Seres Therapeutics, Inc.
Form 10-Q
August 11, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2016

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number: 001-37465

Seres Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	27-4326290
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

200 Sidney Street - 4th Floor

Cambridge, MA 02139
(Address of principal executive offices) (Zip Code)

(617) 945-9626

(Registrant's telephone number, including area code)

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 x No o

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 x No o

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 x (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 o No x

As of August 5, 2016 there were 40,274,503 shares of Common Stock, $0.001 par value per share, outstanding.

Seres Therapeutics, Inc.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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” o 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.

Part I – Financial Information

SERES THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$59,824	$73,933
Investments	152,032	131,149
Prepaid expenses and other current assets	5,247	2,528
Total current assets	217,103	207,610
Property and equipment, net	26,985	7,751
Long-term investments	60,589	-
Restricted cash	1,540	1,539
Total assets	$306,217	$216,900
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$4,454	$5,397
Accrued expenses and other current liabilities	10,865	5,523
Deferred revenue - related party	12,012	—
Total current liabilities	27,331	10,920
Lease incentive obligation	9,119	586
Deferred revenue, net of current portion - related party	102,371	—
Total liabilities	138,821	11,506
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2016 and December 31, 2015; no shares issued and outstanding at June 30, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at June 30, 2016 and December 31, 2015; 39,859,155 and 39,082,017 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	40	39
Additional paid-in capital	297,502	287,937
Accumulated other comprehensive income	83	30
Accumulated deficit	(130,229)	(82,612)
Total stockholders' equity	167,396	205,394
Total liabilities and stockholders' equity	$306,217	$216,900

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

SERES THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenue:				
Collaboration revenue - related party	$3,004	$—	$5,714	$—
Total revenue	3,004	—	5,714	—
Operating expenses:				
Research and development expenses	22,174	8,784	37,590	14,345
General and administrative expenses	8,970	3,556	16,180	6,162
Total operating expenses	31,144	12,340	53,770	20,507
Loss from operations	(28,140)	(12,340)	(48,056)	(20,507)
Other income (expense):				
Interest income	495	151	763	199
Interest expense	(268)	(146)	(324)	(211)
Revaluation of preferred stock warrant liability	—	(220)	—	(7)
Total other income (expense), net	227	(215)	439	(19)
Net loss	$(27,913)	$(12,555)	$(47,617)	$(20,526)
Net loss per share attributable to common stockholders, basic and diluted	$(0.70)	$(1.45)	$(1.21)	$(2.64)
Weighted average common shares outstanding, basic and diluted	39,600,344	8,640,218	39,393,238	7,777,679
Other comprehensive income:				
Unrealized gain/(loss) on investments, net of tax of $0	$(25)	$(8)	$53	$23
Total other comprehensive income	(25)	(8)	53	23
Comprehensive loss	$(27,938)	$(12,563)	$(47,564)	$(20,503)

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)

	Six Months Ended June 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(47,617)	$(20,526)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	8,621	4,400
Depreciation and amortization expense	1,260	212
Gain from revaluation of preferred stock warrant liability	—	7
Non-cash interest expense	1	141
Accretion of discount on investments	(222)	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,719)	(2,230)
Deferred revenue	114,383	—
Accounts payable	395	(141)
Accrued expenses and other current liabilities	1,991	141
Net cash provided by (used in) operating activities	76,093	(17,996)
Cash flows from investing activities:		
Purchases of property and equipment	(9,946)	(1,649)
Purchases of investments	(206,534)	(64,250)
Sales and maturities of investments	125,335	8,725
Changes in restricted cash	(1)	—
Net cash used in investing activities	(91,146)	(57,174)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	(24)
Proceeds from exercise of stock options and common stock warrants	944	95
Repayment of notes payable	—	(600)
Payments of initial public offering costs	—	(2,148)
Net cash provided by (used in) financing activities	944	(2,677)
Net decrease in cash and cash equivalents	(14,109)	(77,847)
Cash and cash equivalents at beginning of period	73,933	114,185
Cash and cash equivalents at end of period	$59,824	$36,338
Supplemental disclosure of cash flow information:		
Cash paid for interest	$108	$75
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of convertible preferred stock into common stock upon listing of the Company's common stock on the NASDAQ	$—	$136,053
Deferred offering costs included in accounts payable and accrued expenses	$—	$780
Property and equipment purchases included in accounts payable and accrued expenses	$4,899	$718

