Filed pursuant to Rule 424(b)(4)
Registration No. 333-204484

PROSPECTUS

7,430,555 Shares

Seres Therapeutics, Inc.

Common Stock

This is the initial public offering of shares of common stock of Seres Therapeutics, Inc. All of the 7,430,555 shares of common stock are being sold by us.

Prior to this offering, there has been no public market for the common stock. The initial public offering price per share is $18.00. The common stock has been approved for listing on The NASDAQ Global Select Market under the symbol "MCRB."

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012, and, as such, have elected to take advantage of certain reduced reporting requirements in this prospectus and may elect to comply with certain reduced public company reporting requirements in future filings.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 12 to read about factors you should consider before buying shares of the common stock.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$ 18.00	$133,749,990
Underwriting discount(1)	$ 1.26	$ 9,362,499
Proceeds, before expenses, to Seres Therapeutics	$ 16.74	$124,387,491

(1) See "Underwriting" beginning on page 160 for additional information regarding underwriting compensation.

To the extent that the underwriters sell more than 7,430,555 shares of common stock, the underwriters have the option to purchase up to an additional 1,114,583 shares from Seres Therapeutics, Inc. at the initial public offering price less the underwriting discount.

Nestlé Health Science US Holdings, Inc., an existing stockholder affiliated with one of our directors, has indicated an interest to purchase $24.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, this stockholder may determine to increase or reduce the amount of its indication of interest, or otherwise elect not to purchase any shares. It is also possible that the number of shares allocated in this offering to this stockholder may be greater or smaller than the amount of its indication of interest, or no shares may be allocated to this stockholder.

The underwriters expect to deliver the shares against payment in New York, New York on July 1, 2015.

Goldman, Sachs & Co. **BofA Merrill Lynch**

Leerink Partners **Canaccord Genuity**

Prospectus dated June 25, 2015

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Through and including July 20, 2015 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

Neither we nor any of the underwriters have taken any action that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons who have come into possession of this prospectus in a jurisdiction outside the United States are required to inform themselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the "Risk Factors" section beginning on page 12 and our financial statements and the related notes appearing at the end of this prospectus, before making an investment decision.

As used in this prospectus, unless the context otherwise requires, references to "we," "us," "our" and "Seres Therapeutics" refer to Seres Therapeutics, Inc. and its subsidiaries, collectively.

Overview

We are a microbiome therapeutics platform company developing a novel class of biological drugs, which we refer to as Ecobiotic microbiome therapeutics. The human microbiome is an ecology of microorganisms, including bacteria, fungi and viruses, that, when unhealthy, or dysbiotic, can leave the body more susceptible to infections, metabolic disorders, allergies, autoimmune disease, inflammation and other conditions. Our drugs are designed to restore health by repairing the function of a dysbiotic microbiome. We are initially focused on implementing our microbiome therapeutics platform to develop Ecobiotic microbiome therapeutics that treat dysbiosis in the colonic microbiome, one of the most diverse microbiomes in the human body. SER-109, our lead product candidate, is designed to prevent further recurrences of *Clostridium difficile* infection, or CDI, a debilitating infection of the colon and, if approved by the U.S. Food and Drug Administration, or FDA, could be a first-in-field drug. In our Phase 1b/2 clinical study of SER-109 in recurrent CDI patients, 97% of patients achieved a clinical cure, which we defined as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing. SER-109 has been granted Breakthrough Therapy designation by the FDA. Breakthrough Therapy designation is intended to expedite the development and review of drugs or biologics that treat serious or life-threatening diseases or conditions and that preliminary clinical evidence indicates may be a substantial improvement over existing therapies. We initiated a Phase 2 clinical study of SER-109 for recurrent CDI and dosed the first patient in May 2015. We expect study results in the middle of 2016.

The human microbiome is one of the richest and most diverse ecosystems on earth, with a population of more than 100 trillion microorganisms that live in our intestines, mouth, skin and elsewhere in the body. Among the various microbiomes in the human body, the colonic microbiome is one of the most diverse microbial communities. In a healthy, symbiotic state the colonic microbiome plays an important role in human health, helping the body digest food, resist pathogens, regulate the metabolic system and synthesize essential nutrients and vitamins. However, the colonic microbiome may change in composition for a variety of reasons, including in response to long-term or high-dose antibiotics and following gastrointestinal infection. These changes in composition result in the loss of key microbes, resulting in a state of dysbiosis. Dysbiosis of the colonic microbiome is associated with a wide range of disease and infections, such as gastrointestinal infection and inflammatory and metabolic diseases.

While the study of the human microbiome is not new, the scientific community's understanding of the microbiome, and the colonic microbiome in particular, has been significantly advanced through genomics, which has enabled the broader understanding of the human microbiome at the organismal, functional and community level. Recently published scientific research has correlated dysbiosis in the colonic microbiome with numerous diseases and conditions in humans and in animal models, including

infections, metabolic disorders, allergies, autoimmune disease, inflammation and other non-specific conditions, such as irritable bowel syndrome, or IBS. Information regarding the impact of the colonic microbiome on various disease states is still emerging, although an increasing number of publications are appearing in leading scientific journals. There are currently no FDA-approved therapeutics that are designed to restore the microbiome to a healthy state.

We are developing a new approach to treating disease by restoring a dysbiotic colonic microbiome to a healthy state using our Ecobiotic microbiome therapeutics. Our approach is premised on the hypothesis that the proximal cause of many diseases is a dysbiosis in the natural state of the colonic microbiome that perpetuates the conditions that allow disease to take hold and flourish. We believe that the restoration of a dysbiotic colonic microbiome using rationally designed therapeutics represents a paradigm shift in the approach to treating the underlying disease. Our Ecobiotic microbiome therapeutics are rationally defined ecological compositions, consisting of discrete combinations of beneficial microorganisms with targeted functional properties that provide the ability to re-establish keystone features of a functional microbiome in settings of disease.

Our approach to discovery and design is based on an iterative bedside-to-bench-to-bedside drug discovery strategy that begins with data on the human microbiome that we gather from clinical studies. From this data, we identify the ecological differences between a healthy and a diseased microbiome, which we then use to rationally design potential Ecobiotic microbiome therapeutics. After further in-lab testing, selected Ecobiotic microbiome therapeutic candidates are moved back into the clinic for testing with humans. We then apply a comparative genomic systems biology framework that leverages proprietary computation, microbiology and screening capabilities to design lead candidates targeted at these ecological deficiencies. We are able to apply this framework and experience to existing clinical data sets, as well as to the proprietary clinical data we have generated through our SER-109 clinical trial. We believe we can utilize our knowledge and data to design Ecobiotic microbiome therapeutics to treat various medical conditions, such as non-*Clostridium difficile* infection and inflammatory and metabolic diseases. We also have advanced capabilities in the fermentation of colonic bacteria and the formulation of vegetative and spore forms of bacteria into therapeutics. We believe that the combination of experience, proprietary data and proprietary know-how that comprise our microbiome therapeutics platform provides us with a competitive advantage in the design and development of microbiome therapeutics. Further, our approach and platform, which enables the rational design, testing, optimization, formulation and manufacturing of Ecobiotic microbiome therapeutics, provide a framework that we believe can significantly reduce the time typically required to advance therapeutics to the clinic.

Clostridium difficile Infection, or CDI

Clostridium difficile, or *C. difficile*, is a Gram-positive, toxin-producing, spore-forming bacterium that generally causes severe and persistent diarrhea in infected individuals, but can also lead to more severe outcomes, including in the most serious cases, death. CDI is most often associated with the prior use of antibiotics, which we believe decreases resistance to CDI by causing dysbiosis in the microbiome. Since *C. difficile* spores are able to survive for long periods of time outside of the body, and because healthcare settings are often sites of significant antibiotic use, CDI transmission rates in hospitals, long-term acute care facilities and nursing homes have been increasing. CDI is also a cause of morbidity and mortality among hospitalized cancer patients and bone marrow transplant patients, as their immune systems are suppressed by cytotoxic drugs, which are drugs that inhibit or prevent the function of cells, and they may be heavily treated with antibiotics for infections. More recently, the rise of community-acquired CDI has been recognized as a growing problem.

The U.S. Centers for Disease Control has identified CDI as one of the top three most urgent antibiotic-resistant bacterial threats in the United States. It is the most common cause of hospital

acquired infection in the United States and has overtaken methicillin-resistant *Staphylococcus aureus* in prevalence. CDI is responsible for the death of approximately 29,000 Americans each year. CDI is also very costly to the healthcare system. According to a summary of studies published in 2009 in *The Journal of Hospital Infection*, the treatment cost per episode of primary CDI was as much as $5,000 and as much as $18,000 per recurrence of CDI. We estimate the incidence of primary CDI in the United States is between 640,000 and 820,000 patients per year. While the epidemiological data are varied outside the United States, we believe that, due to the widespread use of antibiotics, CDI is a growing global disease. Research suggests that the risk of recurrence is approximately 25% after the primary occurrence of CDI, 40% after a first recurrence and greater than 60% for those experiencing two or more recurrences. In addition, a recent randomized trial comparing two antibiotics for the treatment of primary CDI indicated that 8% of patients receiving fidaxomicin and 9% of patients receiving vancomycin did not respond to these antibiotics two days after completing their antibiotic regimen. We estimate that the addressable population of patients in the United States with recurrent CDI, defined as patients who have experienced at least three occurrences of CDI in the past nine months, is between 85,000 and 110,000 patients per year.

The current standard of care, and only FDA-approved option, for CDI is to treat with antibiotics. In many cases, antibiotic treatments may resolve the acute infection caused by *C. difficile*. However, these antibiotic treatments kill bacteria indiscriminately, inducing a dysbiosis of the microbiome and potentially making patients more susceptible to a recurrence of CDI. For those patients who experience a recurrence of CDI, we believe it is this dysbiosis of the microbiome, not the presence of *C. difficile*, which is the proximal cause of disease. Other treatment alternatives for patients with CDI include fecal microbiota transplantation, or FMT, and over-the-counter probiotics. FMT, also known as a stool transplantation, is a procedure during which donated stool, including fecal microbes, is typically instilled via colonoscopy into a patient with CDI. While FMT has demonstrated efficacy, it presents several challenges, including the potential to transmit infectious or allergenic agents between hosts, the invasive nature of administration and the difficulty performing FMT on a mass scale. FMT is not approved by the FDA and we believe it may be unable to gain such approval since the product, to our knowledge, cannot be standardized and characterized according to current regulatory requirements for identity, potency, purity and safety.

Probiotics represent a group of products typically available over the counter in supplements and in some foods, which contain a small number of species of bacteria. However, to date there have been no clinical studies that have established the ability of probiotics to repair a dysbiosis of the microbiome. Further, there is neither a legally recognized definition of, nor a standard of identity for, the term probiotic in the United States or Europe.

We believe that the ability to develop drugs that are able to modulate the microbiome and return a dysbiotic microbiome to its healthy state presents a significant opportunity to improve human health.

Our Product Candidates

Our CDI Franchise

SER-109 is a bacterial spore ecology consisting of an average of 50 bacterial species derived from healthy donors' fecal matter that is designed to prevent further recurrences of CDI in patients suffering from recurrent CDI by restoring the dysbiotic microbiome to a state of health. In our recently completed open label Phase 1b/2 clinical study, 29 of 30 patients, or 97% of patients, achieved a clinical cure, which we defined as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing. Additionally, 26 of 30 patients, or 87% of patients, achieved the primary efficacy endpoint of experiencing no recurrence of CDI associated diarrhea during the eight weeks post-treatment. The study demonstrated a favorable safety profile with no serious adverse events considered by the investigators to

be attributable to SER-109 treatment. We also performed an analysis of the microbiome using sequencing technology and microbiological analysis to demonstrate a re-establishment of keystone organisms and a rapid increase in bacterial diversity, which enable the restoration of the microbiome to a healthy state. SER-109 has been granted Breakthrough Therapy designation by the FDA. We initiated a Phase 2 clinical study of SER-109 for recurrent CDI and dosed the first patient in May 2015. We expect study results in the middle of 2016. In preparation for the Phase 2 clinical study, we refined the formulation of the inner capsule and changed the manufacturing process for SER-109 to enable production to meet commercial requirements. We believe that the manufacturing and formulation changes have resulted in a more pure form of SER-109 that, based on pre-clinical studies, is comparable in potency to that used in the Phase 1b/2 clinical study. The FDA has requested that we evaluate the new formulation of SER-109 prior to commencing a Phase 3 clinical trial. We are conducting pre-validation studies to evaluate the ability of the manufacturing process to inactivate and clear the potential pathogens of concern, and we expect the data from these studies to satisfy the FDA's request and to support a potential biologics license application and commercial launch. The pre-validation studies are also intended to satisfy the FDA's request that we conduct our Phase 3 clinical trial using SER-109 product that is manufactured in a manner identical to the product that will be manufactured post-licensure.

