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;