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

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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, a synthetic microbiome therapeutic, to prevent an initial recurrence of primary CDI, SER-287 to treat inflammatory bowel disease, including ulcerative colitis, SER-301, a synthetic ulcerative colitis product candidate, and SER-155, a synthetic product candidate, 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 June 30, 2016 and for the three and six months ended June 30, 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. The condensed consolidated balance sheet at December 31, 2015 was derived from audited annual financial statements, but does not contain all of the footnote disclosures from the annual financial statements. In the opinion of management, the accompanying unaudited interim consolidated financial statements contain all adjustments which are necessary for a fair statement of the Company's financial position as of June 30, 2016 and consolidated results of operations for the three and six months ended June 30, 2016 and its cash flows for the six months ended June 30, 2016 and 2015. Such adjustments are of a normal and recurring nature. The results of operations for the three and six months ended June 30, 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 and six months ended June 30, 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. The Company's investments in certificates of deposit are carried at amortized cost, which approximates fair value. 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 June 30, 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 June 30, 2016 Using:

	Level 1	Level 2	Level 3	Not Subject to Leveling [1]	Total
Assets:					
Cash Equivalents	$—	$9,971	$ —	$ 7,359	$17,330
Repurchase Agreements	—	5,500	—	—	5,500
Investments:					
Commercial Paper	$—	$45,471	$ —	$ —	$45,471
Certificates of Deposit	—	13,271	—	—	13,271
Corporate Bonds	—	84,728	—	—	84,728
Government Securities	—	51,101	—	—	51,101
Treasury Bonds	—	18,050	—	—	18,050
	$—	$228,092	$ —	$ 7,359	$235,451

[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
Assets:					
Cash Equivalents	$—	$11,952	$ —	$ 11,173	$23,125
Repurchase Agreements	—	20,000	—	—	20,000
Investments:					
Commercial Paper	$—	$64,820	$ —	$ —	$64,820
Corporate Bonds	—	46,490	—	—	46,490
Government Securities	—	15,819	—	—	15,819
Treasury Bonds	—	4,020	—	—	4,020
	$—	$163,101	$ —	$ 11,173	$174,274

[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 June 30, 2016, the Company's cash equivalents, which were invested in money market funds, corporate bonds, and repurchase agreements with original maturities of less than 90 days from the date of purchase, were valued based on Level 2 inputs. Repurchase agreements are agreements with banks to repurchase notes that are collateralized by U.S. government securities.

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, certificates of deposit, corporate bonds, government securities and treasury bonds as of June 30, 2016 and December 31, 2015 were determined using Level 2 inputs. During the three and six months ended June 30, 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 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. 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 and six months ended June 30, 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 and six months ended June 30, 2015 and preferred stockholders do not participate in losses.

The Company's 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 and Six Months Ended	
	June 30,	
	2016	2015
Stock options to purchase common stock	5,612,389	4,809,621
Unvested restricted common stock	—	1,250
Warrants for the purchase of common stock	—	92,127
	5,612,389	4,902,998

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). In May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectibility, non-cash consideration and the presentation of sales and other similar taxes collected from customers. 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 Measurements 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 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.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. The new standard changes the impairment model for most financial assets and certain other instruments. Under the new standard, entities holding financial assets and net investment in leases that are not accounted for at fair value through net income to be presented at the net amount expected to be collected. An allowance for credit losses will be a valuation account that will be deducted from the amortized cost basis of the financial asset to present the net carrying value at the amount expected to be collected on the financial asset. The new standard will be effective for the Company on January 1, 2020. The adoption of this standard is not expected to have a material impact on the Company’s financial position or results of operations.

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 June 30, 2016 and December 31, 2015, the fair value of available-for-sale investments by type of security was as follows:

	June 30, 2016			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Investments:				
Commercial Paper	$45,413	$ 58	$ —	$45,471
Certificates of Deposit	$13,271	$ —	—	$13,271
Corporate Bonds	84,736	27	(35)	84,728
Government Securities	51,088	16	(3)	51,101
Treasury Bonds	18,029	21	—	18,050
	$212,537	$ 122	$ (38)	$212,621

	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
	$131,116	$ 87	$ (54)	$131,149

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. Investments with maturities of less than 12 months are considered current and those investments with maturities greater than 12 months are considered non-current.

As of 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:

	June 30, 2016	December 31, 2015
Laboratory equipment	$6,804	$ 4,370
Computer equipment	971	408
Furniture and office equipment	788	285
Leasehold improvements	9,965	1,856
Construction in progress	10,692	1,843
	29,220	8,762
Less: Accumulated depreciation and amortization	(2,235)	(1,011)
	$26,985	$ 7,751

Construction in progress at June 30, 2016 was comprised primarily of leasehold improvements and laboratory 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 $874, $1,260, $119 and $212 for the three and six months ended June 30, 2016 and 2015, respectively.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	June 30, 2016	December 31, 2015
Development and manufacturing costs	$3,258	$ 1,436
Payroll and payroll-related costs	2,375	2,756
Professional fees	449	184
Facility	4,662	1,053
Other	121	94
	$10,865	$ 5,523

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 June 30, 2016 and December 31, 2015.