We believe the results of our open label Phase 1b/2 clinical study of SER-109 provide validation of the hypothesis underlying our microbiome therapeutics platform, supporting its further use to develop additional Ecobiotic microbiome therapeutics. Using the data we obtained from the SER-109 clinical trial, we are developing SER-262 as an Ecobiotic microbiome therapeutic designed to be used following antibiotic treatment of primary CDI to prevent the initial recurrence of CDI. SER-262 consists of bacteria that are a subset of the bacterial ecology comprising SER-109. Unlike SER-109, SER-262 strains are clonally isolated and produced in fermenters and do not require donations from human sources. Pre-clinical studies of SER-262 have demonstrated efficacy in preventing the recurrence of CDI in mouse and hamster models. We intend to initiate clinical studies of SER-262 in the middle of 2016.

If approved, we believe these two product candidates will enable us to provide a more effective and safer treatment for preventing the recurrence of CDI than the current standard of care.

Our Other Product Candidates

We believe our Ecobiotic microbiome therapeutics represent a novel approach with potential application across a broad range of human diseases. Our most advanced drug development programs are focused on the area of gastrointestinal infections, where the causal link between dysbiosis of the microbiome and susceptibility to disease has been established. In addition to our CDI product candidates, SER-109 and SER-262, we are utilizing our microbiome therapeutics platform to develop SER-287 to treat inflammatory bowel disease, including ulcerative colitis, and SER-155 to treat enteric pathogens, such as antibiotic-resistant bacteria. We are also researching Ecobiotic microbiome therapeutics for the treatment of metabolic diseases, such as early-stage, non-insulin dependent diabetes; other inflammatory diseases, such as Crohn's disease; and infections related to antibiotic use, cancer chemotherapy and immune suppression.

The following chart summarizes our current product pipeline:

(1) We are developing SER-262 to be used following antibiotic treatment of primary CDI to prevent initial recurrence of CDI.

Our Management Team and Investors

We have assembled a world class group of scientists, clinicians, directors and investors who have established our leadership in the field of microbiome therapeutics. We were co-founded by Drs. Noubar Afeyan, David Berry and Geoffrey von Maltzahn of Flagship VentureLabs, the innovation foundry of Flagship Ventures, which has founded 27 life sciences companies. Through Flagship VentureLabs' contribution of foundational scientific concepts and intellectual property, assembly of our management team and critical early-stage support, we launched as a company focused on the ecological nature of the microbiome. Led by Dr. Roger Pomerantz, our Chairman, President and Chief Executive Officer, our experienced management team possesses core capabilities in microbiome therapeutics, infectious disease, drug development, commercialization, chemistry, manufacturing and controls, public company management and finance. Dr. Pomerantz, an infectious disease physician-scientist, has extensive experience in infectious disease drug development and commercialization, licensing and acquisitions gained over a 10-year career in senior executive positions at Merck & Co, Johnson & Johnson and Tibotec Pharmaceuticals. Dr. Pomerantz led the development and commercialization of eight FDA-approved infectious disease drugs in his career. In addition to Dr. Pomerantz, our management team includes Mr. Eric Shaff, Dr. David Cook, Dr. John Aunins, Dr. Michele Trucksis and Dr. Matthew Henn. Collectively, our management team has successfully developed 18 approved pharmaceutical drugs in infectious disease and other indications. Our management team has extensive experience in microbial ecology, microbiology and live biologicals, with a collective 23 years studying the microbiome and over 60 published papers on the science of the microbiome. Additionally, our team has extensive experience in building out commercial capabilities in specialty diseases and has a track record for success in launching vaccine products, which have analogous manufacturing processes to that of Ecobiotic microbiome

therapeutics. In November and December 2014, we completed two preferred stock financings, which included as investors several prominent mutual funds and healthcare dedicated funds, as well as an affiliate of Nestlé Health Science.

Our Strategy

Our goal is to become the leading biopharmaceutical company developing and commercializing microbiome therapeutics to address significant unmet medical needs. The critical components of our strategy include:

- rapidly advancing the development of our lead product candidate, SER-109, for the prevention of further recurrence of CDI in patients with recurrent CDI;
- advancing the clinical development of SER-262 to be used following antibiotic treatment of primary CDI to prevent an initial recurrence of CDI;
- advancing the clinical development of SER-287 for the treatment of inflammatory bowel disease, including ulcerative colitis, and developing SER-155 for the treatment of antibiotic-resistant bacteria;
- leveraging our leading microbiome therapeutics platform to develop additional innovative and novel Ecobiotic microbiome therapeutics across a range of medical conditions with high unmet need;
- commercializing our Ecobiotic microbiome therapeutics, including SER-109, directly in the United States and with collaborators outside the United States; and
- developing manufacturing capabilities sufficient to support commercialization of any approved Ecobiotic microbiome therapeutic candidates.

Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled “Risk Factors” immediately following this prospectus summary. Some of these risks are:

- we have a limited operating history, have incurred significant losses since our inception, expect to incur losses for the foreseeable future and may never achieve or maintain profitability;
- we will need additional funding before we can expect to become profitable from the sales of our products, if approved, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts;
- we are very early in our development efforts and our product candidates, including SER-109, may not be successful in later stage clinical trials and, as a result, may never be approved as marketable therapeutics;
- we rely, and expect to continue to rely, on third parties to conduct our clinical trials and to manufacture our product candidates for pre-clinical and clinical testing, and those third parties may not perform satisfactorily, which could delay our product development activities;
- if we are unable to adequately protect our proprietary technology, or obtain and maintain issued patents which are sufficient to protect our product candidates, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects; and
- we may not be able to retain key executives or to attract, retain and motivate qualified personnel.

Our Corporate Information

We were incorporated in the State of Delaware in 2010 under the name Newco LS21, Inc. In October 2011, we changed our name to Seres Health, Inc., and in May 2015, we changed our name to Seres Therapeutics, Inc. Our principal executive offices are located at 215 First Street, Cambridge, Massachusetts 02142 and our telephone number is (617) 945-9626. Our website address is *www.serestherapeutics.com*. The information contained in, or accessible through, our website does not constitute a part of this prospectus.

Implications of Being an Emerging Growth Company

As a company with less than $1.0 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, enacted in April 2012. An "emerging growth company" may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the closing of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenue exceeds $1.0 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

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

THE OFFERING

Common stock offered by us	7,430,555 shares
Common stock to be outstanding after this offering	37,834,057 shares (or 38,948,640 shares if the underwriters exercise their option to purchase additional shares in full)
Option to purchase additional shares	The underwriters have a 30-day option to purchase up to 1,114,583 additional shares of our common stock.
Use of proceeds	We intend to use the net proceeds from this offering (1) to advance the clinical development of SER-109, (2) to advance the development of our other product candidates, SER-262, SER-287 and SER-155, and (3) the remainder, if any, to fund our current and future research and development activities and for working capital and other general corporate purposes. See “Use of Proceeds” beginning on page 55.
Risk factors	See “Risk Factors” beginning on page 12 and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
NASDAQ Global Select Market symbol	“MCRB”

The number of shares of our common stock to be outstanding after this offering is based on 7,536,515 shares of our common stock outstanding as of May 31, 2015 and 22,866,987 shares of our common stock issuable upon the automatic conversion of all outstanding shares of our preferred stock in connection with this offering, and excludes:

- 3,977,746 shares of common stock issuable upon exercise of stock options outstanding as of May 31, 2015, at a weighted average exercise price of $3.74 per share;
- 92,127 shares of common stock issuable upon the exercise of a warrant to purchase Series A-2 preferred stock that will become a warrant to purchase common stock, at an exercise price of $1.78 per share, in connection with this offering;
- 850,000 shares of common stock issuable upon the exercise of stock options to be granted in connection with this offering under our 2015 Incentive Award Plan, or the 2015 Incentive Plan, which will become effective in connection with this offering, to some of our directors, executive officers and employees, at an exercise price per share equal to the initial public offering price in this offering;
- 1,350,000 shares of our common stock that will become available for future issuance under our 2015 Incentive Plan as well as shares of our common stock that become available pursuant to provisions in our 2015 Incentive Plan that automatically increase the share reserve under our 2015 Incentive Plan as described in “Executive and Director Compensation—Incentive Plans—2015 Incentive Award Plan”; and

- 365,000 shares of our common stock that will become available for future issuance under our 2015 Employee Stock Purchase Plan, or the 2015 ESPP, which will become effective in connection with this offering, as well as shares of our common stock that become available pursuant to provisions in our 2015 ESPP that automatically increase the share reserve under our 2015 ESPP as described in "Executive and Director Compensation—Incentive Plans—2015 Employee Stock Purchase Plan."

Unless otherwise indicated, this prospectus reflects and assumes the following:

- the automatic conversion of all shares of our preferred stock outstanding as of May 31, 2015 into an aggregate of 22,866,987 shares of our common stock in connection with this offering;
- the outstanding warrant to purchase our Series A-2 preferred stock becoming a warrant to purchase our common stock in connection with this offering;
- no exercise of outstanding options or warrants after May 31, 2015;
- the filing of our restated certificate of incorporation and the adoption of our amended and restated bylaws, which will occur upon the closing of this offering; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock.

Nestlé Health Science US Holdings, Inc., or Nestlé, an existing stockholder affiliated with one of our directors, has indicated an interest to purchase $24.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, Nestlé may determine to increase or reduce the amount of its indication of interest, or otherwise elect not to purchase any shares. It is also possible that the number of shares allocated in this offering to Nestlé may be greater or smaller than the amount of its indication of interest, or no shares may be allocated to Nestlé.

SUMMARY CONSOLIDATED FINANCIAL DATA

You should read the following summary consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus. We have derived the consolidated statement of operations data for the years ended December 31, 2012, 2013 and 2014 from our audited consolidated financial statements appearing at the end of this prospectus. The consolidated statement of operations data for the three months ended March 31, 2014 and 2015 and the consolidated balance sheet data as of March 31, 2015 have been derived from our unaudited consolidated financial statements appearing at the end of this prospectus and have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information in those statements. Our historical results are not necessarily indicative of the results that should be expected in the future, and results for the three months ended March 31, 2015 are not necessarily indicative of the results to be expected for the full year ending December 31, 2015.

	Year Ended December 31,			Three Months Ended March 31,	
	2012	2013	2014	2014	2015
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Revenue	$ —	$ —	$ —	$ —	$ —
Operating expenses:					
Research and development	2,077	4,805	10,718	1,032	5,561
General and administrative	956	1,247	4,364	640	2,606
Total operating expenses	3,033	6,052	15,082	1,672	8,167
Loss from operations	(3,033)	(6,052)	(15,082)	(1,672)	(8,167)
Other income (expense):					
Interest income (expense), net	(93)	(42)	(209)	(37)	(17)
Revaluation of preferred stock warrant liability	—	(8)	(1,418)	20	213
Total other income (expense), net	(93)	(50)	(1,627)	(17)	196
Net loss	(3,126)	(6,102)	(16,709)	(1,689)	(7,971)
Accretion of convertible preferred stock to redemption value	(276)	(875)	(1,291)	(233)	—
Net loss attributable to common stockholders	$ (3,402)	$ (6,977)	$ (18,000)	$ (1,922)	$ (7,971)
Net loss per share attributable to common stockholders, basic and diluted[1]	$ (0.59)	$ (1.09)	$ (2.67)	$ (0.29)	$ (1.15)
Weighted average common shares outstanding, basic and diluted[1]	5,725	6,395	6,748	6,686	6,913
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[2]			$ (0.74)		$ (0.27)
Pro forma weighted average common shares outstanding, basic and diluted (unaudited)[2]			20,684		29,780

(1) See Note 11 to our consolidated financial statements appearing at the end of this prospectus for further details on the calculation of basic and diluted net loss per share attributable to common stockholders.

(2) See Note 12 to our consolidated financial statements appearing at the end of this prospectus for further details on the calculation of basic and diluted pro forma net loss per share attributable to common stockholders.

	As of March 31, 2015		
	Actual	Pro Forma[2]	Pro Forma As Adjusted[3]
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash, cash equivalents and investments	$104,316	$ 104,321	$ 227,415
Working capital[1]	101,649	101,654	224,910
Total assets	108,628	108,633	229,648
Preferred stock warrant liability	1,369	—	—
Long-term debt, net of discount, including current portion	2,216	2,216	2,216
Convertible preferred stock	136,053	—	—
Total stockholders' equity (deficit)	(33,245)	104,182	225,359

(1) We define working capital as current assets less current liabilities.

(2) The pro forma balance sheet data give effect to:

- the automatic conversion of all shares of our preferred stock outstanding as of March 31, 2015 into an aggregate of 22,866,987 shares of our common stock in connection with this offering;
- the exercise for cash of a warrant to purchase 454,545 shares of common stock at an exercise price of $0.01 per share, which occurred on April 29, 2015; and
- the outstanding warrant to purchase our Series A-2 preferred stock becoming a warrant to purchase our common stock in connection with this offering.

(3) The pro forma as adjusted balance sheet data give further effect to the sale by us of 7,430,555 shares of our common stock in this offering at the initial public offering price of $18.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Results of Operations and Financial Condition," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment.

