	[***]
<b>Second C Difficile Product</b>	
Commencement of a Phase I Clinical Trial, as contemplated in the Global Development Plan, in respect of the Second C Difficile Product for [***] C Difficile.	\$10,000,000
[***]	[***]
[***]	[***]

<u>Milestone Event</u>	<u>Milestone License Payment</u>
[***]	[***]
[***]	[***]
[***]	[***]

8.3.2 Commercialization Milestone License Payments for C Difficile Products. Subject to the terms of this Agreement, within forty-five (45) days after the achievement of a Milestone Event set forth below, NHSc shall make a one-time, non-refundable Milestone License Payment to Seres in the amount below corresponding to such Milestone Event (which Milestone License Payments pursuant to this Section 8.3.2 shall not exceed, in the aggregate, one hundred twenty million US dollars (\$120,000,000)):

<u>Milestone Event</u>	<u>Milestone License Payment</u>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

8.3.3 C Difficile Product Royalties. Subject to the terms of this Agreement, including Section 8.6, during the C Difficile Royalty Period, NHSc shall make tiered royalty payments to Seres in respect of Net Sales of C Difficile Products in the Territory during each Calendar Year, as set forth below.

<u>Annual Net Sales</u>	<u>Royalties</u>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

8.4 Additional Commercialization Milestone License Payments. Subject to the terms of this Agreement, within [\*\*\*] after the achievement of a Milestone Event set forth below, NHSc shall make a one-time, non-refundable Milestone License Payment to Seres in the amount below corresponding to such Milestone Event (which Milestone License Payments pursuant to this Section 8.4 shall not exceed, in the aggregate, one billion five million US dollars (\$1,005,000,000)):

<u>Milestone Event (Annual Net Sales)</u>	<u>Milestone License Payment</u>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

8.5 Additional Milestone License Payment Terms.

8.5.1 Substitute or Additional Collaboration Products in the Field. Subject to Section 8.5.2, if the Parties mutually agree in writing to Develop one or more Additional Collaboration Product candidates as a substitute for any Collaboration Product for which Milestone Events are contemplated in Section 8.2.1, Section 8.3.1 or Section 8.3.2, and if such Additional Collaboration Product achieves any Milestone Event corresponding to a Milestone License Payment set forth above for the Collaboration Product for which the Additional Collaboration Product was substituted, as set forth in Section 8.2.1, Section 8.3.1. or Section 8.3.2, then [\*\*\*]. For the avoidance of doubt, this Section 8.5.1 shall not apply to any Additional Collaboration Product that is not selected by mutual written agreement of the parties to be a substitute for any Collaboration Product for which Milestone Events are contemplated pursuant to Section 8.2.1, Section 8.3.1. or Section 8.3.2. For the avoidance of doubt (i) in the event that any Milestone Event is achieved with respect to a Collaboration Product and the Parties have agreed in writing to Develop an Additional Collaboration Product as a substitute for such Collaboration Product, such Milestone Event shall not be paid a second time in relation to achievement of such Milestone Event for such Additional Collaboration Product and (ii) no Milestone License Payments shall be owing pursuant to Section 8.2.1 or Section 8.3.1 in respect of any Additional Collaboration Products that the Parties have not agreed in writing shall be substituted for a Collaboration Product contemplated in such Sections.

8.5.2 Certain Limitations. Each of the Development and approval Milestone License Payments shall only be payable once, upon the first occurrence of the corresponding Milestone Event, and no additional payment will be due in the event of any repeated occurrence of such Milestone Event, including in relation to more than one Collaboration Product. The payments expressly set forth in this Article 8 shall constitute the sole consideration for the licenses and other rights contemplated hereunder and any and all Development conducted by Seres of Collaboration Products. Anything to the contrary notwithstanding, if [\*\*\*].

8.5.3 Notice. Seres shall promptly [\*\*\*] notify NHSc in writing in the event that, or Seres believes that, any Milestone Event contemplated in Section 8.2.1 or Section 8.3.1 has been achieved.

8.5.4 Skipped Milestones. If a Milestone Event that is contemplated in Article 8 and is based on the receipt of Regulatory Approval for a Collaboration Product for a particular indication is achieved and any Milestone Event relating to the commencement of a Clinical Trial in respect of such Collaboration Product in such indication was not achieved, then such Milestone License Payment corresponding to such Milestone Event relating to the commencement of such Clinical Trial shall nonetheless be paid concurrently with the Milestone License Payment corresponding to receipt of such Regulatory Approval for such Collaboration Product.

## 8.6 Additional Royalty Terms.

8.6.1 Generic Product Step-Down. In the event that a Generic Product is sold in the Field to a Third Party in a country in the Territory in any given Calendar Quarter, then, for the remaining period of the Royalty Period applicable to such Collaboration Product in such country, the Net Sales of such Collaboration Product in such country to be included in Net Sales for the purpose of the calculation of the royalties due under Section 8.2.2 or Section 8.3.3, as applicable, shall be reduced by [\*\*\*].

8.6.2 Royalty Stacking. If during any Royalty Period, NHSc enters into or becomes subject to any agreement or other arrangement (including any license agreement, settlement or award or judgment) with a Third Party under which it obtains a license or other right (including any covenant not to sue or similar arrangement) under any Patent or intellectual property of such Third Party in a particular country in the Territory that, [\*\*\*], is necessary for NHSc, its Affiliates or any sublicensee to Exploit any Collaboration Product(s) in such country in accordance with this Agreement, then, upon entry into any such agreement or arrangement and thereafter during the remainder of the period during which NHSc owes royalties to such Third Party pursuant to such agreement or arrangement and to Seres under this Agreement based upon sales of any Collaboration Products in such country, the Net Sales of such Collaboration Product(s) in such country to be included in Net Sales for the purpose of the calculation of the royalties due under Section 8.2.2 or Section 8.3.3, as applicable, shall be reduced [\*\*\*]; provided, that the royalties due to Seres under Section 8.2.2 or Section 8.3.3 in respect of any Calendar Quarter, as applicable, shall not be reduced in aggregate by more than [\*\*\*] by virtue of this Section 8.6.2; provided, further, that if NHSc is unable to offset from the royalties owing to Seres during any Calendar Quarter the full amount paid to such Third Parties in such Calendar Quarter, NHSc may reduce the applicable royalty rate due to Seres in any subsequent Calendar Quarter in accordance with the foregoing.

8.6.3 Limitation. Notwithstanding Sections 8.6.1 and 8.6.2, in no event shall the royalties payable by NHSc pursuant to Sections 8.2.2 or 8.3.3 be reduced by more than [\*\*\*] in the aggregate by operation of Sections 8.6.1 or 8.6.2.

8.6.4 Infringing Products. If any Third Party commences commercial sale of any product in the Field in a country in the Territory that, [\*\*\*], infringes any of the Licensed

Patents, and the Net Sales in the Field in such country of any Collaboration Product utilizing or covered by such Licensed Patents thereafter decrease [\*\*\*] (the “**Trigger**”), then the Net Sales of such Collaboration Product in such country to be included in Net Sales for the purpose of the calculation of the royalties otherwise due under Section 8.2.2 or Section 8.3.3, as applicable, shall be reduced by [\*\*\*], commencing with the first Calendar Quarter after the Trigger occurs ending with the Calendar Quarter ending after such other product is withdrawn from the market in such country.

8.6.5 Combination Products. If a Collaboration Product under this Agreement is sold in form of a Combination Product, then Net Sales for such Combination Product shall be determined on a country-by-country basis as follows:

(a) If the Collaboration Product and the Other Product are sold separately, the royalty payments due on the Net Sales of the Combination Product shall be equal to the applicable percentage (royalty rate) multiplied by the Net Sales of the Combination Product multiplied by the fraction,  $A/(A+B)$  where “A” is the mean gross selling price of the Collaboration Product and “B” is the mean gross selling price of the Other Product.

(b) If the Collaboration Product and the Other Product are sold separately, but the mean gross selling price of the Other Product cannot be determined, the royalty payments due on the Net Sales of the Combination Product shall be equal to the applicable percentage (royalty rate) multiplied by the Net Sales of the Combination Product multiplied by the fraction  $A/C$  wherein “A” is the mean gross selling price of the Collaboration Product and “C” is the mean gross selling price of the Combination Product.

(c) If the Collaboration Product and the Other Product are sold separately, but the mean gross selling price of the Collaboration Product cannot be determined, the royalty payments due on the Net Sales of the Combination Product shall be equal to the applicable percentage (royalty rate) multiplied by the Net Sales of the Combination Product multiplied by the following formula: one (1) minus  $B/C$  wherein “B” is the mean gross selling price of the Other Product and “C” is the mean gross selling price of the Combination Product.

(d) If the Collaboration Product and the Other Product are sold separately, but the mean gross selling price of neither the Collaboration Product nor the Other Product can be determined, Net Sales of the Collaboration Product shall be equal to Net Sales of the Combination Product multiplied by a percentage agreed to by the Parties, acting in good faith. If the Parties are unable to agree upon such a percentage, the dispute shall be resolved by arbitration pursuant to Section 14.3.

8.7 Royalty Payments and Reports. NHSc shall make all royalty payments owed under this Agreement within [\*\*\*] following the end of each Calendar Quarter for Net Sales during the previous Calendar Quarter, and together with such payment, shall submit to Seres a written report setting forth, on a Collaboration Product-by-Collaboration Product basis (i) a reasonably detailed calculation of the Net Sales for such Calendar Quarter in each country in the Territory upon which such royalty payments are based including all deductions from gross sales



made in arriving at the same, (ii) year-to-date, total royalty payments due to Seres hereunder, and (iii) any other information reasonably needed to support the calculation of such Net Sales and royalty payments.

8.8 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.

8.9 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 [\*\*\*], as reported by The Wall Street Journal (New York edition) for the first Business Day of such month. Such interest shall be accrued daily.

8.10 Currency Conversion. In the event that any Net Sales or other amounts in respect of which payments from one Party to the other Party are owing hereunder are denominated in a currency other than U.S. dollars, such Net Sales or other amounts shall be converted into U.S. dollars at the rate of exchange as used by NHSc for its internal and external financial reporting.

8.11 Taxes and Withholding. The amounts of the upfront payment to be made to Seres pursuant to Section 8.1 and the Milestone License Payments to be made to Seres under this Article 8 are net of any applicable value-added or withholding taxes. [\*\*\*]. If any applicable Law requires the deduction or withholding of any taxes from such payment [\*\*\*]. 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. [\*\*\*]. Within [\*\*\*] after receipt by [\*\*\*]. For the avoidance of doubt, [\*\*\*].

8.12 Books and Records; Audit. NHSc shall keep and maintain reasonably detailed books and records of Net Sales of Collaboration Products in the Territory and each component of such Net Sales. Seres shall have the right to examine and audit NHSc's relevant books and records to verify the accuracy of any reports and and/or payments prepared and/or delivered by NHSc pursuant to this Agreement. Any such audit shall be on at least thirty (30) days' prior written notice. Seres' rights to perform an audit under this Section 8.12 shall be limited to not more than one (1) such audit in any Calendar Year and shall be limited to the pertinent books and records for any Calendar Year ending not more than thirty-six (36) months before the date of the request. The audit shall be performed at Seres' sole expense by an independent certified public accounting firm of internationally recognized standing that is selected by Seres and reasonably acceptable to the audited Party. The accounting firm shall be required to enter into a reasonable and customary confidentiality agreement with NHSc to protect the confidentiality of its books and records. NHSc shall make the relevant books and records reasonably available during normal business hours for examination by the accounting firm. Except as may otherwise be agreed, the accounting firm shall be provided access to such books and records at NHSc's 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 and/or payments are correct, and the specific details concerning any discrepancies. The accounting firm shall not provide the requesting Party with any additional information or access to the audited Party's confidential information. If the accounting firm conducting an audit pursuant to this Section 8.12 concludes as a result of such audit that any additional amounts were due and payable to a Party, such additional amounts shall be paid to such Party within thirty (30) 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 NHSc to Seres for the audited period exceeds [\*\*\*] of the aggregate total amount that was properly due and payable to such other Party for such period, then the audited Party shall also reimburse Seres for the documented, reasonable out-of-pocket expenses incurred in conducting the audit, except to the extent that such underpayment was due to any inaccurate or incomplete information provided to NHSc by Seres.