The Company recorded losses of $220 and $7 for the three and six months ended June 30, 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:

	Six Months Ended June 30, 2015	
Risk-free interest rate	2.40	%
Expected term (in years)	8.2	
Expected volatility	91.2	%
Expected dividend yield	0	%
Fair value of Series A-2 convertible preferred stock	$ 17.26	

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:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2015	5,026,246	$ 8.01	8.70	$ 136,945
Granted	1,418,625	28.05		
Exercised	(777,138)	1.21		
Forfeited	(55,344)	13.48		
Outstanding as of June 30, 2016	5,612,389	$ 13.96	8.41	$ 88,441
Options exercisable as of June 30, 2016	1,793,436	$ 6.00	7.52	$ 41,438
Options vested and expected to vest as of June 30, 2016	5,491,857	$ 13.85	8.40	$ 87,103

The weighted average grant-date fair value of stock options granted during the three and six months ended June 30, 2016 was $20.64 and $19.87 per share, respectively.

The Company has granted performance-based stock options to certain employees. These stock options are exercisable only upon achievement of specified performance targets. As of June 30, 2016, none of these options were exercisable because none of the specified performance targets had been achieved. During the three months ended June 30, 2016, the Company has determined that the achievement of 60,000 of these specified performance targets is probable and has recorded expense of $212. The grant date fair value of these awards was $3.92 per share.

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		Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Research and development expenses	$2,896	$1,891	$5,082	$2,514
General and administrative expenses	1,821	1,182	3,539	1,886
	$4,717	$3,073	$8,621	$4,400

9. Collaboration Revenue

Nestec Ltd.

In January 2016 the Company entered into a Collaboration and 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 June 30, 2016, the only consideration that is fixed and determinable is the non-refundable upfront payment of $120,000 and $97 for the reimbursement of development services since the inception of the arrangement. 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 and six months ended June 30, 2016, the Company recognized $3,004 and $5,714, respectively, of related party revenue associated with the License Agreement. As of June 30, 2016, there was $114,383 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 for six month period ended June 30, 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 June 30, 2016 and December 31, 2015.

As of June 30, 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 previously leased office and laboratory space with a lease term expiring in January 2018 and no extension periods. In May 2016, upon mutual agreement with the landlord, the Company accelerated the termination of the operating lease to June 30, 2016. Upon termination of the lease, the Company recorded a benefit to rent expense of $136 to write off amounts previously recorded as deferred rent. The outstanding security deposit of $119, which is secured by a cash collateralized letter of credit, will remain in place until 90 days after termination in accordance with the original lease.

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 moved its corporate headquarters to this location in April 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 June 30, 2016, we have recorded a lease incentive obligation of $9,119.

During the three and six months ended June 30, 2016 and 2015, the Company recognized $787, $1,180, $354 and $540, 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 June 30, 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 $1, $17, $131 and $249 during the three and six months ended June 30, 2016 and 2015, respectively. There were no amounts due to Flagship Ventures Management, Inc. related to the services agreement as of June 30, 2016 and December 31, 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 and six months ended June 30, 2016, the Company recognized $3,004 and $5,714 of related party revenue associated with the License Agreement. As of June 30, 2016, there was $114,383 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 and six months ended June 30, 2016. There is $97 due from NHS as of June 30, 2016 for the reimbursement of development costs.

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. During the three and six months ended June 30, 2016, the Company recorded expense of $188 for accrued 401(k) match contributions.

14. Subsequent Events

On August 2, 2016, the Company notified its Phase 3 SER-109 clinical research organization ("CRO") partner that it intends to terminate its agreement with the CRO for work in connection with a planned global, pivotal Phase 3 trial for SER-109. The work performed to date under this agreement was tied to start-up activities of the planned trial. The Company has $690 of prepaid expense related to this agreement on its balance sheet as of June 30, 2016. The Company expects a portion of this amount to be recorded as research and development expense during the remainder of the year ending December 31, 2016.