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 $3.1 million for the year ended December 31, 2012, $6.1 million for the year ended December 31, 2013, $16.7 million for the year ended December 31, 2014 and $1.7 million and $8.0 million for the three months ended March 31, 2014 and 2015, respectively. As of March 31, 2015, we had an accumulated deficit of $35.8 million. To date, we have financed our operations through private placements of our preferred stock, the issuance of convertible promissory notes and borrowings under our loan and security agreement, as amended, 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 our clinical trial. We are in the early stages of development of our product candidates, and we have not completed development of any Ecobiotic microbiome therapeutics or other drugs or biologics. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

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

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

We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our Phase 2 clinical study of SER-109, and continue to research, develop and initiate clinical trials of SER-262, SER-287 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, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We expect that our existing cash, cash equivalents and investments, together with anticipated net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements through at least the first quarter of 2017. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the progress and results of our Phase 2 clinical study of SER-109;
- the cost of manufacturing clinical supplies of our product candidates;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for our other product candidates, including SER-262, SER-287 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, although we currently have no commitments or agreements to complete any such transactions.

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, researching SER-262, building our intellectual property portfolio, developing our supply chain, planning our business, raising capital and providing general and administrative support for these operations. All but one of our product candidates, SER-109, are still in pre-clinical development. We recently completed our Phase 1b/2 clinical study of SER-109, our lead product candidate, but have not completed any other clinical trials for this or any other product candidate. We have not yet demonstrated our ability to successfully complete any Phase 2 clinical study or any Phase 3 or other pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

We are very early in our development efforts and may not be successful in our efforts to use our microbiome therapeutics platform to build a pipeline of product candidates and develop marketable drugs.

We are using our microbiome therapeutics platform to develop Ecobiotic microbiome therapeutics, with an initial focus on developing SER-109 for the prevention of further recurrences of CDI in patients suffering from recurrent CDI. While we believe our pre-clinical and Phase 1b/2 clinical data to date has validated our platform to a degree, we are at an early stage of development and our platform has not yet, and may never lead to, approvable or marketable drugs. We are developing additional product candidates that we intend to be used to prevent non-*Clostridium difficile* infection and to treat inflammatory and metabolic diseases. We may have problems applying our technologies to these other areas, and our new product candidates may not be as effective in preventing infection and disease as our initial product candidates. Even if we are successful in identifying additional product candidates, they may not be suitable for clinical development, including as a result of their harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. The success of our product candidates will depend on several factors, including the following:

- completion of pre-clinical studies and clinical trials with positive results;
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing our own, commercial manufacturing capabilities;
- launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- entering into new collaborations throughout the development process as appropriate, from pre-clinical studies through to commercialization;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our products, if approved;
- protecting our rights in our intellectual property portfolio;
- operating without infringing or violating the valid and enforceable patents or other intellectual property of third parties;
- maintaining a continued acceptable safety profile of the products following approval; and
- maintaining and growing an organization of scientists and business people who can develop and commercialize our products and technology.

If we do not successfully develop and commercialize product candidates based upon our technological approach, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

Our product candidates are based on microbiome therapeutics, which is an unproven approach to therapeutic intervention.

All of our product candidates are based on microbiome therapy, a therapeutic approach that is designed to treat disease by restoring the function of a dysbiotic microbiome. We have not, nor to our knowledge has any other company, received regulatory approval for a therapeutic based on this approach. We cannot be certain that our approach will lead to the development of approvable or marketable products. In addition, our Ecobiotic microbiome therapeutics may have different effectiveness rates in various indications and in different geographical areas. Finally, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of products based on microbiome therapeutics, which could result in a longer than expected regulatory review process, increase our expected development costs and delay or prevent commercialization of our product candidates.

Our microbiome therapeutics platform relies on third parties for biological materials, including human stool. Some biological materials have not always met our expectations or requirements, and any disruption in the supply of these biological materials could materially adversely affect our business. For example, if any supplied biological materials are contaminated with disease organisms, we would not be able to use such biological materials. Although we have control processes and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. Improper storage of these materials, by us or any third-party suppliers, may require us to destroy some of our raw materials or products.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We dosed the first patient in a Phase 2 clinical study of our lead product, SER-109, in May 2015. Our other product candidates are in pre-clinical development. It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval, and the risk of failure through the development process is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete pre-clinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failed clinical trial can occur at any stage of testing. The outcome of pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. For example, in anticipation of our Phase 2 clinical study of SER-109, we have refined the formulation of the inner capsule and changed the manufacturing process that we expect to use for commercial production. This formulation has not previously been clinically tested. The Phase 2 clinical study is the first clinical trial using this formulation and we cannot assure you that the results of this new formulation will be consistent with those experienced in the Phase 1b/2 clinical study of SER-109. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks.

In addition, we cannot be certain as to what type and how many clinical trials the FDA will require us to conduct before we may successfully gain approval to market SER-109 or any of our other product candidates. Prior to approving a new therapeutic product, the FDA generally requires that safety and efficacy be demonstrated in two adequate and well-controlled clinical trials. In some situations, evidence from a Phase 2 trial and a Phase 3 trial or from a single Phase 3 trial can be sufficient for FDA approval, such as in cases where the trial or trials provide highly reliable and statistically strong evidence of an important clinical benefit. In the course of our discussions with the FDA, the FDA has

indicated that we may be required to conduct more than one Phase 3 clinical trial of SER-109 in order to gain approval. Additional clinical trials could cause us to incur significant development costs, delay or prevent the commercialization of SER-109 or otherwise adversely affect our business.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidates may demonstrate undesirable side effects or produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- regarding trials managed by any future collaborators, our collaborators may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but potentially suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- lose the support of any future collaborators, requiring us to bear more of the burden of development of certain compounds;
- not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as we intend or desire;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

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

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our pre-clinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant pre-clinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations.

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

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. We are developing our lead product candidate, SER-109, to prevent further recurrences of CDI in patients suffering from recurrent CDI. We estimate the addressable population of patients with recurrent CDI to be between 85,000 and 110,000 patients per year in the United States, and accordingly, there is a limited number of patients from which to draw for clinical studies.

Patient enrollment is also affected by other factors including:

- the severity of the disease under investigation;
- the patient eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the availability of other treatments for the disease under investigation;
- the existence of competing clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- our payments for conducting clinical trials;

- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates or will not be able to do so as soon as anticipated, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate in any jurisdiction will prevent us from commercializing the product candidate in that jurisdiction, and may affect our plans for commercialization in other jurisdictions as well. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties to assist us in this process. Securing marketing approval requires the submission of extensive pre-clinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years. The scope and amount of clinical data required to obtain marketing approvals can vary substantially from jurisdiction to jurisdiction, and it may be difficult to predict whether a particular regulatory body will require additional or different studies than those conducted by a sponsor, especially for novel product candidates such as our Ecobiotic microbiome therapeutics. The FDA or foreign regulatory authorities may delay, limit, or deny approval to market our product candidates for many reasons, including: our inability to demonstrate that the clinical benefits of our product candidates outweigh any safety or other perceived risks; the regulatory authority's disagreement with the interpretation of data from nonclinical or clinical studies; the regulatory agency's requirement that we conduct additional pre-clinical studies and clinical trials; changes in marketing approval policies during the development period; changes in or the enactment of additional statutes or regulations, or changes in regulatory review process for each submitted product application; or the regulatory authority's failure to approve the manufacturing processes or third-party manufacturers with which we contract. Regulatory authorities have substantial discretion in the approval process and may refuse to accept a marketing application as deficient. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Of the large number of drugs in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized.

Furthermore, our product candidates may not receive marketing approval even if they achieve their specified endpoints in clinical trials. Clinical data is often susceptible to varying interpretations and many companies that have believed that their products performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products. The FDA or foreign regulatory authorities may disagree with our trial design and our interpretation of data from nonclinical and clinical studies. Upon the FDA's review of data from any pivotal trial, it may request that the sponsor conduct additional analyses of the data and, if it believes the data are not satisfactory, could advise the sponsor to delay filing a marketing application.

Even if we eventually complete clinical testing and receive approval of a biologics license application, or BLA, or foreign marketing authorization for one of our product candidates, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials which may be required after approval. The FDA or the applicable foreign regulatory agency may also approve SER-109 for a more limited indication and/or a narrower patient population than we originally request, and the FDA, or applicable foreign regulatory agency, may not approve the labeling that we believe is necessary or desirable for the successful commercialization of SER-109. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of SER-109 and would materially adversely impact our business and prospects.

The development of therapeutic products targeting the underlying biology of the human microbiome is an emerging field, and it is possible that the FDA and other regulatory authorities could issue regulations or new policies in the future affecting our Ecobiotic microbiome therapeutics that could adversely affect our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

A fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We may seek fast track designation for some of our product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition, the drug or biologic sponsor may apply for FDA fast track designation. Fast track designation provides increased opportunities for sponsor meetings with the FDA during pre-clinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Fast track designation does not assure ultimate approval by the FDA. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

A Breakthrough Therapy designation by the FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We have received Breakthrough Therapy designation for SER-109, and we may seek a Breakthrough Therapy designation for our other product candidates. A breakthrough therapy is defined as a drug or biologic that is intended to treat a serious or life-threatening disease or condition, and

preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed in early clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development. Drugs designated as breakthrough therapies by the FDA are also eligible for rolling review of the associated marketing application, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, as well as priority review, where the agency aims to act on the application within six months.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. The availability of Breakthrough Therapy designation was established recently with the passage of the Food and Drug Administration Safety and Innovation Act of 2012, and the FDA has only recently released additional guidance as to the criteria it uses in designating drugs as breakthrough therapies. As a result, we cannot be sure that our evaluation of our product candidates as qualifying for Breakthrough Therapy designation will meet the FDA's expectations. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, not all products designated as breakthrough therapies ultimately will be shown to have the substantial improvement over available therapies suggested by the preliminary clinical evidence at the time of designation. As a result, if the Breakthrough Therapy designation for SER-109 or any future designation we receive is no longer supported by subsequent data, the FDA may rescind the designation.

We may seek orphan drug designation for some of our product candidates, but may not be able to obtain it.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and biologics for relatively small patient populations as orphan drugs. In the United States, the FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, which is defined as a disease or condition that affects fewer than 200,000 individuals annually in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug or biologic for that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug or biologic to meet the needs of patients with the rare disease or condition.

We may seek orphan drug designation and exclusivity for some of our product candidates. However, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Risks Related to our Dependence on Third Parties and Manufacturing

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

We expect to continue to rely on third parties, such as contract research organizations, or CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct and manage our clinical trials, including our Phase 2 clinical study of SER-109.

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

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

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

We rely on third parties for the manufacture of our product candidates for pre-clinical and clinical testing and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or that such quantities may not be available at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for pre-clinical and clinical testing, as well as for commercial manufacture if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates on a timely basis or at all, or that such quantities will be available at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

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

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of manufacturing agreements by the third-party manufacturers;
- failure to manufacture our product according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- misappropriation or disclosure of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of agreements by third-party manufacturers at times that are costly or inconvenient for us.

Third-party manufacturers may not be able to comply with current good manufacturing processes, or cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. The contract manufacturer we rely on to produce SER-109 has never produced a FDA-approved therapeutic. If our contract manufacturer is unable to comply with cGMP regulation or if the FDA does not approve their facility upon a pre-approval inspection, SER-109 may not be approved or may be delayed in obtaining approval. In addition, there are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing our products. Therefore, our product candidates and any future products that we may develop may compete with other products for access to manufacturing facilities. Any failure to gain access to these limited manufacturing facilities could severely impact the clinical development, marketing approval and commercialization of our product candidates.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. Except for a backup facility in California, we do not currently have arrangements in place for redundant supply or a second source for required raw materials used in the manufacture of our product candidates or for the manufacture of finished SER-109 product. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products could delay, prevent or impair our development and commercialization efforts.

We have no experience manufacturing our product candidates at commercial scale, and if we decide to establish our own manufacturing facility, we cannot assure you that we can manufacture our product candidates in compliance with regulations at a cost or in quantities necessary to make them commercially viable.

We have a pilot manufacturing facility at our Cambridge location where we conduct process development, scale-up activities and a portion of the manufacture of Ecobiotic microbiome therapeutics. The FDA and other comparable foreign regulatory agencies must, pursuant to inspections that are conducted after submitting a BLA or relevant foreign marketing submission, confirm that the manufacturing processes for the product meet cGMP. We do not have any manufacturing facilities that meet the FDA's cGMP requirements for the production of any product candidates used in humans.

We may establish a manufacturing facility for our product candidates for production at a commercial scale. We have no experience in commercial-scale manufacturing of our product candidates. We currently intend to develop our manufacturing capacity in part by expanding our current facility or building additional facilities. This activity will require substantial additional funds and we would need to hire and train significant numbers of qualified employees to staff these facilities. We may not be able to develop commercial-scale manufacturing facilities that are adequate to produce materials for additional later-stage clinical trials or commercial use.

The equipment and facilities employed in the manufacture of pharmaceuticals are subject to stringent qualification requirements by regulatory agencies, including validation of facility, equipment, systems, processes and analytics. We may be subject to lengthy delays and expense in conducting validation studies, if we can meet the requirements at all.