## **ARTICLE 9 REPRESENTATIONS AND WARRANTIES**

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

9.1.1 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.

9.1.2 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.

9.1.3 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).

9.1.4 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.

9.1.5 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.

9.1.6 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.

9.1.7 No Debarment. Neither such Party nor its Affiliates' employees who have been, or who such Party currently expects to be, involved in the Exploitation of the Collaboration Products, or, to such Party's Knowledge, any of their respective licensees, contractors, agents and consultants or their respective employees, consultants or contractors who have been, or who such Party currently expects to be, involved, on behalf of such Party, in the Exploitation of the Collaboration Products:

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

(b) has, to such Party's Knowledge, been charged with, or convicted of, any felony or misdemeanor within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or 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; and

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

9.2 Additional Representations and Warranties of Seres. [\*\*\*], Seres further represents and warrants to NHSc, as of the Effective Date, as follows:

9.2.1 Title; Encumbrances; Conflicting Grants. Seres has the right to grant the licenses specified herein and has not granted to any Third Party any rights conflicting with the rights Seres purports to grant to NHSc pursuant to this Agreement. The Licensed Patents and Licensed Know-How are not subject to any liens in favor of, or claims of ownership by, any Third Party.

9.2.2 No Non-Competition Agreements. Neither Seres nor any of its Affiliates are bound by any non-competition agreements related to the Collaboration Products.

9.2.3 Good Practices. Seres and its Affiliates have, and, to Seres' Knowledge, their respective contractors, agents and consultants have, conducted all Development with

respect to the Collaboration Products that has been conducted prior to the Effective Date in accordance with GLP, GCP, and GMP, to the extent applicable.

#### 9.2.4 Licensed Patents.

(a) Schedule 9.2.4 sets forth a true and correct listing of all Patents Controlled by Seres as of the Effective Date that claim or cover or, as to patent applications, if issued as they currently exist, would claim or cover, the Collaboration Products as they exist as of the Effective Date, including the use and methods of Manufacture of the Collaboration Products practiced with respect to Collaboration Products as they exist as of the Effective Date. In each country or jurisdiction in the Territory where Licensed Patents have been issued or applied for, the Licensed Patents are being diligently prosecuted in each country in respect of which applications have been made in the respective patent offices in accordance with all applicable Laws and regulations. In each country or jurisdiction in the Territory where Licensed Patents have been issued or applied for, the Licensed Patents have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment, except as would not result in the abandonment or invalidity of any Patent or any claim thereof, any loss of priority in respect of any Patent or any other material and adverse effect on any Patent.

(b) To Seres' Knowledge, no Third Party has taken any action before any patent and trademark office (or similar Governmental Authority) to challenge the validity or enforceability of the Licensed Patents existing as of the Effective Date or otherwise asserted in writing to Seres that the Licensed Patents are invalid or unenforceable.

(c) All renewal and maintenance fees that have become due prior to the Effective Date with respect to the prosecution and maintenance of the Licensed Patents have been paid.

(d) The inventors named in the Licensed Patents existing as of the Effective Date are, to Seres' Knowledge, all of the true inventors for such Licensed Patents and each of such inventors has assigned, or is under a written obligation to assign, to Seres or its Affiliates all of his or her right, title and interest to such Licensed Patents and the inventions described therein.

(e) Seres has complied in all material respects with all applicable Laws in connection with the prosecution of the Patents claiming any Collaboration Products or any aspect of the Exploitation thereof, in the Field and in the Territory, including the duty of candor owed to any patent office pursuant to such applicable Laws.

9.2.5 Non-Infringement of Third Party Rights. To Seres' Knowledge, the Exploitation by NHSc and its Affiliates and sublicensees hereunder of the Collaboration Products in the Field, as such Collaboration Products exist as of the Effective Date, will not infringe any issued Patent or the claims included in any published patent application in the Territory. Seres has not received any written notice from any Third Party asserting or alleging that (i) any research, Development or Manufacture of the Collaboration Products by Seres prior

to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party or (ii) the Exploitation of Collaboration Products in the Field pursuant to this Agreement would infringe any Third Party intellectual property rights.

9.2.6 No Misappropriation of Third Party Rights. The conception, development and reduction to practice of the Licensed Patents and Licensed Know-How existing as of the Effective Date has not constituted or involved the misappropriation of trade secrets or other proprietary rights or property of any Third Party. There are no claims, judgments or settlements against or amounts with respect thereto owed by Seres or any of its Affiliates relating to the existing Regulatory Filings, the Licensed Patents or the Licensed Know-How.

9.2.7 Non-Infringement of Rights by Third Parties. To Seres' Knowledge, no Person is infringing or threatening to infringe the Licensed Patents or misappropriating or threatening to misappropriate the Licensed Know-How by reason of the Exploitation of products utilizing the Microbiome Technology in the Field. Neither Seres nor any of its Affiliates has received any written notice of any unauthorized use, infringement, misappropriation, or dilution by any Person, including any current or former employee or consultant of Seres or its Affiliates, of any of the Licensed Patents or Licensed Know-How with respect to the Microbiome Technology.

9.2.8 Material Contracts. No Licensed Know-How or Licensed Patents are Controlled by Seres by virtue of any agreement between Seres or any of its Affiliates and one or more Third Parties.

9.2.9 Regulatory Matters.

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

(b) Neither Seres nor any of its Affiliates has received, with respect to the Collaboration Products, any oral or written communication (including any warning letter, untitled letter, or similar notices) from any Governmental Authority and, there is no action pending or, to Seres' Knowledge, threatened (including any prosecution, injunction, seizure, civil fine, suspension or recall), in each case alleging that with respect to the Collaboration Products in the Field, Seres or any of its Affiliates is not currently materially in compliance with any and all applicable Laws implemented by such Governmental Authority. Neither Seres nor any of its Affiliates has received any written notice from any Governmental Authority claiming that the research, development,

manufacture, use, offer for sale, sale, or import of the Collaboration Products in the Field is not in material compliance with all applicable Laws and permits; and

(c) To Seres' Knowledge, none of Seres, any of its Affiliates, or any of their respective officers, employees or agents has made, with respect to the Collaboration Products, an untrue statement of a material fact to any Governmental Authority or failed to disclose a material fact required to be disclosed to such Governmental Authority.

9.2.10 No Proceeding. There are no pending, and to Seres' Knowledge, no threatened, adverse actions, claims, investigations, suits or proceedings against Seres or any of its Affiliates, at law or in equity, or before or by any Governmental Authority, involving the Licensed Patents or Licensed Know-How or the Collaboration Products in the Field, nor to Seres' Knowledge has any such adverse action, claim, investigation, suit or proceeding been brought or threatened during the past three (3) years, in each case, which has been resolved in a manner that impairs any of Seres' rights in and to any such Licensed Patents or Licensed Know-How or to the Collaboration Products in the Field.

9.2.11 Employee Confidentiality Agreements. All current and former employees and paid consultants (in the case of academic consultants, those acting outside the scope of their academic affiliation) of Seres and its Affiliates who are or have been substantively involved in the conception, evaluation, reduction to practice, or development of Licensed Patents and Licensed Know-How in the Field have executed written contracts or are otherwise obligated to protect the confidential status and value thereof and to vest in Seres exclusive ownership of or a license under the Licensed Patents and Licensed Know-How.

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

9.2.13 Safety and Efficacy. Seres has no Knowledge of any material safety issues arising in the Development of the Collaboration Products (including with respect to any of its ingredients) and Seres has informed NHSc of all adverse drug reactions reported in all Clinical Trials that are known to Seres relating to the Collaboration Products or their use.

## **ARTICLE 10 INTELLECTUAL PROPERTY**

### 10.1 Ownership of Intellectual Property.

10.1.1 Ownership of Technology. As between the Parties, each Party shall solely own all right, title, and interest in and to any and all Inventions and Information that are conceived, discovered, or otherwise made solely by or on behalf of such Party (or its Affiliates or sublicensees) in the course of performing activities contemplated in this Agreement, whether or not patented or patentable, and any and all Patents and other intellectual property rights therein.

10.1.2 Ownership of Joint Patents and Joint Know-How. As between the Parties, each Party shall each own an equal, undivided interest in any and all (i) Inventions and

Information that are conceived, discovered, or otherwise made jointly by or on behalf of NHSc, its Affiliates or sublicensees, on the one hand, and Seres, its Affiliates or sublicensees, on the other hand, in the course of performing activities contemplated in this Agreement, whether or not patented or patentable (the “**Joint Know-How**”), and (ii) Joint Patents and other intellectual property rights in the Inventions and Information described in clause (i) (together with Joint Know-How and Joint Patents, the “**Joint Intellectual Property Rights**”). 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 Joint Know-How. Subject to the licenses, covenants and rights of reference granted under Sections 2.1, 2.2 and 2.3, each Party may, and may permit, through sublicensees or otherwise, others to, [\*\*\*].

10.1.3 United States Law. The determination of whether Information and Inventions are conceived, discovered or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with applicable Law in the United States as such Law exists as of the Effective Date irrespective of where such conception, discovery, or making occurs.

10.1.4 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.

10.1.5 Inventors. Seres shall [\*\*\*], pursuant to applicable Law, or otherwise. Each Party shall [\*\*\*], pursuant to applicable Law, or otherwise.

## 10.2 Maintenance and Prosecution of Patents in the Territory.

10.2.1 Prosecution of Licensed Patents. Subject to Section 10.2.2, Seres shall (i) using outside legal counsel reasonably acceptable to NHSc, 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 Licensed Patents) and maintain the Licensed Patents in the Field in the Core Countries (in each case, except to the extent relevant deadlines have occurred prior to the Effective Date), and (ii) have the first right, but not the obligation, using outside legal counsel reasonably acceptable to NHSc, 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 Licensed Patents) and maintain the Licensed Patents in the Field in the Territory outside the Core Countries. [\*\*\*], in the Core Countries, and [\*\*\*], unless it has requested that [\*\*\*]. If NHSc, in accordance with this Section 10.2.1 or Section 10.2.2, files, prosecutes (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 Licensed Patents) or maintains any Licensed Patents pursuant to Section 10.2.2, [\*\*\*]; provided, that [\*\*\*]. For Licensed Patents for which Seres performs such activities, subject to Section 10.2.2, Seres shall (i) [\*\*\*]; and (ii) [\*\*\*]. Seres shall reasonably consider all comments made by NHSc with respect to filing or prosecuting such Patent applications and maintaining such Patents for which it has responsibility pursuant to this Section 10.2 (including pursuing or defending any

oppositions, post-grant reviews, inter partes proceedings or supplementary protection certificates for Licensed Patents).