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, a synthetic microbiome therapeutic, to prevent an initial recurrence of primary CDI, SER-287 to treat inflammatory bowel disease, including ulcerative colitis, SER-301, a synthetic ulcerative colitis product candidate, and SER-155, a synthetic product candidate, 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 June 30, 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, SER-262 and SER-287 are still in pre-clinical development. 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 $47.6 million for the six months ended June 30, 2016. As of June 30, 2016, we had an accumulated deficit of $130.2 million.

On July 29, 2016, we announced the interim 8-week results from our ongoing SER-109 Phase 2 clinical study for the prevention of multiply recurrent CDI. The study's primary endpoint of reducing the relative risk of CDI recurrence at

up to 8-weeks was not achieved. We are in the process of gathering and analyzing data, and in consultation with the FDA, plan to make appropriate adjustments to our SER-109 development plans.

We initiated a Phase 1b clinical trial of SER-287 in December 2015 and expect results from this study in 2017. We initiated a Phase 1b clinical study of SER-262 in July 2016 and expect results from this study in 2017.

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

- evaluate the clinical development of SER-109 for the prevention of further recurrences of CDI in patients suffering from recurrent CDI in light of the Phase 2 interim clinical study results;
- continue the 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. We may also incur such expenses prior to commercialization even if we do not obtain marketing approval. 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 $10 million milestone payment in 2016 associated with the initiation of the Phase 1b study for SER-262 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 and six months ended June 30, 2016, we recorded revenue of $3.0 and $5.7 million, respectively, in connection with the License Agreement.

We continue to expect that our existing cash, cash equivalents and investments, will enable us to fund our operating expenses and capital expenditure requirements well into 2018. This estimate excludes net cash flows from future business development activities. The specifics of future SER-109 related activities could impact capital requirements, and cash projections. 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-262, SER-287, SER-301 and SER-155. 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		Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
	(in thousands)			
Microbiome therapeutics platform	$13,172	$4,867	$21,023	$7,181
SER-109	7,169	3,559	12,658	6,744
SER-262	882	358	2,117	420
SER-287	951	—	1,792	—
Total research and development expenses	$22,174	$8,784	$37,590	$14,345

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. Our research and development expenses may continue to increase in the foreseeable future as we advance the clinical development of SER-109, SER-262 and SER-287 and initiate clinical trials for certain product candidates, continue to discover and develop additional product candidates, including SER-155 and SER-301, and pursue later stages of clinical development of our product candidates. For example, the European Medicines Agency, or EMA, has 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.

In light of the interim results of our Phase 2 SER-109 clinical trial, we are in the process of gathering and analyzing data and will evaluate potential changes to our development plans for SER-109.

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. During the three and six months ended June 30, 2016, 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 and the amortization of purchased premiums and discounts associated with our investments.

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 any of the three or six month periods ended June 30, 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 three and six months ended June 30, 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 June 30, 2016 and 2015

The following table summarizes our results of operations for the three months ended June 30, 2016 and 2015:

	Three Months Ended June 30,		
	2016	2015	Change
	(in thousands)		
Revenue:			
Collaboration revenue - related party	$3,004	$—	$3,004
Total revenue	3,004	—	3,004

Operating expenses:			
Research and development	22,174	8,784	13,390
General and administrative	8,970	3,556	5,414
Total operating expenses	31,144	12,340	18,804
Loss from operations	(28,140)	(12,340)	(15,800)
Other income (expense):			
Interest income	495	151	344
Interest expense	(268)	(146)	(122)
Revaluation of preferred stock warrant liability	—	(220)	220
Total other income (expense), net	227	(215)	442
Net loss	$(27,913)	$(12,555)	$(15,358)

Revenue

Total revenue was $3.0 million for the three months ended June 30, 2016. We had no revenue for the three months ended June 30, 2015. The increase was a result of revenue recorded in connection with our License Agreement with NHS, entered into during January 2016.

Research and Development Expenses

	Three Months Ended June 30,		
	2016	2015	Change
	(in thousands)		
Microbiome therapeutics platform	$13,172	$4,867	$8,305
SER-109	7,169	3,559	3,610
SER-262	882	358	524
SER-287	951	-	951
Total research and development expenses	$22,174	$8,784	$13,390

Research and development expenses were $22.2 million for the three months ended June 30, 2016, compared to $8.8 million for the three months ended June 30, 2015. The increase of $13.4 million was due primarily to the following:

- an increase of $8.3 million in research expenses related to our microbiome therapeutics platform, due primarily to an increase in payroll and consultant costs of $5.3 million, which included an increase in stock-based compensation expense of $1.0 million due primarily to an increase in employee headcount, an increase in facilities and depreciation charges of $1.0 million, an increase in license costs of $1.1 million, and an increase in lab consumables and supplies of $0.6 million;
- an increase of $3.6 million in expenses related to our SER-109 program, due primarily to an increase in clinical trial costs of $2.2 million, an increase in contract manufacturing costs of $0.7 million, an increase in conference costs of $0.4 million, and an increase in other consulting costs of $0.3 million;
- an increase of $0.5 million in expenses for our SER-262 program primarily driven by an increase in clinical trial and consultant costs of $0.3 million and an increase in contract manufacturing costs of $0.1 million due to the initiation of our Phase 1b clinical trial in July 2016; and
- an increase of $1.0 million in expenses for our SER-287 program primarily driven by the initiation of our Phase 1b clinical trial in December 2015.