Risks Related to Commercialization of Our Product Candidates and Other Legal Compliance Matters

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, hospitals, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current CDI treatment involves the use of antibiotics that are well established in the medical community or the use of fecal microbiota transplantation, or FMT, and physicians may continue to rely on these treatments. If our product candidates receive approval but do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our approved product candidates, if any, will depend on a number of factors, including:

- their efficacy, safety and other potential advantages compared to alternative treatments;
- the clinical indications for which our products are approved;
- our ability to offer them for sale at competitive prices;
- their convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for our product candidates;
- the prevalence and severity of their side effects and their overall safety profiles;
- any restrictions on the use of our products together with other medications;
- interactions of our products with other medicines patients are taking; and
- inability of certain types of patients to take our product.

We currently have no sales organization. If we are unable to establish effective sales, marketing and distribution capabilities or enter into agreements with third parties with such capabilities, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish a sales and marketing organization or make arrangements with third parties to perform sales and marketing functions and we may not be successful in doing so.

In the future, we expect to build a focused sales and marketing infrastructure to market or co-promote our product candidates in the United States and potentially elsewhere, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or educate physicians on the benefits of our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies.

Outside the United States, we may rely on third parties to sell, market and distribute our product candidates. We may not be successful in entering into arrangements with such third parties or may be unable to do so on terms that are favorable to us. In addition, our product revenue and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

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

The development and commercialization of new drug and biologic products is highly competitive and is characterized by rapid and substantial technological development and product innovations. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies

worldwide. We are aware of a number of large pharmaceutical and biotechnology companies, including Merck, Shire, Sanofi, Pfizer and Novartis, as well as smaller, early-stage companies, that are pursuing the development of products, including microbiome therapeutics, for the prevention of CDI and other disease indications we are targeting. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others may be based on entirely different approaches. For example, FMT is a procedure that has resulted in high cure rates for recurrent CDI and our competitors and physicians may continue to seek to standardize and implement this procedure. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors.

These third parties compete with us in recruiting and retaining qualified scientific, sales and marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market, especially for any competitor developing a microbiome therapeutic which will likely share our same regulatory approval requirements. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic or biosimilar products.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, any of which would harm our business.

Our ability to commercialize any product candidates successfully will depend, in part, on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

Obtaining and maintaining adequate reimbursement for our products may be difficult. We cannot be certain if and when we will obtain an adequate level of reimbursement for our products by third-party payors. Even if we do obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. We

may also be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control, including possible price reductions, even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. There can be no assurance that our product candidates, if they are approved for sale in the United States or in other countries, will be considered medically necessary for a specific indication or cost-effective, or that coverage or an adequate level of reimbursement will be available.

Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;

- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently hold $3.0 million in product liability insurance coverage in the aggregate, with a per occurrence limit of $3.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, we may face competition from biosimilars. In the United States, the Biologics Price Competition and Innovation Act, or BCPIA, enacted in 2010 as part of the Patient Protection and Affordable Care Act, created an abbreviated approval pathway for biological products that are demonstrated to be “highly similar,” or biosimilar, to or “interchangeable” with an FDA-approved biological product. This new pathway could allow competitors to reference data from innovative biological products 12 years after the time of approval of the innovative biological product. This data exclusivity does not prevent another company from developing a product that is highly similar to the innovative product, generating its own data and seeking approval. Data exclusivity only assures that another company cannot rely upon the data within the innovator’s application to support the biosimilar product’s approval.

In each of his proposed budgets for fiscal years 2013 through 2015, President Obama has proposed to cut this 12-year period of exclusivity down to seven years. He also proposed to prohibit additional periods of exclusivity due to minor changes in product formulations, a practice often referred to as “evergreening.” It is possible that Congress may take these or other measures to reduce or eliminate periods of exclusivity. The BCPIA is complex and only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact is subject to uncertainty. The FDA has issued several guidance documents to date discussing the biosimilar pathway, and the FDA recently approved the first biosimilar under the BCPIA in March 2015. However, several issues still remain unclear with respect to the FDA’s final implementation of the BCPIA, and such FDA implementation could have a material adverse effect on the future commercial prospects for our product candidates.

In Europe, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data supporting approval of an innovative biological product, but will not be able to get on the market until 10 years after the time of approval of the innovative product. This 10-year marketing exclusivity period will be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilars in other countries that could compete with our products. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products in the European Union and many other jurisdictions, we or our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval in foreign countries may differ substantially from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or our collaborators may not obtain approvals for our product candidates from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Any product candidate for which we obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to the continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. We and our contract manufacturers will also be subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to specific conditions of approval, including a requirement to implement a risk evaluation and mitigation strategy, or REMS, which could include requirements for a medication guide, communication plan, or restricted distribution system. If any of our product candidates receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of our approved products. The FDA closely regulates the post-approval marketing and promotion of drugs and biologics to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products outside of their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDA's restrictions relating to the promotion of prescription drugs may also lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, if a regulatory agency or we later discover previously unknown problems with our products, such as adverse events of unanticipated severity or frequency, problems with manufacturers or manufacturing processes, or failure to comply with regulatory requirements, the regulatory agency may impose restrictions on the products or us, including requiring withdrawal of the product from the market. Any failure to comply with applicable regulatory requirements may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of products from the market;
- suspension or termination of ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure or detention;
- injunctions; or
- imposition of civil or criminal penalties.

Noncompliance with similar European Union requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with U.S. and foreign regulatory requirements regarding the development of products for pediatric populations and the protection of personal health information can also lead to significant penalties and sanctions.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues. If regulatory sanctions are applied or if regulatory approval is withheld or withdrawn, the value of our company and our operating results will be adversely affected.

Our relationships with customers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from governmental healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors, physicians and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program, such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payment Sunshine Act requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. Data from the first reporting period, which began in August 2013, is now publicly available. Manufacturers will be required to submit subsequent reports to the government by the 90th day of each calendar year;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and
- state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open

to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain a robust system to comply with multiple jurisdictions with different compliance and reporting requirements increases the possibility that a healthcare company may violate one or more of the requirements.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The MMA expanded Medicare coverage for outpatient drug purchases by those covered by Medicare under a new Part D and introduced a new reimbursement methodology based on average sales prices for Medicare Part B physician-administered drugs. In addition, the MMA authorized Medicare Part D prescription drug plans to limit the number of drugs that will be covered in any therapeutic class in their formularies. The MMA's cost reduction initiatives and other provisions could decrease the coverage and price that we receive for any approved products. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors. Similar regulations or reimbursement policies may be enacted in international markets which could similarly impact our business.

More recently, in 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the Affordable Care Act of importance to our potential product candidates are the following:

- establishment of a new pathway for approval of lower-cost biosimilars to compete with biologic products, such as those we are developing;
- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, including hospitals. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain.

We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with

governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various European Union member states and parallel distribution or arbitrage between low-priced and high-priced member states, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If coverage and reimbursement of our products are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials such as human stool. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Our Intellectual Property

If we are unable to adequately protect our proprietary technology, or obtain and maintain issued patents which are sufficient to protect our product candidates, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner,

or in all jurisdictions. Prosecution of our patent portfolio is at a very early stage, and we are just beginning to reach the statutory deadlines for deciding whether and where to initiate prosecution in specific foreign jurisdictions by filing national state applications based on our Patent Cooperation Treaty, or PCT, applications. As those deadlines come due, we will have to decide whether and where to pursue patent protection for the various inventions claimed in our patent portfolio, and we will only have the opportunity to obtain patents in those jurisdictions where we pursue protection. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as, with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results.

If, in the future, we obtain licenses from third parties, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. We may also require the cooperation of our licensors to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license could have a material adverse impact on our business.

Our patent portfolio is in the early stages of prosecution. We currently have three issued U.S. patents. Although we have numerous patent applications pending, substantive prosecution has begun in only a small number of those applications. We cannot provide any assurances that any of our pending patent applications will mature into issued patents and, if they do, that such patents or our current patents will include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. For example, we are pursuing claims to therapeutic, binary compositions of certain bacterial populations. Any claims that may issue may provide coverage for such binary compositions and/or their use. However, such claims would not prevent a third party from commercializing alternative compositions that do not include both of the bacterial populations claimed in pending applications, potential applications or patents that have or may issue. There can be no assurance that any such alternative composition will not be equally effective. Further, given that our SER-109 product candidate is a complex composition with some variation from lot-to-lot and that, likewise, third-party compositions may have similar complexity and variability, it is possible that a patent claim may provide coverage for some but not all lots of a product candidate or third-party product. These and other factors may provide opportunities for our competitors to design around our patents, should they issue.

Moreover, other parties have developed technologies that may be related or competitive to our approach, and may have filed or may file patent applications and may have received or may receive patents that may overlap or conflict with our patent applications, either by claiming similar methods or by claiming subject matter that could dominate our patent position. In addition, given the early stage of prosecution of our portfolio, it may be some time before we understand how patent offices react to our patent claims and whether they identify prior art of relevance that we have not already considered.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we

were the first to make the inventions claimed in any owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions, nor can we know whether those from whom we may license patents were the first to make the inventions claimed or were the first to file. For these and other reasons, the issuance, scope, validity, enforceability and commercial value of our patent rights are subject to a level of uncertainty. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

We may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates. The issuance, scope, validity, enforceability and commercial value of our patents are subject to a level of uncertainty.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering biotechnological and pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if issued, a patent's validity, inventorship, ownership or enforceability is not conclusive. Accordingly, rights under any existing patent or any patents we might obtain or license may not cover our product candidates, or may not provide us with sufficient protection for our product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our product candidates or any other products or product candidates;
- any of our pending patent applications will issue as patents at all;
- we will be able to successfully commercialize our product candidates, if approved, before our relevant patents expire;
- we were the first to make the inventions covered by any existing patent and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe or design around our patents;
- others will not use pre-existing technology to effectively compete against us;
- any of our patents, if issued, will be found to ultimately be valid and enforceable;
- third parties will not compete with us in jurisdictions where we do not pursue and obtain patent protection;

- we will be able to obtain and/or maintain necessary or useful licenses on reasonable terms or at all;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- our commercial activities or products will not infringe upon the patents or proprietary rights of others.

Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. Even if we are successful, domestic or foreign litigation, or USPTO or foreign patent office proceedings, may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential collaborators, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

If we are unable to protect the confidentiality of our trade secrets and know-how, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also seek to enter into confidentiality and invention or patent assignment agreements with our employees, advisors and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity, and is therefore costly, time-consuming and

inherently uncertain. In addition, recent patent reform legislation could further increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular the first to file provisions, only became effective on March 16, 2013. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Thus, for our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. Moreover, some of the patent applications in our portfolio will be subject to examination under the pre-Leahy-Smith Act law and regulations, while other patents applications in our portfolio will be subject to examination under the law and regulations, as amended by the Leahy-Smith Act. This introduces additional complexities into the prosecution and management of our portfolio.

In addition, the Leahy-Smith Act limits where a patentee may file a patent infringement suit and provides opportunities for third parties to challenge any issued patent in the USPTO. These provisions apply to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a federal court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims because it may be easier for them to do so relative to challenging the patent in a federal court action. It is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, recent United States Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. From time to time, the U.S. Supreme Court, other federal courts, the United States Congress, or the USPTO, may change the standards of patentability and any such changes could have a negative impact on our business.

A number of recent cases decided by the Supreme Court have involved questions of when claims reciting abstract ideas, laws of nature, natural phenomena and/or natural products are eligible for a patent, regardless of whether the claimed subject matter is otherwise novel and inventive. These cases include *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 12-398 (2013) or Myriad; *Alice Corp. v. CLS Bank International*, 573 U.S. 13-298 (2014); and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, or Prometheus, 566 U.S. 10-1150 (2012). In response to these cases, the USPTO has issued guidance to the examining corps.

The full impact of these decisions is not yet known. The Myriad decision, issued on June 13, 2013, is the most recent Supreme Court decision to address patent eligibility of natural products. Our current product candidates include natural products, therefore, this decision and its interpretation by the courts and the USPTO may impact prosecution, defense and enforcement of our patent portfolio. In Myriad, the Court held that claims to isolated genomic DNA are not patentable, but claims to complementary DNA, or cDNA, molecules, which are not genomic sequences, may be patent eligible

because they are not a natural product. The effect of the decision on patents for other isolated natural products is uncertain. However, on March 4, 2014, the USPTO issued a memorandum to patent examiners providing guidance for examining claims that recite laws of nature, natural phenomena or natural products under the Myriad and Prometheus decisions. The guidance did not limit the application of Myriad to DNA but, rather, applied the decision broadly to other natural products, which may include our product candidates. The March 4, 2014 memorandum and the USPTO's interpretation of the cases and announced examination rubric received widespread criticism from stakeholders during a public comment period and was superseded by interim guidance published on December 15, 2014. The USPTO's interpretation of the case law and new guidelines for examination may influence, possibly adversely, prosecution and defense of certain types of claims in our portfolio.

In addition to increasing uncertainty with regard to our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on these and other decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change or be interpreted in unpredictable ways that would weaken our ability to obtain new patents or to enforce any patents that may issue to us in the future. In addition, these events may adversely affect our ability to defend any patents that may issue in procedures in the USPTO or in courts.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. While no such litigation has been brought against us and we have not been held by any court to have infringed a third party's intellectual property rights, we cannot guarantee that our technology, products or use of our products do not infringe third-party patents.