#### 10.2.2 Decisions to Prosecute.

(a) Licensed Patents. Without limitation of Section 10.2.1, if Seres proposes to not (i) [\*\*\*], or (ii) [\*\*\*], then in each such case [\*\*\*]. Subject to the foregoing, Seres may elect not to conduct the relevant activity with respect to such Licensed Patents, except that if such election relates to Licensed Patents in a Core Country, [\*\*\*]. Upon receipt of each such notice by NHSc, and upon [\*\*\*], or if, at any time, [\*\*\*], NHSc shall have the right, but not the obligation, through counsel of its choosing, to pursue the filing or registration, or support the continued prosecution (including any oppositions, post-grant reviews, inter partes proceedings or supplementary protection certificates, in each case in respect of Licensed Patents) or maintenance, of such Licensed Patent in the Field and in the Territory, [\*\*\*]. If NHSc elects to pursue such filing or registration, as the case may be, or continue such support, then NHSc shall notify Seres of such election and Seres shall, and shall cause its Affiliates to, reasonably cooperate with NHSc in this regard.

(b) Joint Patents. Notwithstanding anything to the contrary in Section 10.2, the Parties shall determine, on a case-by-case basis, which Party shall have the responsibility, through counsel of its choosing, for obtaining, prosecuting (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 (such Party, the “**Prosecuting Party**”). In selecting the Prosecuting Party, the Parties shall consider [\*\*\*]. The Prosecuting Party shall have the first right to determine in which countries to obtain, prosecute and maintain a Joint Patent. The other Party shall have the right to request that the Prosecuting Party obtain, prosecute and maintain a Joint Patent in a particular country. If [\*\*\*]. The Parties shall, and shall cause their respective Affiliates, as applicable, to assist and cooperate with one another in, [\*\*\*]. Notwithstanding the above, [\*\*\*].

(c) Cooperation. In connection with the activities set forth in Sections 10.2.1 or 10.2.2: (i) each Party shall consult with the other as to the strategy and prosecution of applications for such Patents and the maintenance or extension of the Licensed Patents (other than Joint Patents) in the Territory and of the Joint Patents worldwide; (ii) each filing Party shall regularly provide the other Party with copies of all Patent applications filed hereunder for Licensed Patents (other than Joint Patents) in the Territory and for Joint Patents worldwide, [\*\*\*]; (iii) such filing 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 (iv) such filing Party shall notify the other Party as early as reasonably practicable, [\*\*\*] concerning the Licensed Patents (other than Joint Patents) in the Territory or the Joint Patents worldwide and shall permit the other Party to [\*\*\*], and the [\*\*\*] shall be taken into consideration in good faith by such Party and its patent counsel in connection with such filing.



### 10.3 Enforcement of Patents.

10.3.1 Procedures and Requirements. In the event that either Party has cause to believe that a Third Party may be infringing any of the Licensed Patents in the Field in the Territory, or 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. In consultation with Seres, NHSc, using counsel reasonably acceptable to Seres, shall have the first right to stop such infringement of the Licensed Patents by such Third Party in the Field in the Territory. If NHSc fails to take action within [\*\*\*] following its receipt of a notice of such infringement, then Seres shall have the right to take action to stop such infringement. With respect to Third Party infringement of Joint Patents that are not Licensed Patents, unless otherwise agreed by the Parties in writing, the Prosecuting Party for a given Joint Patent, using counsel reasonably acceptable to the other Party, shall have the first right to stop such infringement; provided that if the Prosecuting Party fails to take action within [\*\*\*] following its receipt of a notice of such infringement, then the other Party shall have the right to take action to stop such infringement. Upon reasonable request by the Party enforcing a Licensed Patent in the Field in the Territory or a Joint Patent that is not a Licensed Patent worldwide (the “**Enforcing Party**”), the other Party (the “**Non-Enforcing Party**”) shall give the Enforcing Party all reasonable information and assistance, [\*\*\*]. Any such assistance provided by a Non-Enforcing Party shall be [\*\*\*] and [\*\*\*]. For clarity, Seres retains all rights to enforce the Licensed Patents against infringement by Third Parties outside of the Territory, and all rights to enforce the Licensed Patents in the Territory outside the Field.

10.3.2 Settlement of an Enforcement Claim. The Enforcing Party shall have the right to control settlement of any claims that a Third Party may be infringing any Licensed Patents in the Field and in the Territory or Joint Patents that are not Licensed Patents; provided, however, that [\*\*\*].

10.3.3 Expenses and Recovery. As between the Parties, [\*\*\*]. Any amounts recovered by either Party pursuant to Section 10.3.1 or 10.3.2, 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) (i) if NHSc is the Enforcing Party and such settlement relates to Licensed Patents in the Field in the Territory, [\*\*\*], and (ii) if Seres is the Enforcing Party and such enforcement relates to Licensed Patents in the Field in the Territory, or if either Party is the Enforcing Party and such enforcement relates to Joint Patents that are not Licensed Patents, any remainder of such amounts shall be [\*\*\*] by Seres and [\*\*\*] by NHSc.

### 10.4 Infringement Claims by Third Parties.

10.4.1 Defense of Third Party Claims. Except as otherwise provided in the Trademark License Agreement, if a Third Party asserts that a Patent or other intellectual property right owned or controlled by it is infringed by the Exploitation of the Collaboration Products in the Field in the Territory, the Party first obtaining Knowledge of such a claim shall promptly

provide the other Party notice of such claim along with the related facts in reasonable detail. NHSc shall have the first right, but not the obligation, to defend such claim with respect to Collaboration Products in the Field in the Territory in consultation with Seres. If NHSc elects not to defend any such claim, then Seres shall have the right, but not the obligation, to defend such claim in consultation with NHSc and using counsel reasonably acceptable to NHSc. The Parties shall cooperate with one another in any such defense. Subject to Section 10.6, the Party controlling the defense of any such claim [\*\*\*].

10.4.2 Settlement of Third Party Claims. The Party (or its Affiliate or sublicensee) defending against any Third Party claim pursuant to Section 10.4.1, shall have the right to settle such claim; provided that any such settlement that [\*\*\*], it being agreed that (i) a settlement shall not be deemed to [\*\*\*] and (ii) in determining [\*\*\*] following such settlement shall be taken into account.

10.4.3 Patent Oppositions and Challenges. If either Party wishes to challenge the validity of any Third Party's Patent in the Territory as may be necessary or desirable in connection with the Exploitation of any Collaboration Product in the Field in the Territory by filing a pre-grant opposition (e.g., third-party observations), opposition, post-grant or inter partes proceeding (a "**Challenge Proceeding**") at a patent office or by otherwise pursuing a legal action in a court, such Party shall so notify the other Party. The Parties shall discuss the relevant matter and each make recommendations with respect thereto, with the intent of optimizing the success of any such Challenge Proceeding, coordinating the Parties' strategies with respect to the relevant Third Party Patent in any such country and in other countries (for counterparts thereof), and enabling efficiencies of any such proceedings. Each Party shall have the right to bring a Challenge Proceeding in any country in the Territory with respect to such Third Party's Patent unless applicable Laws do not allow each of Seres and NHSc to bring such a Challenge Proceeding, [\*\*\*] and; provided, however, that [\*\*\*] in the event that [\*\*\*]. A Party bringing a Challenge Proceeding shall consult with the other Party with respect thereto and reasonably consider such other Party's comments thereon. Each Party shall cooperate with the other Party in connection with any Challenge Proceeding brought by such other Party as reasonably requested by such other Party. Subject to Section 10.6, the Party seeking the cooperation of the other Party under this Section 10.4.3 [\*\*\*].

10.4.4 Allocation of Costs and Recovery. Subject to Section 10.6, the Party defending, prosecuting or controlling any claim, filing, proceeding or action contemplated by this Section 10.4 shall [\*\*\*].

#### 10.5 Invalidity or Unenforceability Defenses or Actions.

10.5.1 Third Party Defense or Counterclaim. If a Third Party asserts, as a defense or as a counterclaim in any infringement action under Section 10.3, that any Licensed Patent or Joint Patent is invalid or unenforceable, then the Party pursuing such infringement action shall promptly give written notice to the other Party. With respect to the Licensed Patents, Seres shall, through counsel reasonably acceptable to NHSc, respond to such defense and use Diligent Efforts to defend against such counterclaim (as applicable) and, if NHSc is pursuing the applicable infringement action under Section 10.3, NHSc shall allow Seres to control such response or defense (as applicable). Any [\*\*\*] shall be borne initially by the [\*\*\*]. If Seres

fails, notwithstanding the foregoing, to assume such defense and [\*\*\*], NHSc or its Affiliate or sublicensee shall have the right to defend against such action or claim.

10.5.2 Third Party Declaratory Judgment or Similar Action. If a Third Party asserts, in a declaratory judgment action or similar action or claim filed by such Third Party, that any Licensed Patent or Joint Patent is invalid or unenforceable, then the Party first becoming aware of such action or claim shall promptly give written notice to the other Party. Seres shall, through counsel reasonably acceptable to NHSc, use Diligent Efforts to defend against such action or claim. [\*\*\*] shall be borne by the [\*\*\*]. If Seres fails, notwithstanding the foregoing, to assume such defense and [\*\*\*], NHSc or its Affiliate or sublicensee shall have the right to defend against such action or claim.

10.5.3 Assistance. Each Party shall provide to the other Party all reasonable assistance requested by the other Party in connection with any action, claim or suit under this Section 10.5, including [\*\*\*]. In particular, the assisting Party shall promptly make available to the other Party all relevant information in its possession or control that it is aware would assist the other Party in responding to any such action, claim or suit. Any such cooperation by either Party shall be [\*\*\*]

10.6 [\*\*\*]. NHSc shall be entitled to reduce any amounts owed by it to Seres pursuant to Article 8 of this Agreement by [\*\*\*], provided that in no event shall [\*\*\*]. In addition, NHSc shall be entitled to reduce any amounts owed by it to Seres pursuant to Section 8.2.2 or Section 8.3.3 of this Agreement by [\*\*\*], in each case, that are not recouped through any recovery relating thereto.

10.7 Patent Listings. NHSc shall have the sole right to make all filings with Regulatory Authorities with respect to Licensed Patents in the Territory in relation to the Collaboration Product, including as required or allowed under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83, as amended, or other international equivalents; provided that NHSc shall consult with Seres prior to making any such filing and consider Seres' comments on such filing in good faith.

## **ARTICLE 11 CONFIDENTIAL INFORMATION; PUBLICATIONS**

11.1 Nondisclosure. Each Party agrees that during the Term and for a period of [\*\*\*] 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 11. The Parties agree that any Proprietary 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 11.

11.1.1 Exceptions. The obligations in Section 11.1 shall not apply with respect to any portion of the Confidential Information that the Receiving Party to the extent that such information:

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

(b) 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;

(c) 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;

(d) 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

(e) 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.

11.2 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:

(a) to any relevant patent office in preparing, filing, prosecuting and maintaining patents in accordance with the provisions of Article 10;

(b) to Regulatory Authorities in order (i) to obtain authorizations to conduct Clinical Trials or post-approval studies in relation to any Collaboration Product, or (ii) to file, obtain and maintain Approvals in respect of Collaboration Products, or (iii) to Develop, Commercialize or manufacture any Collaboration Product, in each case in accordance with this Agreement;

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

(d) subject to Section 11.4, 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;

(e) disclosure to its Affiliates, and to its (actual or potential) permitted sublicensees, acquirers or assignees under Section 15.3 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 11; provided, however, that the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 11.2(e) to treat such Confidential Information as required under this Article 11; and

(f) to relevant academics or healthcare professionals who are deemed to be "opinion leaders" in order to promote, or raise awareness of, any Collaboration Product; provided, however, that the 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 11.