Our research and development expenses may continue to increase in the foreseeable future as we advance the clinical development of SER-109, SER-262 and SER-287 and initiate clinical trials for certain product candidates, continue to discover and develop additional product candidates, including SER-155 and SER-301, and pursue later stages of clinical development of our product candidates. For example, the EMA has 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.

In light of the interim results of our Phase 2 SER-109 clinical trial, we are in the process of gathering and analyzing data and will evaluate potential changes to our development plans for SER-109.

General and Administrative Expenses

	Three Months Ended June 30,		
	2016	2015	Change
	(in thousands)		
Personnel related (including stock-based compensation)	$3,911	$2,277	$1,634
Professional fees	2,989	790	2,199
Facility-related and other	2,070	489	1,581
Total general and administrative expenses	$8,970	$3,556	$5,414

General and administrative expenses were $9.0 million for the three months ended June 30, 2016, compared to $3.6 million for the three months ended June 30, 2015. The increase of $5.4 million was primarily due to the following:

- an increase in personnel related costs of $1.6 million primarily due to hiring of additional employees from June 30, 2015 to June 30, 2016 to support corporate operations and business development activities, including an increase of $0.6 million in stock-based compensation;
- an increase in professional fees of $2.2 million due to an increase of $1.7 million in consulting costs and $0.3 million in legal fees as a result of ongoing business activities; and
- an increase in facility costs of $1.6 million primarily due to an increase in office-related expenses, insurance cost and depreciation charges.

Other Income (Expense), Net

Other income (expense), net for each of the three months ended June 30, 2016 and June 30, 2015 was $0.2 million and $(0.2) million, respectively. The $0.2 million of other income (expense), net for the three months ended June 30, 2016 was primarily due to interest income from investing activities. The $(0.2) million of other income (expense), net for the three months ended June 30, 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.

Results of Operations

Comparison of six months ended June 30, 2016 and 2015

The following table summarizes our results of operations for the six months ended June 30, 2016 and 2015

	Six Months Ended June 30,		
	2016	2015	Change
	(in thousands)		
Revenue	$5,714	$—	$5,714
Operating expenses:			
Research and development	37,590	14,345	23,245
General and administrative	16,180	6,162	10,018
Total operating expenses	53,770	20,507	33,263
Loss from operations	(48,056)	(20,507)	(27,549)
Other income (expense):			
Interest income	763	199	564
Interest expense	(324)	(211)	(113)
Revaluation of preferred stock warrant liability	—	(7)	7
Total other income (expense), net	439	(19)	458
Net loss	$(47,617)	$(20,526)	$(27,091)

Revenue

Total revenue was $5.7 million for the six months ended June 30, 2016. We had no revenue for the six months ended June 30, 2015. The increase was a result of revenue recorded in connection with our License Agreement with NHS, entered into during January 2016.

Research and Development Expenses

	Six Months Ended		
	June 30,		
	2016	2015	Change
	(in thousands)		
Microbiome therapeutics platform	$21,023	$7,181	$13,842
SER-109	12,658	6,744	5,914
SER-262	2,117	420	1,697
SER-287	1,792	—	1,792
Total research and development expenses	$37,590	$14,345	$23,245

Research and development expenses were $37.6 million for the six months ended June 30, 2016, compared to $14.3 million for the six months ended June 30, 2015. The increase of $23.2 million was due primarily to the following:

- an increase of $13.8 million in research expenses related to our microbiome therapeutics platform, due primarily to an increase in payroll and consultant costs of $10.1 million, which included an increase in stock-based compensation expense of $2.6 million due primarily to an increase in employee headcount, an increase in facilities and depreciation costs of $1.6 million, an increase in license costs of $1.1 million, an increase in lab consumables and supplies of $0.6 million, and an increase in travel costs of $0.3 million;
- an increase of $5.9 million in expenses related to our SER-109 program, due primarily to an increase in clinical trial costs of $3.5 million, an increase in contract manufacturing costs of $0.6 million, an increase in lab consumables and supplies of $0.9 million, an increase in conference costs of $0.4 million, and an increase in other consulting costs of $0.4 million;
- an increase of $1.7 million in expenses for our SER-262 program primarily driven by an increase bioprocess development costs of $0.9 million, an increase in clinical trial costs of $0.3 million, an increase in lab consumables and supplies of $0.2 million, and an increase in animal studies costs of $0.2 million due to the initiation of our Phase 1b clinical trial in June 2016; and
- an increase of $1.8 million in expenses for our SER-287 program primarily driven by the initiation of our Phase 1b clinical trial in December 2015.