We are aware of numerous patents and pending applications owned by third parties in the fields in which we are developing product candidates, both in the United States and elsewhere. However, we may have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products. We are aware of several pending patent applications containing one or more claims that could be construed to cover some of our product candidates or technology, should those claims issue in their original form or in the form presently being pursued. In addition, we are aware of a third-party patent family that includes issued and allowed patents, including in the United States, with claims that, if valid and enforceable, could be construed to cover some of our product candidates or their methods of use.

The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that our product candidates or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the USPTO and similar bodies in other countries. Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future. If we were to challenge the validity of an issued U.S. patent in court, such as an issued U.S. patent of potential relevance to some of our product candidates or methods of use, we would need to overcome a statutory presumption of validity that attaches to every U.S. patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. There is no assurance that a court would find in our favor on questions of infringement or validity.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. If we are found, or believe there is a risk we may be found, to infringe a third party's intellectual property rights, we could be required or may choose to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any such license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our products. Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease developing, selling or otherwise commercializing our product candidates;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and
- in the case of trademark claims, redesign, or rename, some or all of our product candidates or other brands to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

Issued patents covering our product candidates could be found invalid or unenforceable or could be interpreted narrowly if challenged in court.

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. If we initiated legal proceedings against a third party to enforce a patent, if and when issued, covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement, or failure to claim patent eligible subject matter. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Moreover, even if not found invalid or unenforceable, the claims of our patents could be construed narrowly or in a manner that does not cover the allegedly infringing technology in question. Such a loss of patent protection would have a material adverse impact on our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and, in some jurisdictions, during the pendency of a patent application. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

It is our policy to enter into confidentiality and intellectual property assignment agreements with our employees, consultants, contractors and advisors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual

property rights to us. For example, even if we have a consulting agreement in place with an academic advisor pursuant to which such academic advisor is required to assign any inventions developed in connection with providing services to us, such academic advisor may not have the right to assign such inventions to us, as it may conflict with his or her obligations to assign all such intellectual property to his or her employing institution.

Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may also engage advisors and consultants who are concurrently employed at universities or other organizations or who perform services for other entities. Although we try to ensure that our employees, advisors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, advisors or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such party's former or current employer or in violation of an agreement with another party. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims.

In addition, while it is our policy to require our employees, consultants, advisors and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Similarly, we may be subject to claims that an employee, advisor or consultant performed work for us that conflicts with that person's obligations to a third party, such as an employer, and thus, that the third party has an ownership interest in the intellectual property arising out of work performed for us. Litigation may be necessary to defend against these claims. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition

among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than in the United States, assuming that rights are obtained in the United States and assuming that rights are pursued outside the United States. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications. For all of the patent families in our portfolio, including the families that may provide coverage for our lead product candidates, the relevant statutory deadlines have not yet expired. Therefore, for each of the patent families that we believe provide coverage for our lead product candidates, we will need to decide whether and where to pursue protection outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, even if we do elect to pursue patent rights outside the United States, we may not be able to obtain relevant claims and/or we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biotechnology. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

If our ability to obtain and, if obtained, enforce our patents to stop infringing activities is inadequate, third parties may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Accordingly, our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property we develop or license.

Risks Related to Employee Matters and Managing Growth and Other Risks Related to Our Business

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

We are highly dependent on Roger Pomerantz, our President and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical team, including Eric Shaff, our Chief Financial Officer and Executive Vice President, David Cook, our Chief Scientific Officer and Executive Vice President of Research & Development, John Aunins, our Chief Technology Officer and Executive Vice President of Bioprocess Development, Michele Trucksis, our Chief Medical Officer and Executive Vice President, and Matthew Henn, our Head of Drug Discovery & Bioinformatics and Vice President. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of lead discovery and product development, regulatory affairs, clinical affairs and manufacturing and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train

additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

We currently have limited international operations, but our business strategy incorporates potentially expanding internationally if any of our product candidates receive regulatory approval. We currently plan to rely on collaborators to commercialize any approved products outside of the United States. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our results of operations.

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

Despite the implementation of security measures, our internal computer systems and those of our current and future contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we are not aware of any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture our product candidates and conduct clinical trials, and similar events relating to their

computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Acquisitions or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. We have not made any acquisitions to date, and our ability to do so successfully is unproven. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with future customers or with current or future distributors or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- diversion of management time and focus from operating our business to acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- possible write-offs or impairment charges relating to acquired businesses; and
- inability to develop a sales force for any additional product candidates.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the anticipated benefit of any acquisition may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

Risks Related to Our Common Stock and this Offering

An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock was determined through negotiations with the underwriters. Although our common stock has been approved for listing on The NASDAQ Global Select Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult for you to sell shares you purchase in this offering without depressing the market price for the shares or at all.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

Our stock price is likely to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- actual or anticipated changes in our growth rate relative to our competitors;
- results of clinical trials of our product candidates or those of our competitors;
- developments related to any future collaborations;
- regulatory or legal developments in the United States and other countries;
- development of new product candidates that may address our markets and may make our product candidates less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

After this offering, our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to control or significantly influence all matters submitted to stockholders for approval.

Upon the closing of this offering, based on the number of shares of common stock outstanding as of May 31, 2015, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock before this offering and their respective affiliates will, in the aggregate, hold shares representing approximately 70.7% of our outstanding voting stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all

matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management and the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

If you purchase shares of common stock in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. To the extent shares subsequently are issued under outstanding options or warrants, you will incur further dilution. Based on the initial public offering price of $18.00 per share, you will experience immediate dilution of $12.04 per share as of March 31, 2015, representing the difference between our pro forma as adjusted net tangible book value per share, which gives effect to this offering, and the initial public offering price. In addition, purchasers of common stock in this offering will have contributed approximately 49.9% of the aggregate price paid by all purchasers of our stock but will own only approximately 19.6% of our common stock outstanding after this offering.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. We intend to use the net proceeds of this offering, together with our existing cash, cash equivalents and investments, to advance the clinical development of SER-109 for the prevention of further recurrences of CDI in patients suffering from recurrent CDI; to advance the development of our other product candidates, SER-262, SER-287 and SER-155; and the remainder, if any, to fund current and future research and development activities and for working capital and other general corporate purposes. However, our use of these proceeds may differ substantially from our current plans. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have outstanding 37,834,057 shares of common stock based on the number of shares outstanding as of May 31, 2015. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates or existing stockholders. The remaining

30,403,502 shares are currently restricted as a result of securities laws or lock-up agreements but will become eligible to be sold 180 days after the date of this offering, unless held by one of our affiliates, in which case the resale of those securities will be subject to volume limitations under Rule 144 of the Securities Act. Moreover, after this offering, holders of an aggregate of 22,959,114 shares of our common stock, including shares issuable upon the exercise of warrants, will have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 or until the rights terminate pursuant to the terms of the investors' rights agreement between us and such holders. We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

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

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably

elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The NASDAQ Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our

stock performance, or if our target animal studies and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and our amended and restated bylaws that will become effective upon the closing of this offering may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period

of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Furthermore, our restated certificate of incorporation that will become effective upon the closing of this offering specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders. We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in such action.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, our loan and security agreement with Comerica Bank currently prohibits us from paying dividends on our equity securities, and any future debt agreements may likewise preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this prospectus 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 prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. These forward-looking statements are subject to numerous risks, including, without limitation, the following:

- our status as a development-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.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. 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. 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.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement relating to this offering 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.

INDUSTRY AND OTHER DATA

We obtained the industry, market and competitive position data in this prospectus from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we are not aware of any misstatements regarding the market or industry data presented herein, our estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading “Risk Factors,” “Special Note Regarding Forward-Looking Statements” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this prospectus.

TRADEMARKS, SERVICE MARKS AND TRADENAMES

We own or have rights to use a number of registered and common law trademarks, service marks and/or trade names in connection with our business in the United States and/or in certain foreign jurisdictions, including, but not limited to, “Ecobiotic”.

Solely for convenience, the trademarks, service marks, logos and trade names referred to in this prospectus are without the ® and ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and trade names. This prospectus contains additional trademarks, service marks and trade names of others, which are the property of their respective owners. All trademarks, service marks and trade names appearing in this prospectus are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies’ trademarks, service marks, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

USE OF PROCEEDS

We estimate that our net proceeds from the sale of shares of our common stock in this offering will be approximately $121.2 million, or $139.8 million if the underwriters exercise in full their option to purchase additional shares, based on the initial public offering price of $18.00 per share and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

We currently estimate that we will use the net proceeds from this offering as follows:

- approximately $25 million to advance the clinical development of SER-109 for the prevention of further recurrences of CDI in patients suffering from recurrent CDI, which we expect will be sufficient to complete our Phase 2 clinical study that we initiated in May 2015;
- approximately $40 million to advance the development of our other product candidates, SER-262, SER-287 and SER-155, which we expect will be sufficient to complete pre-clinical studies and, if supported, file an investigational new drug application, for one or more of these product candidates; and
- the remainder, if any, to fund current and future research and development activities and for working capital and other general corporate purposes.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. We may also use a portion of the net proceeds to in-license, acquire, or invest in additional businesses, technologies, products or assets, although currently we have no specific agreements, commitments or understandings in this regard. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. Predicting the cost necessary to develop product candidates can be difficult and we anticipate that we will need additional funds to complete the development of SER-262, SER-287, SER-155 and any other product candidates we identify. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from pre-clinical studies and any ongoing clinical trials or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

DIVIDEND POLICY

We have never declared or paid dividends on our capital stock. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. We do not anticipate paying any dividends on our capital stock in the foreseeable future. In addition, the terms of our existing loan and security agreement with Comerica Bank preclude us from paying cash dividends without Comerica's consent.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and investments and our capitalization as of March 31, 2015:

- on an actual basis;
- on a pro forma basis, after giving effect to:
  - the automatic conversion of all shares of our preferred stock outstanding at March 31, 2015 into an aggregate of 22,866,987 shares of our common stock in connection with this offering;
  - the exercise for cash of a warrant to purchase 454,545 shares of common stock at an exercise price of $0.01 per share, which occurred on April 29, 2015;
  - the outstanding warrant to purchase our Series A-2 preferred stock becoming a warrant to purchase our common stock in connection with this offering; and
  - the filing and effectiveness of our restated certificate of incorporation; and
- on a pro forma as adjusted basis, after giving effect to the pro forma adjustments listed above as well as the sale by us of 7,430,555 shares of our common stock in this offering at the initial public offering price of $18.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with our consolidated financial statements and related notes appearing at the end of this prospectus and the sections of this prospectus titled “Selected Consolidated Financial Data,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Description of Capital Stock.”

	As of March 31, 2015		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share data)		
Cash, cash equivalents and investments	$104,316	$104,321	$227,415
Preferred stock warrant liability	$ 1,369	$ —	$ —
Long-term debt, net of discount, including current portion	2,216	2,216	2,216
Convertible preferred stock (Series A, A-2, B, C, D and D-1), $0.001 par value per share; 24,348,003 shares authorized, 22,866,987 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	136,053	—	—
Stockholders’ equity (deficit):			
Preferred stock, $0.001 par value per share; no shares authorized, issued or outstanding, actual; 10,000,000 shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, $0.001 par value per share; 38,000,000 shares authorized, 7,081,970 shares issued and outstanding, actual; 200,000,000 shares authorized, 30,403,502 shares issued and outstanding, pro forma; 200,000,000 shares authorized, 37,834,057 shares issued and outstanding, pro forma as adjusted	7	30	38
Additional paid-in capital	2,520	139,924	261,093
Accumulated other comprehensive income	31	31	31
Accumulated deficit	(35,803)	(35,803)	(35,803)
Total stockholders’ equity (deficit)	(33,245)	104,182	225,359
Total capitalization	$106,393	$106,398	$227,575

The number of shares of common stock shown as outstanding in the table above excludes:

- 3,989,246 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2015, at a weighted average exercise price of $3.63 per share;
- 92,127 shares of common stock issuable upon the exercise of a warrant to purchase Series A-2 preferred stock that will become a warrant to purchase common stock, at an exercise price of $1.78 per share, in connection with this offering;
- 850,000 shares of common stock issuable upon the exercise of stock options to be granted in connection with this offering under our 2015 Incentive Plan, which will become effective in connection with this offering, to some of our directors, executive officers and employees, at an exercise price per share equal to the initial public offering price in this offering;
- 1,350,000 shares of our common stock that will become available for future issuance under our 2015 Incentive Plan as well as shares of our common stock that become available pursuant to provisions in our 2015 Incentive Plan that automatically increase the share reserve under our 2015 Incentive Plan as described in “Executive and Director Compensation—Incentive Plans—2015 Incentive Award Plan”; and
- 365,000 shares of our common stock that will become available for future issuance under our 2015 ESPP, which will become effective in connection with this offering, as well as shares of our common stock that become available pursuant to provisions in our 2015 ESPP that automatically increase the share reserve under our 2015 ESPP as described in “Executive and Director Compensation—Incentive Plans—2015 Employee Stock Purchase Plan.”