If and whenever any Confidential Information is disclosed in accordance with this Section 11.2, 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 11.4 and other than pursuant to Section 11.2(e), the Receiving Party shall:

(i) give the Disclosing Party reasonable advance notice of the Receiving Party's intent to make such disclosure pursuant to this Section 11.2, to the extent practicable; and

(ii) 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.

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

11.4 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 ten (10) 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 three (3) 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 Diligent 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 11.4 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 11, or is otherwise approved in advance in writing by the other Party.

11.5 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 Development and Commercialization of Collaboration Products. All publications, and other forms of public disclosure such as abstracts and presentations, of results of studies carried out under this Agreement or otherwise relating to the Collaboration Product (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 [\*\*\*] 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 [\*\*\*] 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 [\*\*\*] 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 [\*\*\*], 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 11.5 after the [\*\*\*] 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.

11.6 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.

## **ARTICLE 12 INDEMNIFICATION**

12.1 Indemnification of NHSc. Subject to Section 12.3, Seres shall indemnify, defend and hold harmless NHSc 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 or willful misconduct in performing any of its obligations under this Agreement, (ii) any violation of applicable Law in connection with the Development, Commercialization, Manufacture, use, handling, storage, marketing, sale, distribution or other disposition of Collaboration Products by Seres, its agents, subcontractors or sublicensees (other than NHSc, its Affiliates or sublicensees), (iii) any breach by Seres of any of its representations, warranties or covenants under this Agreement, or (iv) any personal injury, death or property damage resulting from the Development, Commercialization, Manufacture, use, handling, storage, marketing, sale, distribution or other disposition of Collaboration Products by Seres, its Affiliates, its agents, subcontractors or sublicensees (other than NHSc, its Affiliates or sublicensees). 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 NHSc's indemnification obligations pursuant to Section 12.2 or to the extent otherwise attributable to any of the circumstances set forth in clauses (i) through (iv) thereof.

12.2 Indemnification of Seres. Subject to Section 12.3, NHSc 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) NHSc'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 or willful misconduct in performing any of its obligations under this Agreement, (ii) any violation of applicable Law in relation to the Development, Commercialization, Manufacture, use, handling, storage, marketing, sale, distribution or other disposition of Collaboration Products by NHSc, its agents, subcontractors or sublicensees, (iii) any breach by NHSc of any of its representations, warranties or covenants under this Agreement, or (iv) any personal injury, death or property damage resulting from the Development, Commercialization, Manufacture, use, handling, storage, marketing, sale, distribution or other disposition of Collaboration Products by NHSc, its Affiliates, its agents, subcontractors or sublicensees. Notwithstanding the preceding sentence, NHSc 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 12.1 or to the extent otherwise attributable to any of the circumstances set forth in clauses (i) through (iv) thereof.

12.3 Procedure for Indemnification.

12.3.1 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.

12.3.2 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 [\*\*\*] 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 [\*\*\*] 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 [\*\*\*].

12.4 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 Development, manufacture and Commercialization of any Collaboration Products and upon such terms (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 13**  
**TERM AND TERMINATION**

13.1 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**”).



## 13.2 Termination Rights.

13.2.1 Termination by NHSc for Serious Safety Issue. NHSc shall have the right to terminate this Agreement upon [\*\*\*] days' prior written notice to Seres in the event that NHSc reasonably determines that a serious safety or public health issue in the Territory has arisen with respect to the Collaboration Product in the Field, as demonstrated by clinically relevant events which are documented and are directly related to the use of Collaboration Product in the Field; provided that the JSC shall, promptly after Seres' receipt of such notice, commence discussions of and require the Parties to engage in an orderly process in which to wind down the Parties' activities with respect to Collaboration Product in the Field and in the Territory in compliance with applicable Laws, and further provided that such termination right shall lapse in relation to any such issue if not exercised within [\*\*\*] following the date on which such issue is identified. If this Agreement is terminated pursuant to this Section 13.2.1, then subject to applicable Law, applicable data privacy laws, and on Seres' request, NHSc shall provide Seres with reasonable access to all relevant data relating to the relevant Collaboration Product, to the extent not previously or otherwise provided to Seres for the purposes of Seres obtaining one or more quotations for product liability insurance with respect to future Development and Commercialization of such Collaboration Product. Upon Seres' obtaining and providing NHSc evidence of product liability insurance that is substantially equivalent in terms of insured amount and scope of coverage with respect to product liability under a policy that would typically be held by a biopharmaceutical company commercializing similar products for use in similar Fields, which insurance policy(ies) shall name NHSc as an additional insured thereunder, Section 13.3.2 shall apply.

13.2.2 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 [\*\*\*] 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 [\*\*\*] 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 [\*\*\*], or (xi) has an order for relief against it entered in an involuntary case under the Bankruptcy Code of any country.

13.2.3 Termination for Material Breach.

(a) Breach. Subject to Section 13.2.3(b) 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 [\*\*\*] 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 [\*\*\*] 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 [\*\*\*].

(b) Disputed Breach. If a Party disputes in good faith (i) the existence or materiality of a material breach specified in a notice provided by the other Party pursuant to Section 13.2.3(a), (ii) any assertion by the other Party that such Party has failed to cure or reasonably alleviate any such material breach, or (iii) 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 Article 14. It is understood and acknowledged that, subject to Section 13.3, 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. The Parties further agree that any payments that are made by one Party to the other Party pursuant to this Agreement pending resolution of the dispute shall be promptly refunded if the arbitrator determines pursuant to Section 14.3 that such payments are to be refunded by one Party to the other Party.

13.2.4 Patent Challenge by NHSc. Seres shall have the right to terminate this Agreement immediately upon written notice if NHSc or its Affiliate challenges in a court of competent jurisdiction, the validity, scope or enforceability of, or otherwise opposes, any Patent included in the Licensed Patents in the Territory (other than in connection with NHSc's or its Affiliate's defense of any claim brought against it that is not a claim by Seres that NHSc's or its Affiliate's Exploitation of the Licensed Patents is outside the scope of the license hereunder). If a sublicensee of NHSc or its Affiliate challenges the validity, scope or enforceability of or otherwise opposes any Patent included in the Licensed Patents in the Territory under which such sublicensee is sublicensed (other than in connection with such sublicensee's defense of any claim brought against it that is not a claim by Seres that such sublicensee's Exploitation of the Licensed Patents is outside the scope of permitted sublicenses hereunder), shall, upon written notice from Seres, terminate such sublicense. NHSc and its Affiliates shall use reasonable efforts to include provisions in all agreements under which a Third Party obtains a license under any Patent included in the Licensed Patents providing that, if the sublicensee challenges the

validity or enforceability of or otherwise opposes any such Patent under which the sublicensee is sublicensed in the manner contemplated in this Section 13.2.4, then NHSc or such Affiliate may terminate such sublicense agreement with such sublicensee, and NHSc or such Affiliate shall, upon request by Seres, enforce such right if such sublicensee breaches such restriction.

### 13.3 Effect of Termination.

13.3.1 Milestone License Payments. In the event of any termination of this Agreement in its entirety by either Party pursuant to Section 13.2, NHSc shall not be obligated to make any Milestone License Payment that would otherwise be owing in respect of any Milestone Event achieved after the terminating Party notifies the other Party in writing of its intention to so terminate; provided, however, that if this Agreement is not ultimately terminated pursuant to such notice, any such Milestone License Payments that would have become due following such notice shall be due and payable at such time as it is determined that such termination shall not occur.

13.3.2 Transition to Seres. Upon the effectiveness of any termination of this Agreement in its entirety:

(a) All rights and licenses granted to NHSc in Article 2 shall terminate, all rights of NHSc under the Licensed Patents and Licensed Know-How shall revert to Seres, and NHSc shall cease all use of the Licensed Patents and Licensed Know-How;

(b) To the extent that NHSc or its Affiliates holds any Regulatory Filings and/or Regulatory Approvals for Collaboration Products in the Territory, all of NHSc's and its Affiliates' rights, title and interests therein, shall be assigned and/or transferred to Seres or its designee. All documents relating to or necessary to further Develop and Commercialize the Collaboration Products in the Field to the extent Controlled by NHSc, as they exist as of the date of such termination, and all of NHSc's and its Affiliates' right, title and interest therein and thereto, shall be assigned and transferred to Seres or its designee. Any existing agreements between NHSc or its Affiliates and any Third Party that are solely or primarily related to the Development or Commercialization of Collaboration Products in the Field, and all of NHSc's and its Affiliates' right, title and interest therein and thereto, shall at Seres' option be terminated or assigned and transferred to Seres or its designee. NHSc shall provide Seres with one (1) copy of the foregoing documents and filings and all documents and filings contained in or referenced in any such filings, together with the raw and summarized data for any preclinical and clinical trials of the Collaboration Product in the Field (and where reasonably available, electronic copies thereof);

(c) subject to Section 13.3.1, 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 shall remain due and payable; 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;

(d) should NHSc or its Affiliates own or control any inventory of any Collaboration Product suitable for use or sale in the Territory, NHSc shall notify Seres in writing and Seres shall have the right (but not the obligation) to purchase such Collaboration Product from NHSc [\*\*\*], except that NHSc shall be entitled to retain such quantity of any Collaboration Product as it requires in order to (i) comply with the requirements of any Regulatory Authority and (ii) satisfy any binding order for the Collaboration Product from a Third Party entered into by NHSc or any of its Affiliates prior to the date of termination (subject to payment of royalties therefor hereunder). NHSc, if requested by Seres, shall use reasonable efforts to cause its sublicensees to sell any inventory of Collaboration Products they may own or control to Seres in accordance with and subject to the foregoing terms. For the avoidance of doubt, the supply of any Collaboration Product by NHSc or any of its Affiliates to any Third Party following the date of termination in satisfaction of any binding order for Collaboration Product from that Third Party entered into by NHSc prior to the date of termination shall not constitute a breach of this Agreement or an infringement of any intellectual property rights Controlled by Seres (provided royalties are paid in respect thereof as provided in this Agreement);

(e) NHSc shall assign (or, if applicable, cause its Affiliate to assign) to Seres all of NHSc's (and such Affiliates') right, title and interest in and to any registered or unregistered Trademark, Trademark application or internet domain name that is specific to a Collaboration Product in the Territory, [\*\*\*], except that, other than in the case of a termination by Seres pursuant to Section 13.2.3 [\*\*\*];

(f) NHSc shall and hereby does grant to Seres an exclusive license, with the right to grant sublicenses through multiple tiers of sublicensees, under all Patents, trade secrets, know-how and other intellectual property rights Controlled by NHSc or its Affiliates as of the termination date that, absent the license granted in this Section 13.3.2(f), would be infringed by the sale of any Collaboration Products in the Field in any country in the Territory or the Retained Territory, to Manufacture, use, import, sell and offer for sale and otherwise Develop and Commercialize Collaboration Products in the Field in the Territory or the Retained Territory;

(g) NHSc will return to Seres or, upon election of Seres, destroy all Product Literature, samples and other sales or sales training materials in the possession of NHSc and its sales representatives and sales management as promptly as practical after the date of termination;

(h) subject to Section 13.2.1, to the extent permissible pursuant to applicable Laws, NHSc shall transition all Development, Commercialization and other activities undertaken by NHSc and its Affiliates hereunder to Seres or Seres' designee and shall use Diligent Efforts to cause to be transitioned any such activities undertaken by any of NHSc's sublicensees. Notwithstanding the foregoing, NHSc shall only transition any ongoing Development activities undertaken by NHSc or its Affiliates or sublicensees hereunder to Seres or its designee upon Seres' written notice to NHSc that Seres or its designee intends to continue such Development following the effective time of such termination; and

(i) unless termination is by Seres pursuant to Section 13.2.3, [\*\*\*].