Our research and development expenses may continue to increase in the foreseeable future as we advance the clinical development of SER-109, SER-262 and SER-287 and initiate clinical trials for certain product candidates, continue to discover and develop additional product candidates, including SER-155 and SER-301, 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.

In light of the interim results of our Phase 2 SER-109 clinical trial, we are in the process of gathering and analyzing data and will evaluate potential changes to our development plans for SER-109.

General and Administrative Expenses

	Six Months Ended June 30,		
	2016	2015	Change
	(in thousands)		
Personnel related (including stock-based compensation)	$7,237	$3,676	$3,561
Professional fees	5,709	1,617	4,092
Facility-related and other	3,234	869	2,365
Total general and administrative expenses	$16,180	$6,162	$10,018

General and administrative expenses were $16.2 million for the six months ended June 30, 2016, compared to $6.2 million for the six months ended June 30, 2015. The increase of $10.0 million was primarily due to the following:

- an increase in personnel related costs of $3.6 million primarily due to hiring of additional employees from June 30, 2015 to June 30, 2016 to support corporate operations and business development activities, including an increase of $1.7 million in stock-based compensation;
- an increase in professional fees of $4.1 million due to an increase in consulting costs of $2.5 million and legal fees of $1.1 million as a result of ongoing business activities; and
- an increase in facility costs of $2.4 million primarily due to an increase in office-related expenses, insurance cost and depreciation charges.

Other Income (Expense), Net

Other income (expense), net for each of the six months ended June 30, 2016 and June 30, 2015 was $0.4 million and less than $(0.1) million, respectively. The $0.4 million of other income (expense), net for the six months ended June 30, 2016 was primarily due to interest income from investing activities. The expense for the six months ended June 30, 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.

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 $10 million milestone payment in 2016 associated with the initiation of the Phase 1b study for SER-262 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 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 June 30, 2016, we had cash, cash equivalents and investments totaling $272.4 million and an accumulated deficit of $130.2 million.

Cash Flows

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

	Six Months Ended June 30,	
	2016	2015
	(in thousands)	
Cash provided by (used in) operating activities	$76,093	$(17,996)
Cash used in investing activities	(91,146)	(57,174)
Cash provided by (used in) financing activities	944	(2,677)
Net decrease in cash and cash equivalents	$(14,109)	$(77,847)

Operating Activities. During the six months ended June 30, 2016, operating activities provided $76.1 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 $47.6 million, cash used from changes in our operating assets and liabilities of $0.3 million and by non-cash charges of $9.7 million. Net cash used for changes in our operating assets and liabilities during the six months ended June 30, 2016 consisted of a $2.7 million increase in prepaid expenses and other current assets, offset in part by a $2.0 million increase in accrued expenses and other current liabilities and an increase in accounts payable of $0.4 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 six months ended June 30, 2015, operating activities used $18.0 million of cash, primarily resulting from our net loss of $20.5 million and cash used from changes in our operating assets and liabilities of $2.2 million, partially offset by non-cash charges of $4.8 million. Net cash used for changes in our operating assets and liabilities during the six months ended June 30, 2015 consisted of a $2.2 million increase in prepaid expenses and other current assets and a $0.1 million increase in in accrued expenses and other current liabilities, offset in part by a decrease in accounts payable of $0.1 million. The decrease 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.

Investing Activities. During the six months ended June 30, 2016, net cash used in investing activities was $91.1 million, consisting of purchases of investments of $206.5 million and purchases of property and equipment of $9.9 million. The decrease was partially offset by sales and maturities of investments of $125.3 million.

During the six months ended June 30, 2015, we used $57.2 million of cash in investing activities, consisting of purchases of investments of $64.3 million and purchases of property and equipment of $1.7 million. The decrease was partially offset by maturities of investments of $8.7 million.

Financing Activities. During the six months ended June 30, 2016, net cash provided by financing activities was $0.9 million in connection with the exercise of options to purchase our common stock.