Mayo Warrants

On June 6, 2014, we issued two warrants to the Mayo Foundation for Medical Education and Research, or the Mayo Foundation, in connection with our research and option agreement with the Mayo Foundation. The first warrant, or the funding warrant, for the purchase of 454,545 shares of our common stock at an exercise price of $0.01 per share was exercised in full on April 29, 2015. The second warrant is an incentive warrant tied to certain milestones that, as of the date of this prospectus, had not been accomplished. The incentive warrant will terminate upon the closing of this offering.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value (deficit) as of March 31, 2015 was $(35.3) million, or $(4.99) per share of common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and preferred stock, which is not included within stockholders' equity (deficit). Historical net tangible book value per share is our historical net tangible book value (deficit) divided by the number of shares of common stock outstanding as of March 31, 2015.

Our pro forma net tangible book value as of March 31, 2015 was $102.1 million, or $3.36 per share of common stock. Pro forma net tangible book value represents the amount of our total tangible assets less total liabilities, after giving effect to (1) the automatic conversion of all shares of our preferred stock outstanding as of March 31, 2015 into an aggregate of 22,866,987 shares of our common stock in connection with this offering, (2) the exercise for cash of a warrant to purchase 454,545 shares of common stock at an exercise price of $0.01 per share, which occurred on April 29, 2015, and (3) the outstanding warrant to purchase our Series A-2 preferred stock becoming a warrant to purchase our common stock in connection with this offering. Pro forma net tangible book value per share represents our pro forma net tangible book value divided by the total number of shares outstanding as of March 31, 2015, after giving effect to the pro forma adjustments described in (1) and (2) above.

After giving effect to our sale of 7,430,555 shares of common stock in this offering at the initial public offering price of $18.00 per share and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2015 would have been approximately $225.3 million, or $5.96 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of $2.60 per share to existing stockholders and an immediate dilution of $12.04 per share to new investors purchasing common stock in this offering at the initial public offering price. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Initial public offering price per share		$18.00
Historical net tangible book value (deficit) per share as of March 31, 2015	$(4.99)	
Increase per share attributable to the conversion of all shares of preferred stock outstanding, the exercise of a warrant to purchase common stock and a warrant to purchase preferred stock becoming a warrant to purchase common stock in connection with this offering	8.35	
Pro forma net tangible book value per share as of March 31, 2015	3.36	
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing shares in this offering	2.60	
Pro forma as adjusted net tangible book value per share after this offering		5.96
Dilution per share to new investors purchasing shares in this offering		$12.04

If the underwriters exercise their option to purchase additional shares in full, our pro forma as adjusted net tangible book value per share after this offering would be $6.26 per share, representing an immediate increase in pro forma as adjusted net tangible book value per share of $2.90 to existing

stockholders and immediate dilution of $11.74 in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering, based on the initial public offering price of $18.00 per share.

The following table summarizes, on a pro forma as adjusted basis described above, the number of shares of our common stock, the total consideration and the average price per share (i) paid to us by existing stockholders and (ii) to be paid by new investors purchasing shares of common stock in this offering at the initial public offering price of $18.00 per share, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	30,403,502	80.4%	$134,241,021	50.1%	$ 4.42
New investors	7,430,555	19.6	133,749,990	49.9	$ 18.00
Total	37,834,057	100.0%	$267,991,011	100.0%	

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to 78.1% of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors participating in the offering would be increased to 21.9% of the total number of shares of our common stock outstanding after this offering.

The above discussion and tables exclude:

- 3,989,246 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2015, at a weighted average exercise price of $3.63 per share;
- 92,127 shares of common stock issuable upon the exercise of a warrant to purchase Series A-2 preferred stock that will become a warrant to purchase common stock, at an exercise price of $1.78 per share, in connection with this offering;
- 850,000 shares of common stock issuable upon the exercise of stock options to be granted in connection with this offering under our 2015 Incentive Plan, which will become effective in connection with this offering, to some of our directors, executive officers and employees, at an exercise price per share equal to the initial public offering price in this offering;
- 1,350,000 shares of our common stock that will become available for future issuance under our 2015 Incentive Plan as well as shares of our common stock that become available pursuant to provisions in our 2015 Incentive Plan that automatically increase the share reserve under our 2015 Incentive Plan as described in "Executive and Director Compensation—Incentive Plans—2015 Incentive Award Plan"; and
- 365,000 shares of our common stock that will become available for future issuance under our 2015 ESPP, which will become effective in connection with this offering, as well as shares of our common stock that become available pursuant to provisions in our 2015 ESPP that automatically increase the share reserve under our 2015 ESPP as described in "Executive and Director Compensation—Incentive Plans—2015 Employee Stock Purchase Plan."

To the extent that outstanding options are exercised, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that

additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

Nestlé Health Science US Holdings, Inc., or Nestlé, an existing stockholder affiliated with one of our directors, has indicated an interest to purchase $24.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, Nestlé may determine to increase or reduce the amount of its indication of interest, or otherwise elect not to purchase any shares. It is also possible that the number of shares allocated in this offering to Nestlé may be greater or smaller than the amount of its indication of interest, or no shares may be allocated to Nestlé.

SELECTED CONSOLIDATED FINANCIAL DATA

You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus. We have derived the consolidated statement of operations data for the years ended December 31, 2012, 2013 and 2014 and the consolidated balance sheet data as of December 31, 2013 and 2014 from our audited consolidated financial statements appearing at the end of this prospectus. We have derived the consolidated balance sheet data as of December 31, 2012 from our audited consolidated financial statements not included in this prospectus. The consolidated statement of operations data for the three months ended March 31, 2014 and 2015 and the consolidated balance sheet data as of March 31, 2015 have been derived from our unaudited consolidated financial statements appearing at the end of this prospectus and have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information in those statements. Our historical results are not necessarily indicative of the results that should be expected in the future, and results for the three months ended March 31, 2015 are not necessarily indicative of the results to be expected for the full year ending December 31, 2015.

	Year Ended December 31,			Three Months Ended March 31,	
	2012	2013	2014	2014	2015
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Revenue	$ —	$ —	$ —	$ —	$ —
Operating expenses:					
Research and development	2,077	4,805	10,718	1,032	5,561
General and administrative	956	1,247	4,364	640	2,606
Total operating expenses	3,033	6,052	15,082	1,672	8,167
Loss from operations	(3,033)	(6,052)	(15,082)	(1,672)	(8,167)
Other income (expense):					
Interest income (expense), net	(93)	(42)	(209)	(37)	(17)
Revaluation of preferred stock warrant liability	—	(8)	(1,418)	20	213
Total other income (expense), net	(93)	(50)	(1,627)	(17)	196
Net loss	(3,126)	(6,102)	(16,709)	(1,689)	(7,971)
Accretion of convertible preferred stock to redemption value	(276)	(875)	(1,291)	(233)	—
Net loss attributable to common stockholders	$(3,402)	$(6,977)	$(18,000)	$(1,922)	$ (7,971)
Net loss per share attributable to common stockholders, basic and diluted[1]	$ (0.59)	$ (1.09)	$ (2.67)	$ (0.29)	$ (1.15)
Weighted average common shares outstanding, basic and diluted[1]	5,725	6,395	6,748	6,686	6,913
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[2]			$ (0.74)		$ (0.27)
Pro forma weighted average common shares outstanding, basic and diluted (unaudited)[2]			20,684		29,780

(1) See Note 11 to our consolidated financial statements appearing at the end of this prospectus for further details on the calculation of basic and diluted net loss per share attributable to common stockholders.

(2) See Note 12 to our consolidated financial statements appearing at the end of this prospectus for further details on the calculation of basic and diluted pro forma net loss per share attributable to common stockholders.

	As of December 31,			As of March 31,
	2012	2013	2014	2015
	(in thousands)			
Consolidated Balance Sheet Data:				
Cash, cash equivalents and investments	$ 6,215	$ 1,654	$114,185	$104,316
Working capital[1]	6,067	649	109,140	101,649
Total assets	6,538	2,125	117,345	108,628
Preferred stock warrant liability	—	164	1,582	1,369
Long-term debt, net of discount, including current portion	—	838	2,504	2,216
Convertible preferred stock	10,708	11,583	136,077	136,053
Total stockholders' deficit	(4,348)	(11,116)	(26,721)	(33,245)

(1) We define working capital as current assets less current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of financial condition and results of operations together with the section titled "Selected Consolidated Financial Data" and our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors" section of this prospectus.

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 FDA, could be a first-in-field drug. Using our microbiome therapeutics platform, we are developing additional product candidates, including SER-262 to prevent an initial recurrence of primary CDI, SER-287 to treat inflammatory bowel disease, or IBD, including ulcerative colitis and SER-155 to treat enteric pathogens, such as antibiotic-resistant bacteria. We are also conducting research on metabolic diseases, such as early-stage, non-insulin dependent diabetes; other inflammatory diseases, such as Crohn's disease; and infections related to antibiotic use, cancer chemotherapy and immune suppression.

Since our inception in October 2010, we have devoted substantially all of our resources to developing SER-109, researching SER-262 and SER-287, 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 March 31, 2015, we have 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, as amended, with Comerica Bank, or the loan and security agreement. Through March 31, 2015, we had received gross proceeds of $137.0 million from such transactions and we had repaid $0.7 million of the total $3.0 million borrowed under the loan and security agreement.

We are a development stage company and have not generated any revenue. All of our product candidates other than SER-109 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 $3.1 million for the year ended December 31, 2012, $6.1 million for the year ended December 31, 2013, $16.7 million for the year ended December 31, 2014 and $1.7 million and $8.0 million for the three months ended March 31, 2014 and 2015, respectively. As of March 31, 2015, we had an accumulated deficit of $35.8 million.

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

- advance the clinical development of SER-109 for the prevention of further recurrences of CDI in patients suffering from recurrent CDI, through a Phase 2 clinical study;
- initiate clinical development of SER-262 to be used following antibiotic treatment of primary CDI to prevent an initial recurrence of CDI;

- initiate Phase 1 clinical development of SER-287 for the treatment of IBD, including ulcerative colitis;
- conduct research and continue pre-clinical development of additional Ecobiotic microbiome therapeutics, including SER-155 for the treatment of antibiotic-resistant bacteria;
- 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; and
- seek to obtain regulatory approvals for our product candidates.

In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, upon the closing of this offering, we expect 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.

We expect that our existing cash, cash equivalents and investments, together with anticipated net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements through at least the first quarter of 2017. See "—Liquidity and Capital Resources."

Financial Operations Overview

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future.

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.

Our primary focus of research and development since inception has been on our microbiome therapeutics platform and the subsequent development of SER-109 and SER-262. 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.

	Year Ended December 31,			Three Months Ended March 31,	
	2012	2013	2014	2014	2015
			(in thousands)		
Microbiome therapeutics platform	$2,077	$3,424	$ 7,584	$ 877	$2,314
SER-109	—	729	3,122	143	3,185
SER-262	—	652	12	12	62
Total research and development expenses	$2,077	$4,805	$10,718	$ 1,032	$5,561

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase in the foreseeable future as we initiate clinical trials for certain product candidates, including SER-262 and SER-287, continue to discover and develop additional product candidates, including SER-155, and pursue later stages of clinical development of our product candidates.

General and Administrative Expenses

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

We 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 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 (Expense), Net. Interest income (expense), net consists of interest earned on our cash, cash equivalents and investments as well as interest expense incurred on our debt. During the years ended December 31, 2013 and 2014 and the three months ended March 31, 2014 and 2015, interest expense consisted of interest at the stated rate on borrowings under our loan and security agreement, amortization of deferred financing costs and interest expense related to the accretion of debt discount associated with (1) the fair value of preferred stock warrant we issued in connection with the loan and security agreement and (2) a final payment due at maturity. In 2012, interest expense consisted of interest on our outstanding convertible promissory notes at the stated interest rate and interest expense related to the amortization of deferred financing costs. In June 2012, all of our outstanding convertible promissory notes and accrued interest were converted into shares of our Series A convertible preferred stock.

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. We have issued a warrant for the purchase of our Series A-2 convertible preferred stock that we believe is a financial instrument that may require a transfer of assets because of the redemption feature of the underlying stock. Therefore, we have classified this warrant as a liability that we remeasure to fair value at each reporting period, and we record the changes in the fair value as a component of other income (expense), net. In connection with this offering, the underlying convertible preferred stock will be converted into common stock, the preferred stock warrant will become exercisable for common stock instead of preferred stock and the fair value of the warrant liability at that time will be reclassified to additional paid-in capital.

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. As of December 31, 2014, we had federal and state net operating loss carryforwards of $20.3 million and $19.9 million, respectively, both of which begin to expire in 2031. As of December 31, 2014, we also had federal and state research and development tax credit carryforwards of $0.8 million and $0.4 million, respectively, which begin to expire in 2031 and 2026, respectively.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles, or GAAP, in the United States of America. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amount of assets, liabilities, revenue, costs and expenses and related disclosures. We believe that the estimates and assumptions involved in the accounting policies described below may have the greatest potential impact on our consolidated financial statements and, therefore, consider these to be our critical accounting policies. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing research services on our behalf and clinical trials;
- investigative sites or other providers in connection with clinical trials;
- vendors in connection with pre-clinical and clinical development activities; and
- vendors related to product manufacturing, development and distribution of pre-clinical and clinical supplies.