13.3.3 Further Effects of Termination. If this Agreement is terminated as provided in Section 13.2, 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: 2.1.5, 2.1.6, 2.2, 4.7, 4.8, 8.12, 10.1, 11, 12, 13.3, 13.4, 14.3, 15.1, 15.2, 15.3, 15.4, 15.6, 15.7, 15.8, 15.9, 15.10, 15.13, 15.14 and 15.15; (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.

13.4 Post-Termination Royalties. Except if this Agreement is terminated by Seres pursuant to Section 13.2.3, as further consideration for the licenses, assignments and transfers set forth in Section 13.3.2, following termination of this Agreement, until NHSc has recouped an amount equal to (i) [\*\*\*] in respect of all Collaboration Products and (ii) [\*\*\*] in respect of all Collaboration Products, Seres shall pay to NHSc a royalty of [\*\*\*] of Net Sales of all Collaboration Products in the Territory, excluding those Net Sales in any Decision Country in which NHSc did not retain its rights under Section 4.1. Sections [\*\*\*] shall apply to Seres with respect to such royalties owing by Seres, *mutatis mutandis*, except that all references in the definition of Net Sales to NHSc shall be deemed to refer to Seres and only to Net Sales in the Territory.

13.5 NHSc's Rights in Lieu of Termination. If NHSc is entitled to terminate this Agreement pursuant to Section 13.2.2 or Section 13.2.3, NHSc may elect either to (i) terminate this Agreement (in which case the applicable provisions of Sections 13.3 and 13.4 shall apply), or (ii) continue this Agreement, subject to the following provisions which shall be effective upon NHSc's notice of such election pursuant to this clause (ii) (the "**NHSc Election Notice**"):

13.5.1 the licenses and rights granted to NHSc pursuant to Section 2.1 and Section 2.3 shall remain in effect for the duration of the Term.

13.5.2 if NHSc is entitled to terminate this Agreement pursuant to 13.2.3 due to Seres' material breach in respect of one or more of the Collaboration Products, the Affected Product(s) and the Exploitation thereof shall thereafter no longer be within the purview of the JSC.

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

13.5.4 promptly following the provision by NHSc of the NHSc Election Notice, the Parties shall establish a working group comprised of an equal number of representatives of

each Party, which representatives shall have the requisite seniority, authority and experience level to make recommendations in accordance with this Section 13.5 (the “**Transition Working Group**” or the “**TWG**”). The TWG shall meet promptly following its formation to discuss and, as applicable, facilitate the transitioning of then-ongoing Development activities in respect of the Affected Products (as further discussed below) and make recommendations to the Parties with respect thereto. To the extent, following the NHSc Election Notice, there are any then-ongoing Development activities conducted by either Party under any Development Plan which relate exclusively to an Affected Product(s) in the Territory, then Section 13.5.5 shall apply. If such then-ongoing Development activities relate to an Affected Product in both the Territory and the Retained Territory, then, except as the Parties may otherwise agree taking into consideration the recommendations of the TWG, (x) if NHSc’s termination right in relation to such Affected Product does not relate to a material breach on the part of Seres relating to its conduct of such Development activities, Seres shall complete such then-ongoing Development activities in accordance with this Agreement, or (y) if NHSc’s termination right in relation to such Affected Product does relate to a material breach on the part of Seres relating to its conduct of such Development activities, NHSc shall have the right, at its election and in its discretion, to require the transition of such Development activities to NHSc. Notwithstanding anything to the contrary contained herein, Seres shall be permitted to continue any Development activity which has been conducted solely by Seres prior to the NHSc Election Notice and which relates exclusively to the Retained Territory and would not reasonably be expected to impact the NHSc Territory. In furtherance of the foregoing:

(a) If any applicable Development activity is to be continued pursuant to this Section 13.5.4, then the Party that is to conduct such activity, in accordance with the foregoing, shall carry out such activity under the applicable Development Plan then in effect and the Parties shall continue to be responsible for the associated Shared Development Costs under such Development Plan in accordance with the Development Budget included therein and each Party shall retain its rights to use data derived from such Development activity as provided under this Agreement, provided that such Party continues to fund its share of Shared Development Costs of such Development activity in accordance with Section 4.8.

(b) If NHSc elects to have a particular Development activity which has previously been conducted by Seres under the applicable Development Plan transitioned to NHSc in accordance with the foregoing, then Seres shall, at its cost, effect an orderly transition to NHSc or NHSc’s designee of such Development activity.

(c) If NHSc has the right to require the transition of a particular Development activity in respect of an Affected Product to NHSc in accordance with the foregoing, and elects to not exercise such right, then Seres shall have the right (but not the obligation) to continue such Development activity; provided that NHSc shall retain of the rights to use the data derived therefrom as provided in this Agreement if NHSc continues to fund its share of the Shared Development Costs of such Development activity in accordance with Section 4.8. In the event that Seres decides not to continue such Development activity, Seres shall bear the wind-up costs related thereto.

13.5.5 Seres shall use Diligent Efforts to effect an orderly transition, [\*\*\*], to NHSc or NHSc's designee of all Development activities that are undertaken by Seres and its sublicensees pursuant to all Development Plans and that are exclusively related to Development of the Affected Products for Commercialization in the Territory by NHSc and its sublicensees, pursuant to this Agreement. Notwithstanding the foregoing, Seres shall only transition any ongoing Development activities undertaken by Seres or its sublicensees to NHSc or its designee upon NHSc's written notice to Seres that NHSc or its designee intends to continue such Development following the effective time of such termination, and Seres shall wind down, as soon as practicable [\*\*\*], any Development activities in respect of the Affected Products which NHSc does not elect to have so transitioned.

13.5.6 at NHSc's request, Seres shall use Diligent Efforts to terminate or to assign to NHSc or its designated Affiliate any agreement (other than a license agreement) solely relating to the Development, Commercialization or Manufacture of the Affected Products in or for the Territory, provided that such agreement is in effect as of the date of the NHSc Election Notice and in the case of an assignment, if assignment is permitted under the relevant agreement or by the applicable Third Party. To the extent any such agreement is not terminated or assigned to NHSc, then after the date of the NHSc Election Notice, Seres or its Affiliate shall continue to exercise its rights under and in accordance with such agreement with respect to the Affected Products and the Territory, as directed by and for the benefit of NHSc until such time as NHSc obtains an agreement with such Third Party.

13.5.7 NHSc may continue to purchase the Affected Products then Manufactured by Seres for NHSc under and in accordance with the terms of any Development Supply Agreement or Commercial Supply Agreement then in effect for the term of such agreement. However, if the Commercial Supply Agreement has not yet been executed (which agreement was expected to provide provisions for [\*\*\*]), unless the Parties enter into the Commercial Supply Agreement [\*\*\*] after NHSc exercises its rights under this Section 13.5, [\*\*\*], including providing [\*\*\*]. Such technology transfer may be implemented by means of [\*\*\*]. Each such Third Party Manufacturer [\*\*\*]. Recognizing the importance of [\*\*\*].

13.5.8 Royalties payable to Seres pursuant to Section 8.2.2. or Section 8.3.3, as applicable, with respect to Net Sales of Affected Products from and after the effective date of the NHSc Election Notice shall be reduced by [\*\*\*]; provided that [\*\*\*]. Sections [\*\*\*] shall apply to all such royalties payable pursuant to this Section 13.5.8. NHSc shall remain obligated to pay Milestone License Payments pursuant to Section 8.2.1 and Section 8.3.1 relating to the Affected Products that become payable after the effective date of the NHSc Election Notice; provided that (a) any Milestone License Payment set forth in Section 8.2.1 or Section 8.3.1 that becomes payable after the effective date of the NHSc Election Notice based upon achievement of a Milestone Event in respect of the receipt of Regulatory Approval for such Affected Products, shall be reduced by [\*\*\*] and (b) any Milestone License Payment set forth in Section 8.2.1 or Section 8.3.1 that becomes payable after the effective date of the NHSc Election Notice based upon achievement of a Milestone Event other than those referred to in the immediately preceding clause (a) shall be reduced by [\*\*\*]. Net Sales of Affected Products from and after the effective date of the NHSc Election Notice shall be included for purposes of determining whether any Milestone Event contemplated in Section 8.3.2 or Section 8.4 has been achieved, but for

purposes of determining whether such Milestone Event has been achieved, the Net Sales of such Affected Products shall be reduced by [\*\*\*].

13.5.9 Nothing herein shall limit NHSc's rights to pursue damages pursuant to a claim under this Agreement. In addition, without limiting any rights NHSc may have to pursue damages pursuant to a claim hereunder, NHSc may offset against any amounts payable to Seres pursuant to this Agreement amounts due NHSc for damages which Seres agrees are owed to NHSc or which have been determined to be owed to NHSc pursuant to a final and binding arbitral award obtained pursuant to Section 14.3 or pursuant to a final judgment or order of a court of competent jurisdiction (in each case, subject to the preceding sentence).

13.5.10 Except to the extent provided in this Section 13.5, this Agreement shall remain in full force and effect.

13.6 Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Seres or NHSc 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 14 DISPUTE RESOLUTION

14.1 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 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 14.1. 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 [\*\*\*] of the Notice of Dispute, the Parties shall promptly refer the Dispute to, as appropriate, Seres' and Nestlé Health Science S.A.'s respective [\*\*\*] senior officers (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 [\*\*\*] 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 Nestlé Health Science S.A. for resolution.

14.2 Casting Votes. If for any reason any Dispute cannot be resolved in accordance with Section 14.1, then, subject to the remaining provisions of this Section 14.2, (i) Seres shall have final decision making authority with respect to such Dispute if [\*\*\*], including [\*\*\*]; provided, in each case, that [\*\*\*] under this Agreement, and (ii) NHSc shall have final decision making authority with respect to such Dispute if the [\*\*\*], including the [\*\*\*]; provided, in each case, that [\*\*\*] under this Agreement. The foregoing notwithstanding, Seres and NHSc, as applicable, may not use its final decision-making authority pursuant to this Section 14.2 to: (i) [\*\*\*]. For the avoidance of doubt, with respect to any matter coming before the JSC or any subcommittee or subgroup thereof for which Seres or NHSc, as applicable, has a casting vote (i.e., final decision making authority), nothing herein will prevent the relevant vote or decision from being taken by Seres or NHSc, as applicable, but such casting vote and resulting decision shall not preclude the other Party from asserting or pursuing as a Related Claim in accordance with Section 14.3 any claim that such decision, or any actions or omissions that are undertaken by or on behalf of Seres or NHSc, as applicable, pursuant to such decision, constitutes a breach of this Agreement. For the further avoidance of doubt, either Party may commence arbitration under Section 14.3 if the Party believes that the other Party has not properly exercised its final decision-making authority under the terms of this Section 14.2.