During the six months ended June 30, 2015, net cash used in financing activities was $2.7 million as a result of principal repayments of $0.6 million of borrowings under our Loan and Security Agreement and payments of initial public offering costs of $2.1 million, both of which were partially offset by proceeds from the exercise of stock options and warrants to purchase common stock of $0.1 million.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing development activities related to SER-109, SER-262 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.

On July 29, 2016, we announced the interim 8-week results from our ongoing SER-109 Phase 2 clinical study for the prevention of multiply recurrent CDI. The study’s primary endpoint of reducing the relative risk of CDI recurrence at up to 8-weeks was not achieved. We are in the process of gathering and analyzing data, and in consultation with the FDA, plan to make appropriate adjustments to our SER-109 development plans.

We anticipate that our expenses may increase substantially if and as we:

- evaluate our development plans for SER-109, our lead product candidate, in light of the Phase 2 interim clinical study results;
- conduct our Phase 1b clinical studies of SER-287 and SER-262;
- continue the research and development of our other product candidates;
- 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 sales 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 continue to expect that our existing cash, cash equivalents and investments will enable us to fund our operating expenses and capital expenditure requirements well into 2018. This estimate excludes net cash flows from future business development activities. The specifics of future SER-109 related activities could impact capital requirements, and cash projections. 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-262 and 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-262 and SER-287 or our other programs will depend on many factors, including:

- our evaluation of changes to our development plans for SER-109, in light of the Phase 2 interim clinical study results;
- the progress and results of our Phase 1b clinical study of SER-287;
- the progress and results of our Phase 1b clinical study of SER-262;
- 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-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.

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.

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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, except as outlined below.

We previously leased office and laboratory space with a lease term expiring in January 2018 and no extension periods. In May 2016, upon mutual agreement with the landlord, we accelerated the termination of the operating lease to June 30, 2016. Upon termination of the lease, we recorded a benefit to rent expense of $0.1 million to write off amounts previously recorded as deferred rent. The outstanding security deposit of $0.1 million, which is secured by a cash collateralized letter of credit, will remain in place until 90 days after the termination in accordance with the original lease.

Off-Balance Sheet Arrangements

As of June 30, 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 June 30, 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 June 30, 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 June 30, 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 $47.0 million and $20.5 million for the six months ended June 30, 2016 and 2015, respectively. As of June 30, 2016, we had an accumulated deficit of $129.6 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 may increase substantially as we:

- evaluate the clinical development of SER-109, our lead product candidate in light of the interim 8-week results from our ongoing SER-109 Phase 2 clinical study for the prevention of multiply recurrent CDI;
- conduct our Phase 1b clinical studies of SER-287 and SER-262;
- continue the research and development of our other product candidates, including completing pre-clinical studies and commencing clinical trials for SER-301 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 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.

Our expenses may increase in connection with our ongoing activities, particularly as we evaluate the clinical development of SER-109 and our Phase 1b clinical studies of SER-287 and SER-262, and continue to research, develop and initiate clinical trials of SER-301 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.

On July 29, 2016, we announced the interim 8-week results of our ongoing Phase 2 clinical study of SER-109 indicating that the primary endpoint was not achieved. We are in the process of gathering and analyzing data, and in consultation with the FDA, plan to make appropriate adjustments to our SER-109 development plans.

We continue to expect that our existing cash, cash equivalents and investments will enable us to fund our operating expenses and capital expenditure requirements well into 2018. This estimate excludes net cash flows from future business development activities. The specifics of future SER-109 related activities could impact capital requirements, and cash projections. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the analysis of data related to our Phase 2 clinical study of SER-109, as well as future or potential additional clinical studies for SER-109;
- 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-301 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, SER-262 and SER-287, 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 three of our product candidates, SER-109, SER-262 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. The interim 8-week results of our Phase 2 clinical study of SER-109 were not statistically significant. We are in the process of gathering and analyzing data, and in consultation with the FDA, plan to make appropriate adjustments to our SER-109 development plans. 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 early in our development efforts and may not be successful in our efforts to use our microbiome therapeutics platform to build a pipeline of product candidates and develop marketable drugs.

We are using our microbiome therapeutics platform to develop Ecobiotic microbiome therapeutics. We are at an early stage of development and our platform has not yet, and may never lead to, approvable or marketable drugs. We are developing additional product candidates that we intend to be used to prevent non-Clostridium difficile infection and to treat inflammatory and metabolic diseases. We may have problems applying our technologies to these areas, and our product candidates may not be effective in preventing infection and disease. Our product candidates may not be suitable for clinical development, including as a result of their harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance.