We base our expenses related to pre-clinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We measure stock options and other stock-based awards granted to employees and directors based on the fair value on the date of grant and recognize the corresponding compensation expense of those awards, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. Generally, we issue stock options and restricted stock awards with only service-based vesting conditions and record the expense for these awards using the straight-line method.

We measure stock-based awards granted to consultants and non-employees based on the fair value of the award on the date at which the related service is complete. Compensation expense is recognized over the period during which services are rendered by such consultants and non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option-pricing model.

We estimate the fair value of each stock option grant using the Black-Scholes option-pricing model. Use of this model requires that we make assumptions as to the volatility of our common stock,

the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. Because we are currently a private company and lack company-specific historical and implied volatility information, we estimate our expected volatility based on the historical volatility of a group of publicly traded peer companies. We expect to continue to do so until such time as we have adequate historical data regarding the volatility of our traded stock price. We use the simplified method prescribed by Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term of options granted to employees and directors. We base the expected term of options granted to consultants and non-employees on the contractual term of the options. We determine the risk-free interest rate by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future.

The assumptions we used to determine the fair value of stock options granted to employees and directors are as follows, presented on a weighted average basis:

	Year Ended December 31,			Three Months Ended March 31, 2015
	2012	2013	2014	
Risk-free interest rate	0.92%	1.27%	1.83%	1.57%
Expected term (in years)	6.0	6.0	6.0	6.0
Expected volatility	109.4%	85.9%	83.5%	76.0%
Expected dividend yield	0%	0%	0%	0%

These assumptions represented our best estimates, but the estimates involve inherent uncertainties and the application of our judgment.

We did not grant any stock options to employees or directors during the three months ended March 31, 2014.

We recognize compensation expense for only the portion of awards that are expected to vest. In developing a forfeiture rate estimate for pre-vesting forfeitures, we have considered our historical experience of actual forfeitures.

The following table summarizes the classification of our stock-based compensation expenses recognized in our consolidated statements of operations:

	Year Ended December 31,			Three Months Ended March 31,	
	2012	2013	2014	2014	2015
			(in thousands)		
Research and development	$ 26	$ 177	$1,068	$ 32	$ 623
General and administrative	2	32	1,000	13	704
	$ 28	$ 209	$2,068	$ 45	$ 1,327

Determination of the Fair Value of Common Stock

We are a privately held company with no active public market of our common stock. Therefore, our board of directors has estimated the fair value of our common stock at various dates, with input from management, considering our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant.

In the absence of a public trading market for our common stock, our determination of the fair value of our common stock was performed using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. We performed these contemporaneous valuations, with the assistance of a third-party specialist, at various dates, which resulted in valuations of our common stock of $0.48 per share as of April 1, 2013, $0.71 per share as of May 23, 2014, $3.14 per share as of October 1, 2014, $7.79 per share as of November 17, 2014 and $15.77 per share as of February 18, 2015. In addition to these valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status of pre-clinical studies and clinical trials for our product candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biotechnology industry;
- trends within the biotechnology industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or sale of our company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

There are significant judgments and estimates inherent in these valuations. These judgments and estimates include assumptions regarding our future operating performance, the stage of development of our product candidates, the timing of a potential IPO or other liquidity event and the determination of the appropriate valuation methodology at each valuation date. If we had made different assumptions, our stock-based compensation expense, net loss attributable to common stockholders and net loss per share attributable to common stockholders could have been significantly different.

Once a public trading market for our common stock has been established in connection with the closing of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and restricted stock, as the fair value of our common stock will be its trading price on The NASDAQ Global Select Market.

Valuation Methodologies

Our common stock valuations were performed using the option-pricing method, or OPM, or a hybrid of the probability-weighted expected return method, or PWERM, and the OPM, which we refer to as the hybrid method. The method selected was based on availability and the quality of information to develop the assumptions for the methodology.

OPM. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceed the value of the liquidation preferences at the time of a liquidity event, such as a strategic sale or merger. The common stock is

modeled as a call option on the underlying equity value at a predetermined exercise price. In the model, the exercise price is based on a comparison with the total equity value rather than, as in the case of a regular call option, a comparison with a per share stock price. Thus, common stock is considered to be a call option with a claim on the enterprise at an exercise price equal to the remaining value immediately after the preferred stock liquidation preference is paid.

The OPM uses the Black-Scholes option-pricing model to price the call options. This model defines the fair values of securities as functions of the current fair value of a company and uses assumptions such as the anticipated timing of a potential liquidity event and the estimated volatility of the equity securities.

PWERM. Under the PWERM methodology, the fair value of common stock is estimated based upon an analysis of future values for the company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock.

Hybrid Method. The hybrid method is a PWERM where the equity value in one of the scenarios is calculated using an OPM. In the hybrid method used by us, two types of future-event scenarios were considered: an IPO and a remaining private scenario. The enterprise value for the IPO scenario was determined using a market approach. The enterprise value for the remaining private scenario was determined using the OPM backsolve approach. The relative probability of each type of future-event scenario was determined by our board of directors based on an analysis of market conditions at the time, including then-current IPO valuations of similarly situated companies, and expectations as to the timing and likely prospects of the future-event scenarios.

Option Grants

The following table summarizes by grant date the number of shares subject to options granted since January 1, 2013, the per share exercise price of the options, the fair value of common stock underlying the options on date of grant and the per share estimated fair value of the options:

Grant Date	Number of Shares Subject to Options Granted	Per Share Exercise Price of Options[1]	Fair Value of Common Stock per Share on Date of Option Grant	Per Share Estimated Fair Value of Options[2][3]
May 17, 2013	700,000	$ 0.48	$ 0.48	$ 0.35
November 6, 2013	299,000	$ 0.48	$ 0.48	$ 0.34
August 7, 2014	1,775,751	$ 0.71	$ 4.32[4]	$ 3.92
August 21, 2014	59,500	$ 0.71	$ 4.32[4]	$ 3.92
October 7, 2014	206,500	$ 3.14	$ 6.70[5]	$ 5.42
December 9, 2014	320,192	$ 7.79	$ 7.79	$ 5.38
March 25, 2015	606,624	$ 15.77	$ 15.77	$ 10.50
March 30, 2015	5,000	$ 15.77	$ 15.77	$ 10.50
April 2, 2015	25,000	$ 15.77	$ 15.77	$ 10.50

(1) The Per Share Exercise Price of Options represents the fair value of our common stock on the date of grant, as determined by our board of directors, after taking into account our most recently available contemporaneous valuation of our common stock as well as additional factors that may have changed since the date of such contemporaneous valuation through the date of grant.

(2) The Per Share Estimated Fair Value of Options reflects the weighted average fair value of options granted on each grant date, determined using the Black-Scholes option-pricing model.

(3) For purposes of recording stock-based compensation for grants of options to non-employees, we measure the fair value of the award on the service completion date (vesting date). At the end of each reporting period prior to completion of the services, we remeasure the value of any unvested portion of the option based on the then-current fair value of the option and adjust the expense accordingly. The weighted average fair value amounts presented in this column for grants to employees, directors and non-employees reflect only the grant-date fair value of options granted to non-employees and not any subsequently remeasured fair value of those options.

(4) At the time of the option grants on August 7, 2014 and August 21, 2014, our board of directors determined that the fair value of our common stock of $0.71 per share calculated in the contemporaneous valuation as of May 23, 2014 reasonably reflected the per share fair value of common stock as of the grant date. However, as described below, the fair value of common stock at the date of these grants was subsequently adjusted to $4.32 per share in connection with a retrospective fair value assessment for accounting purposes.

(5) At the time of the option grants on October 7, 2014, our board of directors determined that the fair value of our common stock of $3.14 per share calculated in the contemporaneous valuation as of October 1, 2014 reasonably reflected the per share fair value of common stock as of the grant date. However, as described below, the fair value of common stock at the date of these grants was subsequently adjusted to $6.70 per share in connection with a retrospective fair value assessment for accounting purposes.

In the course of preparing for this offering, in November 2014, we performed a retrospective fair value assessment and concluded that the fair value of our common stock underlying stock options we granted during August 2014, with an exercise price of $0.71 per share, was $4.32 per share for accounting purposes and that the fair value of our common stock underlying stock options we granted on October 7, 2014, with an exercise price of $3.14 per share, was $6.70 per share for accounting purposes. The values of $4.32 per share and $6.70 per share, which we applied to determine the fair values of the August 2014 and October 2014 options for accounting purposes and to determine related stock-based compensation expense, were based in part upon a valuation of our common stock as of August 7, 2014, performed on a retrospective basis with the assistance of a third-party specialist, and upon a revised valuation of our common stock as of October 1, 2014, performed on a retrospective basis with the assistance of a third-party specialist, taking into account an increased probability of executing a successful IPO in 2015 and initial feedback from potential investors in our Series C convertible preferred stock offering. These common stock valuations as of August 7, 2014 and October 1, 2014 were performed using the hybrid method.

Valuation of Warrant to Purchase Convertible Preferred Stock

We classify a warrant to purchase shares of our Series A-2 convertible preferred stock as a liability on our balance sheets as this warrant is a free-standing financial instrument that may require us to transfer assets upon exercise. The warrant was initially recorded at fair value on date of grant, and it is subsequently remeasured to fair value at each balance sheet date. Changes in fair value of this warrant are recognized as a component of other income (expense), net in our consolidated statement of operations and comprehensive loss. We will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant.

We use the Black-Scholes option-pricing model, which incorporates assumptions and estimates, to value the preferred stock warrant. We assess these assumptions and estimates on a quarterly basis as additional information impacting the assumptions is obtained. Estimates and assumptions impacting the fair value measurement include the fair value per share of the underlying Series A-2 convertible preferred stock, the remaining contractual term of the warrant, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying preferred stock. We determine the fair value per share of the underlying preferred stock by taking into consideration our most recent sales of our convertible preferred stock, results obtained from third-party valuations and additional factors that we deem relevant. We have historically been a private company and lack company-specific historical and implied volatility information of our stock. Therefore, we estimate expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrant. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrant. We have

estimated a 0% dividend yield based on the expected dividend yield and the fact that we have never paid or declared dividends.

In connection with this offering, the underlying convertible preferred stock will be converted to common stock, the preferred stock warrant will become exercisable for common stock instead of preferred stock and the fair value of the warrant liability at that time will be reclassified to additional paid-in capital.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an ‘‘emerging growth company’’ such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to ‘‘opt out’’ of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Results of Operations

Comparison of Three Months Ended March 31, 2014 and 2015

The following table summarizes our results of operations for the three months ended March 31, 2014 and 2015:

	Three Months Ended March 31,		Increase (Decrease)
	2014	2015	
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	1,032	5,561	4,529
General and administrative	640	2,606	1,966
Total operating expenses	1,672	8,167	6,495
Loss from operations	(1,672)	(8,167)	(6,495)
Other income (expense):			
Interest income (expense), net	(37)	(17)	20
Revaluation of preferred stock warrant liability	20	213	193
Total other income (expense), net	(17)	196	213
Net loss	$(1,689)	$(7,971)	$ (6,282)

Research and Development Expenses

	Three Months Ended March 31,		Increase (Decrease)
	2014	2015	
	(in thousands)		
Microbiome therapeutics platform	$ 877	$ 2,314	$ 1,437
SER-109	143	3,185	3,042
SER-262	12	62	50
Total research and development expenses	$ 1,032	$ 5,561	$ 4,529

Research and development expenses were $1.0 million for the three months ended March 31, 2014, compared to $5.6 million for the three months ended March 31, 2015. The increase of $4.5 million was due primarily to the following:

- an increase of $1.4 million in research expenses related to our microbiome therapeutics platform, due primarily to higher payroll and consultant costs of $1.3 million, which included an increase in stock-based compensation expense of $0.6 million, due primarily to an increase in employee headcount and, to a lesser extent, an increase in laboratory supply costs and facility-related costs;
- an increase of $3.0 million in expenses related to our SER-109 program, due primarily to higher clinical trial costs of $1.7 million, higher bioprocess development costs of $1.1 million and higher sequencing costs of $0.2 million; and
- an increase of $0.1 million in expenses of our SER-262 program in connection with various pre-clinical and development activities related to the program.

We expect that our research and development expenses will continue to increase in the foreseeable future as we initiate clinical trials for certain product candidates, including SER-262 and SER-287, continue to discover and develop additional product candidates, including SER-155, and pursue later stages of clinical development of our product candidates.