14.3 Arbitration. Any Dispute not resolved by an executed written agreement of the Parties in accordance with Section 14.1 or any Dispute about a Party's proper use of its casting vote in accordance with Section 14.2, as well as any related claims or other disputes arising out of or in connection with this Agreement including any question regarding its existence, validity or termination, whether for breach of contract, tortious conduct or otherwise and whether predicated on common law, statute or otherwise (collectively, the "**Related Claims**"), shall be referred to and finally resolved by arbitration under the London Court of International Arbitration (the "**LCIA**") rules (the "**Rules**"), which Rules are deemed to be incorporated by reference into this clause. The number of arbitrators shall be [\*\*\*], appointed in accordance with the Rules. The seat or legal place of arbitration shall be London, England. The language to be used in the arbitral proceedings shall be English.

(a) Within [\*\*\*] after the appointment of the arbitrator by the LCIA, the arbitrator and the Parties shall meet, and each Party shall provide to the arbitrator a written summary of: [\*\*\*]. The arbitrator shall set a date for a hearing, which shall be no later than [\*\*\*] after the appointment of the arbitrator by the LCIA, for the presentation of evidence and legal arguments concerning each of the issues identified by the Parties; provided, however, that the Parties may jointly agree in writing to extend the foregoing

deadlines, or the arbitrator may unilaterally extend this deadline if he or she determines in his or her sole discretion that this is required in the interests of justice.

(b) The arbitrator shall use his or her best efforts to rule on each disputed issue within [\*\*\*] after the completion of the hearing described in Section 14.3(a); provided, however, that the Parties may jointly agree in writing to extend the foregoing deadlines, or the arbitrator may unilaterally extend this deadline if he or she determines in his or her sole discretion that this is required in the interests of justice. Nothing contained herein shall be construed to permit the arbitrator to: [\*\*\*]

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

(d) The arbitrator shall have the power to grant any remedy or relief that he or she deems just and equitable, including but not limited to [\*\*\*]. Notwithstanding the foregoing, nothing in this Agreement shall prevent either party from seeking any provisional/preliminary relief (including, but not limited to, injunctions, attachments or other such orders in aid of arbitration) from any court of competent jurisdiction, and any such application to a court for provisional/preliminary relief shall not be deemed incompatible with the agreement to arbitrate or a waiver of the right to arbitrate.

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

(f) Notwithstanding anything in this Article 14, any dispute to determine [\*\*\*] shall be [\*\*\*].

## **ARTICLE 15 MISCELLANEOUS**

15.1 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.

15.2 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 NHSc:

Nestec Ltd.  
Avenue Nestlé 55  
1800 Vevey  
Switzerland  
Attention: General Counsel, Nestlé Health Science

with a copy to:

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

If to Seres:

Seres Therapeutics, Inc.  
215 First Street  
Cambridge, MA 02142  
Attention: [\*\*\*]

with a copy to:

Latham & Watkins LLP  
John Hancock Tower  
200 Clarendon Street  
Boston, MA 02116  
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 [\*\*\*] 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 15.2.

15.3 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, such consent not to be unreasonably withheld, delayed or conditioned; 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 15.3 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, [\*\*\*]. The Licensed Patents and Licensed Know-How shall [\*\*\*]. For purposes of this Section 15.3, "**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.

15.4 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.

15.5 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.

15.6 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.

15.7 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 Commonwealth of Massachusetts, 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.

15.8 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.

15.9 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 11.4, 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 [\*\*\*] 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 15.9) can be re-released by either Party without a requirement for re-approval.

15.10 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 NHSc as partners, agents 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.

15.11 Entire Agreement. The Parties and Nestlé Health Science SA 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 Amended and Restated Confidential Disclosure Agreement, dated as of October 30, 2014, between Seres (f/k/a Seres Health, Inc.) and Nestlé Health Science SA (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.

15.12 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.

15.13 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.

15.14 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.

15.15 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/ Roger Pomerantz  
(Signature)

Name: Roger Pomerantz

Title: President, CEO and Chairman

**NESTEC LTD.**

By: /s/ Claudio Vuoni  
(Signature)

Name: Claudio Vuoni

Title: General Counsel NHSc

*Solely for purposes of Section 15.11:*

**NESTLÉ HEALTH SCIENCE SA**

By: /s/ Claudio Vuoni  
(Signature)

Name: Claudio Vuoni

Title: General Counsel

*[Signature page to Collaboration and License Agreement]*

**Exhibit A**

**Description of SER-109**

[\*\*\*]

**Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4), 200.83 and 240.24b-2**

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Description of SER-262

[\*\*\*]

Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4), 200.83 and 240.24b-2

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**Exhibit C**

**Description of SER-287**

[\*\*\*]

**Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4), 200.83 and 240.24b-2**

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**Exhibit D**

**Description of SER-301**

[\*\*\*]

**Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4), 200.83 and 240.24b-2**

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**Exhibit E**

**Elements of Global Development Plan**

[\*\*\*]

**Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4), 200.83 and 240.24b-2**

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**Exhibit F**

**Licensed Patents**

TITLE	COUNTRY	STATUS	MATTER-SUB MATTER TYPE	APPLICATION NUMBER	FILING DATE	NATIONAL ENTRY DATE
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***

**Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4), 200.83 and 240.24b-2**

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TITLE	COUNTRY	STATUS	MATTER-SUB MATTER TYPE	APPLICATION NUMBER	FILING DATE	NATIONAL ENTRY DATE
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***

Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4), 200.83 and 240.24b-2

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TITLE	COUNTRY	STATUS	MATTER-SUB MATTER TYPE	APPLICATION NUMBER	FILING DATE	NATIONAL ENTRY DATE
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***

**Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4), 200.83 and 240.24b-2**

TITLE	COUNTRY	STATUS	MATTER-SUB MATTER TYPE	APPLICATION NUMBER	FILING DATE	NATIONAL ENTRY DATE
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***

Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4), 200.83 and 240.24b-2



TITLE	COUNTRY	STATUS	MATTER-SUB MATTER TYPE	APPLICATION NUMBER	FILING DATE	NATIONAL ENTRY DATE
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***

Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4), 200.83 and 240.24b-2

TITLE	COUNTRY	STATUS	MATTER-SUB MATTER TYPE	APPLICATION NUMBER	FILING DATE	NATIONAL ENTRY DATE
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***
***	***	***	***	***	***	***

Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4), 200.83 and 240.24b-2

TITLE	COUNTRY	STATUS	MATTER-SUB MATTER TYPE	APPLICATION NUMBER	FILING DATE	NATIONAL ENTRY DATE
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]

**Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4), 200.83 and 240.24b-2**



**Exhibit G**

**Core Countries**

[\*\*\*]

**Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4), 200.83 and 240.24b-2**

**EMPLOYMENT AGREEMENT**

This Employment Agreement (this "Agreement"), dated as of December 11, 2015, is made by and between Seres Therapeutics, Inc., a Delaware corporation (together with any successor thereto, the "Company"), and Wael Hashad ("Executive") (collectively referred to as the "Parties" or individually referred to as a "Party").

**RECITALS**

- A. It is the desire of the Company to assure itself of the services of Executive by entering into this Agreement.
- B. Executive and the Company mutually desire that Executive be employed by the Company on the terms herein provided, commencing on January 4, 2016 or another date mutually agreed by the Parties (the date Executive actually commences such employment, the "Effective Date").
- C. This Agreement will become effective upon the Effective Date.

**AGREEMENT**

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

**1. Employment.**

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

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

(c) Positions and Duties. Executive shall serve as Executive Vice President and Chief Commercial Officer of the Company with such responsibilities, duties and authority normally associated with such positions and as may from time to time be assigned to Executive by the Chief Executive Officer of the Company. Executive shall devote substantially all of Executive's working time and efforts to the business and affairs of the Company (which shall include service

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

## **2. Compensation and Related Matters.**

(a) Annual Base Salary. During the Term, Executive shall receive a base salary at a rate of \$340,000 per annum, which shall be paid in accordance with the customary payroll practices of the Company and shall be pro-rated for partial years of employment. Such annual base salary shall be reviewed (and may be adjusted) from time to time by the Board of Directors of the Company or an authorized committee of the Board (in either case, the "Board") (such annual base salary, as it may be adjusted from time to time, the "Annual Base Salary").

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

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

(d) Vacation. During the Term, Executive shall be entitled to paid personal leave in accordance with the Company's Policies, which currently provide for 20 days of vacation per full calendar year of employment. Any vacation shall be taken at the reasonable and mutual convenience of the Company and Executive.

(e) Business Expenses. During the Term, the Company shall reimburse Executive for all reasonable travel and other business expenses incurred by Executive in the performance of Executive's duties to the Company in accordance with the Company's expense reimbursement Policy.

(f) Key Person Insurance. At any time during the Term, the Company shall have the right to insure the life of Executive for the Company's sole benefit. The Company shall have the right to determine the amount of insurance and the type of policy. Executive shall reasonably

cooperate with the Company in obtaining such insurance by submitting to physical examinations, by supplying all information reasonably required by any insurance carrier, and by executing all necessary documents reasonably required by any insurance carrier, provided that any information provided to an insurance company or broker shall not be provided to the Company without the prior written authorization of Executive. Executive shall incur no financial obligation by executing any required document, and shall have no interest in any such policy.

(g) Equity. Subject to approval by the Board, the Company will grant Executive an option (the “Option”) under the Company’s 2015 Incentive Award Plan (the “Plan”) to purchase 100,000 shares of the Company’s common stock (subject to adjustment for corporate events as set forth in the Plan) at an exercise price per share equal to the per share fair market value of the Company’s common stock on the date of grant, as determined in accordance with the Plan. The Option will vest as to 25% of the shares subject to the Option on the first anniversary of the Effective Date and as to an additional 6.25% of such shares upon Executive’s completing each three months of continuous service to the Company thereafter. In all respects, the Option will be governed by and subject to the terms of the Plan and a separate stock option agreement to be entered into between Executive and the Company.

(h) Relocation Assistance. The Company will reimburse Executive for, or directly pay on Executive’s behalf, up to \$50,000 of reasonable moving expenses Executive incurs prior to December 1, 2016 in relocating Executive’s primary residence to the Cambridge, Massachusetts area, which will include the costs of providing Executive with relocation coordination services from the Company’s third-party provider in accordance with Company Policies to help Executive manage the logistics of Executive’s relocation (collectively, the “Relocation Assistance”). The Company will also provide Executive with an additional payment (a “Gross-Up Payment”) in an amount such that, after payment by Executive of all income and employment taxes imposed on the Gross-Up Payment, Executive retains from the Gross-Up Payment an amount equal to all of the income and employment taxes imposed on the Relocation Assistance Executive receives. All payments to Executive or for Executive’s benefit under this Section shall be subject to Section 9(l), except that notwithstanding anything in such Section to the contrary, Executive will promptly, and in no event later than December 15, 2016, submit all requests for Relocation Assistance payments, together with any supporting documentation that the Company reasonably requests, and the Company will make all Relocation Assistance payments in 2016, regardless of when the corresponding expenses were incurred. In the event Executive voluntarily terminates Executive’s employment with the Company other than for Good Reason or the Company terminates Executive’s employment for Cause, in either case, prior to the second anniversary of the Effective Date, Executive will repay the Company the Relocation Assistance and Gross-Up Payment Executive has received as follows:

(i) If the termination of employment occurs on or prior to the first anniversary of the Effective Date, Executive will repay 100% of the Relocation Assistance and Gross-Up Payment Executive has received;

(ii) If the termination of employment occurs after the first anniversary of the Effective Date and on or prior to the 15-month anniversary of the Effective Date, Executive



will repay 75% of the Relocation Assistance and Gross-Up Payment Executive has received;

(iii) If the termination of employment occurs after the 15-month anniversary of the Effective Date and on or prior to the 18-month anniversary of the Effective Date, Executive will repay 50% of the Relocation Assistance and Gross-Up Payment Executive has received; and

(iv) If the termination of employment occurs after the 18-month anniversary of the Effective Date and prior to the second anniversary of the Effective Date, Executive will repay 25% of the Relocation Assistance and Gross-Up Payment Executive has received.