On July 29, 2016, we announced the interim 8-week results from our ongoing SER-109 Phase 2 clinical study for the prevention of multiply recurrent CDI. The study’s primary endpoint of reducing the relative risk of CDI recurrence at up to 8-weeks was not achieved. The results of this study may impact our microbiome therapeutics platform and the success of our other product candidates.

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;
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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. For example, on July 29, 2016, we announced the interim 8-week results from our ongoing SER-109 Phase 2 clinical study for the prevention of multiply recurrent CDI. The study's primary endpoint of reducing the relative risk of CDI recurrence at up to 8-weeks was not achieved.

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.

It is difficult to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval, and the risk of failure through the development process is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete 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. 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 light of the interim results from our Phase 2 clinical trial of SER-109, we are in the process of gathering and analyzing data and will evaluate potential changes to our development plans for SER-109. 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, dosed the first patient in a Phase 2 clinical study for this product candidate in May 2015 and completed enrollment in May 2016. 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 intended 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. For subsequent product candidates, we have initiated INDs.

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 and the interim 8-week results of our Phase 2 clinical study of SER-109 indicated that the primary endpoint of reducing the relative risk of CDI recurrence at up to 8 weeks was not achieved. 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 from the FDA 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, outside of the United States and Canada, without first expanding our internal capabilities or entering into another agreement with a third party. Any alternative collaboration or license could also be on less favorable terms to us. In addition, under the License Agreement, NHS agreed to provide funding for certain clinical development activities. If the License Agreement were terminated, we may need to refund those payments and seek additional financing to support the research and development of any terminated products or discontinue any terminated products, which could have a material adverse effect on our business.

Under the License Agreement, we are dependent upon NHS to successfully commercialize any NHS Collaboration Products outside of the United States and Canada. We cannot directly control NHS' commercialization activities or the resources it allocates to our product candidates. Our interests and NHS' interests may differ or conflict from time to time, or we may disagree with NHS' level of effort or resource allocation. NHS may internally prioritize our product candidates differently than we do or it may not allocate sufficient resources to effectively or optimally commercialize them. If these events were to occur, our business would be adversely affected.

We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We expect to continue to rely on third parties, such as contract research organizations, or CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct and manage our clinical trials.

Our reliance on these third parties for research and development activities will reduce our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, safety and welfare of trial participants are protected. Other countries' regulatory agencies also have requirements for clinical trials with which we must comply. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, do not meet expected deadlines, experience work stoppages, terminate their agreements with us or need to be replaced, or do not conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed, or terminated or may need to be repeated. If any of the foregoing occur, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We rely on third parties for certain aspects of the manufacture of our product candidates for 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 certain aspects 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, SER-262 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 backup facilities in Massachusetts and 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 manufacturing facilities at our Cambridge locations where we conduct process development, scale-up activities and a portion of the manufacture of Ecobiotic microbiome therapeutics. The FDA and other comparable foreign regulatory agencies must, pursuant to inspections that are conducted after submitting a BLA or relevant foreign marketing submission, confirm that the manufacturing processes for the product meet cGMP. We have not yet had any of our manufacturing facilities inspected.

We may establish a manufacturing facility for our product candidates for production at a commercial scale. We have no experience in commercial-scale manufacturing of our product candidates. We currently intend to develop our manufacturing capacity in part by expanding our current facility or building additional facilities. 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.

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 rely on third parties, including NHS, to sell, market and distribute our product candidates. We may not be successful in entering into arrangements with such third parties or may be unable to do so on terms that are favorable to us. In addition, our product revenue and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over

such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The development and commercialization of new drug and biologic products is highly competitive and is characterized by rapid and substantial technological development and product innovations. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. We are aware of a number of large pharmaceutical and biotechnology companies, as well as smaller, early-stage companies, that are pursuing the development of products, including microbiome therapeutics, for 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, not-for-profits and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, 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 $5.0 million in product liability insurance coverage in the aggregate, with a per occurrence limit of $5.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, we may face competition from biosimilars. In the United States, the Biologics Price Competition and Innovation Act, or 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 BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. This 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 restrict the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program, such as Medicare and Medicaid; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (described below);
- the 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. For example, in June 2016, a majority of voters in the United Kingdom elected to withdraw from the European Union in a national referendum. While non-binding, the referendum has created significant uncertainty about the future relationship between the United Kingdom and the European Union, including with respect to the laws and regulations for approving and marketing drugs that will apply as the United Kingdom determines which European Union laws to replace or replicate in the event of a withdrawal.

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