If Executive is required to repay any Relocation Assistance or Gross-Up Payment hereunder, the Company will be entitled in its discretion to deduct from any other compensation or amounts payable by the Company or its affiliates to Executive all or any portion of the Relocation Assistance and the Gross-Up Payment that Executive is required to repay.

### **3. Termination.**

Executive's employment hereunder may be terminated by the Company or Executive, as applicable, without any breach of this Agreement under the following circumstances:

(a) Circumstances.

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

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

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

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

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

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

(b) Notice of Termination. Any termination of Executive's employment by the Company or by Executive under this Section 3 (other than termination pursuant to paragraph (a)(i)) shall be communicated by a written notice to the other Party hereto (i) indicating the specific termination provision in this Agreement relied upon, (ii) setting forth in reasonable detail the facts

and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, if applicable, and (iii) specifying a Date of Termination which, if submitted by Executive, shall be at least forty-five (45) days following the date of such notice (a "Notice of Termination"); *provided, however*, that in the event that Executive delivers a Notice of Termination to the Company, the Company may, in its sole discretion, change the Date of Termination to any date that occurs following the date of Company's receipt of such Notice of Termination and is prior to the date specified in such Notice of Termination. A Notice of Termination submitted by the Company may provide for a Date of Termination on the date Executive receives the Notice of Termination, or any date thereafter elected by the Company in its sole discretion. The failure by the Company to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Cause shall not waive any right of the Company hereunder or preclude the Company from asserting such fact or circumstance in enforcing the Company's rights hereunder.

(c) Company Obligations upon Termination. Upon termination of Executive's employment pursuant to any of the circumstances listed in this Section 3, Executive (or Executive's estate) shall be entitled to receive the sum of: (i) the portion of Executive's Annual Base Salary earned through the Date of Termination, but not yet paid to Executive; (ii) any expenses owed to Executive pursuant to Section 2(e) or Section 2(h) (subject to Executive's repayment obligations under such Section); and (iii) any amount accrued and arising from Executive's participation in, or benefits accrued under any employee benefit plans, programs or arrangements, which amounts shall be payable in accordance with the terms and conditions of such employee benefit plans, programs or arrangements (collectively, the "Company Arrangements"). Except as otherwise expressly required by law (e.g., COBRA) or as specifically provided herein, all of Executive's rights to salary, severance, benefits, bonuses and other compensatory amounts hereunder (if any) shall cease upon the termination of Executive's employment hereunder. In the event that Executive's employment is terminated by the Company for any reason, Executive's sole and exclusive remedy shall be to receive the payments and benefits described in this Section 3(c) or Section 4, as applicable.

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

#### **4. Severance Payments.**

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

(b) Termination without Cause, or Resignation from the Company for Good Reason. If Executive's employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive's resignation for Good Reason, then, subject to Executive signing

on or before the 21<sup>st</sup> day following Executive's Separation from Service (as defined below), and not revoking, a release of claims substantially in the form attached as Exhibit A to this Agreement (the "Release"), and Executive's continued compliance with Section 5, Executive shall receive, in addition to payments and benefits set forth in Section 3(c), the following:

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

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

(iii) if Executive elects to receive continued medical, dental or vision coverage under one or more of the Company's group healthcare plans pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company shall directly pay, or reimburse Executive for, the COBRA premiums for Executive and Executive's covered dependents under such plans during the period commencing on Executive's Separation from Service and ending upon the earliest of (X) the last day of the Severance Period, (Y) the date that Executive and/or Executive's covered dependents become no longer eligible for COBRA or (Z) the date Executive becomes eligible to receive healthcare coverage from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility). Notwithstanding the foregoing, if the Company determines in its sole discretion that it cannot provide the foregoing benefit without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act) or incurring an excise tax, the Company shall in lieu thereof provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive's and Executive's covered dependents' group health coverage in effect on the Date of Termination (which amount shall be based on the premium for the first month of COBRA coverage), less the amount Executive would have had to pay to receive group health coverage for Executive and his or her covered dependents based on the cost sharing levels in effect on the Date of Termination, which payments shall be made regardless of whether Executive elects COBRA continuation coverage and shall commence in the month following the month in which the Date of Termination occurs and shall end on the earlier of (X) the last day of the Severance Period, (Y) the date that Executive and/or Executive's covered dependents become no longer eligible for COBRA or (Z) the date Executive becomes eligible to receive healthcare coverage from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility).

(c) Change in Control. Notwithstanding anything to the contrary in Section 4(b), in the event Executive's employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive's resignation for Good Reason, in either case, within 60 days prior to or 12 months following the date of a Change in Control, subject to Executive signing on or before the 21<sup>st</sup> day following Executive's Separation from Service, and not revoking, the Release, all unvested equity or equity-based awards held by Executive under any Company equity compensation plans that vest solely based on the passage of time shall immediately become 100% vested (for the avoidance of doubt, with any such awards that vest in whole or in part based on the attainment of performance-vesting conditions being governed by the terms of the applicable award agreement).

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

5. **Restrictive Covenants**. As a condition to the effectiveness of this Agreement, Executive will execute and deliver to the Company prior to the Effective Date the Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement attached as Exhibit B (the "Proprietary Information Agreement"). Executive agrees to abide by the terms of the Proprietary Information Agreement, which are hereby incorporated by reference into this Agreement. Executive acknowledges that the provisions of the Proprietary Information Agreement will survive the termination of Executive's employment and the termination of the Term for the periods set forth in the Proprietary Information Agreement.

6. **Assignment and Successors**.

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

7. **Certain Definitions**.

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

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

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

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

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

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

(vi) Executive's commission of an act of fraud, embezzlement, misappropriation, willful misconduct, or breach of fiduciary duty against the Company or any of its affiliates.

(b) Change in Control. "Change in Control" shall have the meaning set forth in the version of the Seres Therapeutics, Inc. 2015 Incentive Award Plan in effect on the Effective Date.

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

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

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

(f) Good Reason. For the sole purpose of determining Executive's right to severance payments and benefits as described above, Executive's resignation will be for "Good Reason" if Executive resigns within ninety days after any of the following events, unless Executive consents

to the applicable event: (i) a decrease in Executive's Annual Base Salary, other than a reduction in Annual Base Salary of less than 10% that is implemented in connection with a contemporaneous reduction in annual base salaries affecting other senior executives of the Company, (ii) a material decrease in Executive's authority or areas of responsibility as are commensurate with Executive's title or positions, or (iii) the relocation of Executive's primary office to a location more than 50 miles from the Boston metropolitan area. Notwithstanding the foregoing, no Good Reason will have occurred unless and until Executive has: (a) provided the Company, within 60 days of Executive's knowledge of the occurrence of the facts and circumstances underlying the Good Reason event, written-notice stating with specificity the applicable facts and circumstances underlying such finding of Good Reason; and (b) provided the Company with an opportunity to cure the same within 30 days after the receipt of such notice.

## **8. Parachute Payments.**

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

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

(c) All determinations regarding the application of this Section 8 shall be made by an accounting firm or consulting group with experience in performing calculations regarding the applicability of Section 280G of the Code and the Excise Tax selected by the Company (the "Independent Advisors"). For purposes of determinations, no portion of the Total Payments shall be taken into account which, in the opinion of the Independent Advisors, (i) does not constitute a

“parachute payment” within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) or (ii) constitutes reasonable compensation for services actually rendered, within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the “base amount” (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation. The costs of obtaining such determination and all related fees and expenses (including related fees and expenses incurred in any later audit) shall be borne by the Company.

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

## **9. Miscellaneous Provisions.**

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

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

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

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

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

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

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

(e) Entire Agreement. The terms of this Agreement, and the Proprietary Information Agreement incorporated herein by reference as set forth in Section 5, are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and supersede all prior understandings and agreements, whether written or oral. The Parties further intend that this Agreement shall constitute the complete and exclusive statement of their terms and that no extrinsic evidence whatsoever may be introduced in any judicial, administrative, or other legal proceeding to vary the terms of this Agreement.

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

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

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

(i) Arbitration. Any controversy, claim or dispute arising out of or relating to this Agreement, shall be settled solely and exclusively by a binding arbitration process administered by JAMS/Endispute in Boston, Massachusetts. Such arbitration shall be conducted in accordance with the then-existing JAMS/Endispute Rules of Practice and Procedure, with the following exceptions if in conflict: (i) one arbitrator who is a retired judge shall be chosen by JAMS/Endispute; (ii) each Party to the arbitration will pay one-half of the expenses and fees of the arbitrator, together with other expenses of the arbitration incurred or approved by the arbitrator; and (iii) arbitration may proceed in the absence of any Party if written notice (pursuant to the JAMS/Endispute rules and regulations) of the proceedings has been given to such Party. Each Party shall bear its own attorney’s fees and expenses; provided that the arbitrator may assess the prevailing Party’s fees and costs against the non-prevailing Party as part of the arbitrator’s award. The Parties agree to abide by all decisions and awards rendered in such proceedings. Such decisions and awards rendered by the arbitrator shall be final and conclusive. All such controversies, claims or disputes shall be settled in this manner in lieu of any action at law or equity; *provided, however*, that nothing in this subsection shall be construed as precluding the bringing of an action for injunctive relief or specific performance as provided in this Agreement.



This dispute resolution process and any arbitration hereunder shall be confidential and neither any Party nor the neutral arbitrator shall disclose the existence, contents or results of such process without the prior written consent of all Parties, except where necessary or compelled in a Court to enforce this arbitration provision or an Award from such arbitration or otherwise in a legal proceeding. If JAMS/Endispute no longer exists or is otherwise unavailable, the Parties agree that the American Arbitration Association (“AAA”) shall administer the arbitration in accordance with its then-existing rules as modified by this subsection. In such event, all references herein to JAMS/Endispute shall mean AAA. Notwithstanding the foregoing, Executive and the Company each have the right to resolve any issue or dispute over intellectual property rights by Court action instead of arbitration.

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

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

(l) Section 409A.

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

(ii) *Separation from Service.* Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is considered nonqualified deferred compensation under Section 409A and is designated under this Agreement as payable upon Executive’s termination of employment shall be payable only upon Executive’s “separation from service” with the Company within the meaning of Section 409A (a “Separation from Service”) and, except as provided below, any such compensation or benefits described in Section 4 shall not be paid, or, in the case of installments, shall not commence payment, until the thirtieth (30th) day following Executive’s Separation from Service (the “First Payment Date”). Any installment payments that would have been made to Executive during the thirty (30) day period immediately following Executive’s Separation from Service but for the preceding sentence shall be paid to Executive on the First Payment Date and the remaining payments shall be made as provided in this Agreement.

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

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

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

**10. Executive Acknowledgement.**

Executive acknowledges that Executive has read and understands this Agreement, is fully aware of its legal effect, has not acted in reliance upon any representations or promises made by the Company other than those contained in writing herein, and has entered into this Agreement freely based on Executive's own judgment.

[Signature Page Follows]

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

**SERES THERAPEUTICS, INC.**

By: /s/ Roger J. Pomerantz  
Name: Roger J. Pomerantz, M.D.  
Title: President and Chief Executive Officer

Wael Hashad

/s/ Wael Hashad

*[Signature Page to Employment Agreement]*

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## EXHIBIT A

### **Separation Agreement and Release**

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

WHEREAS, the Parties have previously entered into that certain Employment Agreement, dated as of December 11, 2015 (the “Employment Agreement”); and

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

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

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

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

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unsuspected, that Executive may possess against any of the Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the Effective Date of this Agreement (as defined in Section 7 below), including, without limitation:

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

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

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

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

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

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

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

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

Executive agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not release claims that cannot be released as a matter of law, including, but not limited to, Executive's right to report possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of

1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation, Executive's right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company (with the understanding that Executive's release of claims herein bars Executive from recovering such monetary relief from the Company or any Releasee), claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims to continued participation in certain of the Company's group benefit plans pursuant to the terms and conditions of COBRA, claims to any benefit entitlements vested as the date of separation of Executive's employment, pursuant to written terms of any employee benefit plan of the Company or its affiliates and Executive's right under applicable law and any Retained Claims. This release further does not release claims for breach of Section 3(c), Section 4(b) or Section 4(c) of the Employment Agreement.

3. Acknowledgment of Waiver of Claims under ADEA. Executive understands and acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive understands and agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the Effective Date of this Agreement. Executive understands and acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further understands and acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney prior to executing this Agreement; (b) Executive has 21 days within which to consider this Agreement; (c) Executive has 7 days following Executive's execution of this Agreement to revoke this Agreement pursuant to written notice to the General Counsel of the Company; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the 21 day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement.

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

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

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

7. Effective Date. If Executive has attained or is over the age of 40 as of the date of Executive's termination of employment, then each Party has seven days after that Party signs this

Agreement to revoke it and this Agreement will become effective on the eighth day after Executive signed this Agreement, so long as it has been signed by the Parties and has not been revoked by either Party before that date (the "Effective Date"). If Executive has not attained the age of 40 as of the date of Executive's termination of employment, then the "Effective Date" shall be the date on which Executive signs this Agreement.

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

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

Dated: \_\_\_\_\_

Wael Hashad

**SERES THERAPEUTICS, INC.**

Dated:

By:

Name:

Title:

## **EXHIBIT B**

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

In consideration and as a condition of my employment or continued employment by Seres Therapeutics, Inc. (the "Company"), I hereby agree as follows:

1. **Proprietary Information.** I agree that all information, whether or not in writing, whether or not disclosed before or after I was first employed by the Company, concerning the Company's business, technology, business relationships or financial affairs that the Company has not released to the general public (collectively, "Proprietary Information"), and all tangible embodiments thereof, are and will be the exclusive property of the Company. By way of illustration, Proprietary Information may include information or material that has not been made generally available to the public, such as: (a) *corporate information*, including plans, strategies, methods, policies, resolutions, notes, email correspondence, negotiations or litigation; (b) *marketing information*, including strategies, methods, customer identities or other information about customers, prospect identities or other information about prospects, or market analyses or projections; (c) *financial information*, including cost and performance data, debt arrangements, equity structure, investors and holdings, purchasing and sales data and price lists; and (d) *operational and technological information*, including plans, specifications, manuals, forms, templates, software, designs, methods, procedures, formulas, discoveries, inventions, improvements, biological or chemical materials, concepts and ideas; and (e) *personnel information*, including personnel lists, reporting or organizational structure, resumes, personnel data, compensation structure, performance evaluations and termination arrangements or

documents. Proprietary Information includes, without limitation, (1) information received in confidence by the Company from its customers or suppliers or other third parties, and (2) all biological or chemical materials and other tangible embodiments of the Proprietary Information. Nothing in this Agreement shall prohibit me from reporting possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 805 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation.

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

3. **Rights of Others.** I understand that the Company is now and may hereafter be subject to non-disclosure or confidentiality

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agreements with third persons which require the Company to protect or refrain from use of proprietary information. I agree to be bound by the terms of such agreements in the event I have access to such proprietary information.

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

5. **Developments.** I hereby assign and transfer and, to the extent any such assignment cannot be made at present, will assign and transfer, to the Company and its successors and assigns, all my right, title and interest in and to all Developments (as defined below) that: (a) are created, developed, made, conceived or reduced to practice by me (alone or jointly with others) or under my direction (collectively, "conceived") during the period of my employment and six (6) months thereafter and that relate to the business of the Company or to products, methods or services being researched, developed, manufactured or sold by the Company; or (b) result from tasks assigned to me by the Company; or (c) result from the use of premises, Proprietary Information or personal property (whether tangible or intangible) owned, licensed or leased by the Company (collectively, "Company-Related Developments"), and all patent rights, trademarks, copyrights and other intellectual

property rights in all countries and territories worldwide claiming, covering or otherwise arising from or pertaining to Company-Related Developments (collectively, "Intellectual Property Rights"). I further agree that "Company-Related Developments" include, without limitation, all Developments that (i) were conceived by me before my employment, (ii) relate to the business of the Company or to products, methods or services being researched, developed, manufactured or sold by the Company, and (iii) were not subject to an obligation to assign to another entity when conceived. I will make full and prompt disclosure to the Company of all Company-Related Developments, as well as all other Developments conceived by me during the period of my employment and six (6) months thereafter. I acknowledge that all work performed by me as an employee of the Company is on a "work for hire" basis. I hereby waive all claims to any moral rights or other special rights which I may have or accrue in any Company-Related Developments. "Developments" mean inventions, discoveries, designs, developments, methods, modifications, improvements, processes, biological or chemical materials, algorithms, databases, computer programs, formulae, techniques, trade secrets, graphics or images, audio or visual works, and other works of authorship.

To preclude any possible uncertainty, I have set forth on Appendix A attached hereto a complete list of Developments conceived by me before my employment that are not Company-Related Developments ("Prior Inventions"). I have also listed on Appendix A all patent rights of which I am an inventor, other than those contained within Intellectual Property Rights ("Other Patent Rights"). If no such disclosure is attached, I represent that there are no Prior Inventions or Other Patent

Rights. If, in the course of my employment with the Company, I incorporate a Prior Invention into a Company product, process or research or development program or other work done for the Company, I hereby grant to the Company a nonexclusive, royalty-free, fully paid-up, irrevocable, perpetual, worldwide license (with the full right to sublicense through multiple tiers) to make, have made, modify, use, offer for sale, import and sell such Prior Invention. Notwithstanding the foregoing, I will not incorporate, or permit to be incorporated, Prior Inventions in any Company-Related Development without the Company's prior written consent.

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

**6. Documents and Other Materials.** I will keep and maintain adequate and current records of all Proprietary Information and Company-Related Developments conceived by me, which records will be available to and remain the sole property of the Company at all times. All files, letters, notes, memoranda, reports, records, data, sketches, drawings, notebooks, layouts, charts, quotations and proposals, specification sheets, program listings, blueprints, models, prototypes, materials or other written, photographic or other tangible material containing or embodying Proprietary Information, whether created by me or others, which come into my custody or possession, are the exclusive property of the Company to be used by me only in the performance of my duties for the Company.

In the event of the termination of my employment for any reason, I will deliver to the Company all of the foregoing, and all other materials of any nature pertaining to the Proprietary Information of the Company and to my work, and will not take or keep in my possession any of the foregoing or any copies. Any property situated on the Company's premises and owned by the Company, including laboratory space, computers, disks and other storage media, filing cabinets or other work areas, is subject to inspection by the Company at any time with or without notice.

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

**8. Non-Competition and Non-Solicitation.** In order to protect the

Company's Proprietary Information and good will, during my employment and for a period of twelve (12) months following the termination of my employment for any reason (the "Restricted Period"), I will not directly or indirectly, whether as owner, partner, shareholder, director, consultant, agent, employee, co-venturer or otherwise:

(a) Engage, participate or invest in any business that develops, manufactures or markets microbiome therapeutics, or products or services that the Company has under development or that are the subject of active planning at any time during my employment (collectively, the "Competitive Products"); provided that this will not prohibit any possible investment in publicly traded stock of a company representing less than one percent of the stock of such company;

(b) Directly or indirectly, in any manner, other than for the benefit of the Company, (i) call upon, solicit, divert or take away any of the customers, business or prospective customers of the Company or any of its suppliers, and/or (ii) solicit, entice or attempt to persuade any other employee or consultant of the Company to leave the services of the Company for any reason.

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

(d) I acknowledge and agree that the provisions of this agreement shall apply during and following my employment by the Company, and shall not be affected by any

change in my job duties, whether material or immaterial.

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

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

belonging to any previous employer or others.

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

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

13. **Publications and Public Statements.** I will obtain the Company's written approval before publishing or submitting for publication any material that relates to my work at the Company and/or incorporates any Proprietary Information. To ensure that the Company delivers a consistent message about its products, services and operations to the public, and further in recognition that even positive statements may have a detrimental effect on the Company in certain securities transactions and other contexts, any statement about the Company which I create, publish or post during my period of employment and for six (6) months thereafter, on any media accessible by the public, including but not limited to electronic bulletin boards and Internet-based chat rooms, must first be reviewed and approved by an officer of the Company before it is released in the public domain.

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

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

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

17. **Exit Interview.** If and when I depart from the Company, I may be required to attend an exit interview and sign an "Employee Exit Acknowledgement" to reaffirm my acceptance and

acknowledgement of the obligations set forth in this Agreement. During the Restricted Period following termination of my employment, I will notify the Company of any change in my address and of each subsequent employment or business activity, including the name and address of my employer or other post-Company employment plans and the nature of my activities.

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

19. **Entire Agreement.** This Agreement constitutes the entire and only agreement between the Company and me respecting the

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

20. **Interpretation.** This Agreement will be deemed to be made and entered into in the Commonwealth of Massachusetts, and will in all respects be interpreted, enforced and governed under the laws of the Commonwealth of Massachusetts. I hereby agree to consent to personal jurisdiction of the state and federal courts situated within Suffolk County, Massachusetts for purposes of enforcing this Agreement, and waive any objection that I might have to personal jurisdiction or venue in those courts. As used in this Agreement, "including" means "including but not limited to".

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

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

Signed: \_\_\_\_\_  
(Employee's full name)

Type or print name: Wael Hashad

Last four digits of SSN: \_\_\_\_\_ Date: \_\_\_\_\_

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**Appendix A**

To: Seres Therapeutics, Inc.

From: Wael Hashad

Date: \_\_\_\_\_

SUBJECT: **Prior Inventions**

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

No inventions or improvements

See below:

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Additional sheets attached

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

None

See below:

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## CERTIFICATIONS

I, Roger J. Pomerantz, 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(s) 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)) 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) [OMITTED]

(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(s) 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.

May 16, 2016

/s/ Roger J. Pomerantz

Roger J. Pomerantz  
President and Chief Executive Officer  
(Principal Executive Officer)

## 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(s) 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)) 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) [OMITTED]

(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(s) 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.

May 16, 2016

/s/ Eric D. Shaff

Eric D. Shaff

Executive Vice President and Chief Financial Officer  
(Principal Financial Officer)



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

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

- (1) The Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2016 (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 16, 2016

/s/ Roger J. Pomerantz  
\_\_\_\_\_  
Roger J. Pomerantz  
President and Chief Executive Officer  
(Principal Executive Officer)

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

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

- (1) The Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2016 (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 16, 2016

/s/ Eric D. Shaff

Eric D. Shaff

Executive Vice President and Chief Financial Officer  
(Principal Financial Officer)