General and Administrative Expenses

	Three Months Ended March 31,		Increase (Decrease)
	2014	2015	
	(in thousands)		
Personnel related (including stock-based compensation)	$ 149	$ 1,400	$ 1,251
Professional fees	438	827	389
Facility-related and other	53	379	326
Total general and administrative expenses	$ 640	$ 2,606	$ 1,966

General and administrative expenses were $0.6 million for the three months ended March 31, 2014, compared to $2.6 million for the three months ended March 31, 2015. The increase of $2.0 million was primarily due to an increase in personnel related costs of $1.3 million, which included an increase of $0.7 million in stock-based compensation, an increase in professional fees of $0.4 million and an increase in facility-related and other costs of $0.3 million. Personnel related costs increased primarily due to the hiring of eight additional employees from March 31, 2014 to March 31, 2015 to support corporate operations and business development activities, including the hiring of our Chief Executive Officer in June 2014 and our Chief Financial Officer in November 2014. The increase in professional fees was due to an increase in accounting, audit and legal fees as a result of ongoing business activities. The increase in facility-related and other costs was primarily due to an increase in office-related expenses and rent expense resulting from our new facility for research and development that commenced in February 2015.

Other Income (Expense), Net

Other income (expense), net for the three months ended March 31, 2014 was an expense of less than $0.1 million, compared to income of $0.2 million for the three months ended March 31, 2015. The $0.2 million increase in other income, net was primarily due to gains recorded to adjust the fair value of our preferred stock warrant liability due to a decrease in the fair value of the underlying Series A-2 convertible preferred stock over that period.

Comparison of Years Ended December 31, 2013 and 2014

The following table summarizes our results of operations for the years ended December 31, 2013 and 2014:

	Year Ended December 31,		Increase (Decrease)
	2013	2014	
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	4,805	10,718	5,913
General and administrative	1,247	4,364	3,117
Total operating expenses	6,052	15,082	9,030
Loss from operations	(6,052)	(15,082)	(9,030)
Other income (expense):			
Interest income (expense), net	(42)	(209)	(167)
Revaluation of preferred stock warrant liability	(8)	(1,418)	(1,410)
Total other income (expense), net	(50)	(1,627)	(1,577)
Net loss	$ (6,102)	$ (16,709)	$ (10,607)

Research and Development Expenses

	Year Ended December 31,		Increase (Decrease)
	2013	2014	
	(in thousands)		
Microbiome therapeutics platform	$3,424	$ 7,584	$ 4,160
SER-109	729	3,122	2,393
SER-262	652	12	(640)
Total research and development expenses	$4,805	$10,718	$ 5,913

Research and development expenses were $4.8 million for the year ended December 31, 2013, compared to $10.7 million for the year ended December 31, 2014. The increase of $5.9 million was due primarily to the following:

- an increase of $4.2 million in research expenses related to our microbiome therapeutics platform, due primarily to higher payroll and consultant costs of $2.1 million, which included an increase in stock-based compensation expense of $0.9 million; an increase in laboratory supply costs of $0.7 million; an increase in facility-related costs of $0.5 million; and an increase in licensing costs of $0.3 million;
- an increase of $2.4 million in expenses related to our SER-109 program, due primarily to higher clinical trial costs of $2.1 million and higher contract manufacturing costs of $0.4 million, partially offset by lower animal studies costs; and
- a decrease of $0.6 million in expenses of our SER-262 program due to our shifted focus to SER-109 and our microbiome therapeutics platform research. Beginning in 2015, we expect to increase our expenses in connection with our current pre-clinical and planned clinical development activities related to SER-262.

We expect that our research and development expenses will continue to increase in the foreseeable future as we initiate clinical trials for certain product candidates, including SER-262 and SER-287, continue to discover and develop additional product candidates, including SER-155, and pursue later stages of clinical development of our product candidates.

General and Administrative Expenses

	Year Ended December 31,		Increase (Decrease)
	2013	2014	
	(in thousands)		
Personnel related (including stock-based compensation)	$ 419	$ 2,047	$ 1,628
Professional fees	691	1,785	1,094
Facility-related and other	137	532	395
Total general and administrative expenses	$ 1,247	$ 4,364	$ 3,117

General and administrative expenses were $1.2 million for the year ended December 31, 2013, compared to $4.4 million for the year ended December 31, 2014. The increase of $3.2 million was primarily due to an increase in personnel related costs of $1.6 million, which included an increase of $1.0 million in stock-based compensation, an increase in professional fees of $1.1 million and an increase in facility-related and other costs of $0.4 million. Personnel related costs increased primarily due to the hiring of 11 new employees to support corporate operations and business development activities, including the hiring of our Chief Executive Officer in June 2014 and our Chief Financial Officer in November 2014. The increase in professional fees was due to an increase in accounting, audit and legal fees as a result of ongoing business activities. The increase in facility-related and other costs was primarily due to an increase in rent expense resulting from exercising an option of our lease to increase the rentable square footage.

Other Income (Expense), Net

Other income (expense), net for the year ended December 31, 2013 was an expense of $0.1 million, compared to an expense of $1.6 million for the year ended December 31, 2014. During the year ended December 31, 2014, there was an increase of $0.2 million in interest expense incurred on borrowings under our loan and security agreement, as compared to the year ended December 31, 2013. In addition, the revaluation of preferred stock warrant liability for the year ended December 31, 2014 consisted of a $1.4 million loss to adjust the fair value of our preferred stock warrant liability due primarily to an increase in the fair value of the underlying Series A-2 convertible preferred stock over that period. This preferred stock warrant liability relates to a warrant we issued in September 2013 in connection with entering into the loan and security agreement.

Comparison of Years Ended December 31, 2012 and 2013

The following table summarizes our results of operations for the years ended December 31, 2012 and 2013:

	Year Ended December 31,		Increase (Decrease)
	2012	2013	
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	2,077	4,805	2,728
General and administrative	956	1,247	291
Total operating expenses	3,033	6,052	3,019
Loss from operations	(3,033)	(6,052)	(3,019)
Other income (expense):			
Interest income (expense), net	(93)	(42)	51
Revaluation of preferred stock warrant liability	—	(8)	(8)
Total other income (expense), net	(93)	(50)	43
Net loss	$(3,126)	$(6,102)	$ (2,976)

Research and Development Expenses

	Year Ended December 31,		Increase (Decrease)
	2012	2013	
	(in thousands)		
Microbiome therapeutics platform	$2,077	$3,424	$ 1,347
SER-109	—	729	729
SER-262	—	652	652
Total research and development expenses	$2,077	$4,805	$ 2,728

Research and development expenses for the year ended December 31, 2012 were $2.1 million, compared to $4.8 million for the year ended December 31, 2013. The increase of $2.7 million was primarily due to the following:

- an increase of $1.3 million in research expenses related to our microbiome therapeutics platform, due primarily to increased spending on employee headcount and animal studies;
- $0.7 million in initial expenses related to our SER-109 program, consisting primarily of spending on animal studies; and
- $0.7 million in initial expenses of our SER-262 program, consisting primarily of spending on animal studies.

General and Administrative Expenses

	Year Ended December 31, 2012	2013	Increase (Decrease)
		(in thousands)	
Personnel related (including stock-based compensation)	$633	$ 419	(214)
Professional fees	233	691	458
Facility-related and other	90	137	47
Total general and administrative expenses	$956	$1,247	$ 291

General and administrative expenses were $1.0 million for the year ended December 31, 2012, compared to $1.2 million for the year ended December 31, 2013. The increase of $0.3 million was primarily due to increased professional fees of $0.5 million due to increased accounting and legal fees as a result of ongoing business activities, partially offset by decreased personnel related costs of $0.2 million.

Other Income (Expense), Net

Other income (expense), net for the year ended December 31, 2012 was a net expense of $0.1 million, consistent with the amount of expense for the year ended December 31, 2013.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue and have incurred recurring net losses. We have financed our operations since inception primarily through private placements of our convertible preferred stock, the issuance of convertible promissory notes and borrowings under our loan and security agreement. From our inception through March 31, 2015, we had received gross proceeds of $137.0 million from such transactions and we had repaid $0.7 million of the total $3.0 million borrowed under the loan and security agreement. As of March 31, 2015, we had cash, cash equivalents and investments totaling $104.3 million and an accumulated deficit of $35.8 million.

On September 9, 2013, we entered into the loan and security agreement, which provided for total borrowings of up to $3.0 million. Through March 31, 2015, we had borrowed the full $3.0 million available under the loan and security agreement and had made $0.7 million of scheduled principal repayments. Under the loan and security agreement, we are obligated to make monthly, interest-only payments on any term loans funded under the facility until August 1, 2014 and, thereafter, to pay 30 consecutive, equal monthly installments of principal and interest from September 1, 2014 through February 1, 2017, the maturity date. Term loans under the loan and security agreement bear interest at an annual rate equal to 3.0% plus the greater of (1) the bank's prime rate and (2) the LIBOR rate plus 2.5% (the greater of which equated to 6.25% at March 31, 2015). In addition, a final payment of $60,000 is due upon the earlier of the maturity date, acceleration of the term loans or prepayment of all or part of the term loans. Borrowings under the loan and security agreement are secured by substantially all of our assets, except for our intellectual property, which is subject to a negative pledge.

There are no financial covenants associated with the loan and security agreement. There are negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions; encumbering our intellectual property; incurring indebtedness or liens; paying dividends; making investments; and engaging in certain other business transactions. The obligations under the loan and security agreement are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in our business, operations or financial or other condition.

In connection with entering into the loan and security agreement, in September 2013, we issued the lender a warrant to purchase 92,127 shares of our Series A-2 convertible preferred stock at an exercise price of $1.78 per share.

Cash Flows

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

	Year Ended December 31,			Three Months Ended March 31,	
	2012	2013	2014	2014	2015
			(in thousands)		
Cash used in operating activities	$(2,925)	$(5,321)	$ (10,358)	$(1,423)	$ (8,340)
Cash used in investing activities	(319)	(184)	(1,103)	(80)	(59,469)
Cash provided by (used in) financing activities	9,435	944	123,992	500	(1,331)
Net increase (decrease) in cash and cash equivalents	$ 6,191	$(4,561)	$112,531	$(1,003)	$(69,140)

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

During the three months ended March 31, 2014, operating activities used $1.4 million of cash, primarily resulting from our net loss of $1.7 million, partially offset by non-cash charges of $0.1 million and by cash provided by changes in our operating assets and liabilities of $0.2 million. Net cash provided by changes in our operating assets and liabilities during the three months ended March 31, 2014 consisted primarily of a $0.1 million increase in accounts payable and a $0.1 million increase in accrued expenses and other current liabilities. The increase in accounts payable was due to the timing of vendor invoicing and payments. The increase in our accrued expenses was primarily due to an increase in our accruals for consultant fees.

During the year ended December 31, 2014, operating activities used $10.4 million of cash, primarily resulting from our net loss of $16.7 million, partially offset by non-cash charges of $4.1 million and by cash provided by changes in our operating assets and liabilities of $2.3 million. Net cash provided by changes in our operating assets and liabilities during the year ended December 31, 2014 consisted primarily of a $0.8 million increase in accounts payable and a $1.5 million increase in accrued expenses and other current liabilities. The increase in accounts payable was due to an overall increase in our development activities, primarily driven by expenditures in connection with advancing the development of SER-109. The increase in accrued expenses and other current liabilities was due to an increase in accruals for development and manufacturing costs related to SER-109; payroll and payroll-related costs due primarily to bonuses; legal and audit-related professional fees; and facility-related costs.

During the year ended December 31, 2013, operating activities used $5.3 million of cash, resulting from our net loss of $6.1 million, partially offset by non-cash charges of $0.3 million and from cash provided by changes in our operating assets and liabilities of $0.5 million. Net cash provided by

changes in our operating assets and liabilities during the year ended December 31, 2013 consisted primarily of a $0.3 million increase in accounts payable and a $0.2 million increase in accrued expenses and other current liabilities. The increase in accounts payable was due to the timing of vendor invoicing and payments. The increase in accrued expenses and other current liabilities was primarily due to an increase in our accruals for consultant fees.

During the year ended December 31, 2012, operating activities used $3.0 million of cash, primarily resulting from our net loss of $3.1 million, partially offset by cash provided by changes in our operating assets and liabilities of $0.1 million. Net cash provided by changes in our operating assets and liabilities during the year ended December 31, 2012 consisted primarily of a $0.1 million increase in accounts payable due to the timing of vendor invoicing and payments.

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

During the three months ended March 31, 2014, we used $0.1 million of cash in investing activities, consisting of purchases of property and equipment.

During the year ended December 31, 2014, we used $1.1 million of cash in investing activities, primarily consisting of purchases of property and equipment of $1.0 million.

During the years ended December 31, 2012 and 2013, we used $0.3 million and $0.2 million of cash, respectively, in investing activities, primarily for purchases of property and equipment.

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

During the three months ended March 31, 2014, net cash provided by financing activities was $0.5 million as a result of net proceeds of $0.5 million received from borrowings under our loan and security agreement.

During the year ended December 31, 2014, net cash provided by financing activities was $124.0 million as a result of net proceeds of $123.2 million received from our sale of Series B, Series C, Series D and Series D-1 convertible preferred stock and $2.0 million from borrowings under our loan and security agreement. These amounts were partially offset by principal repayments of $0.4 million of borrowings under our loan and security agreement and payments of IPO costs related to this offering of $0.8 million.

During the year ended December 31, 2013, net cash provided by financing activities was $0.9 million as a result of net proceeds of $0.9 million borrowings under our loan and security agreement.

During the year ended December 31, 2012, net cash provided by financing activities was $9.4 million as a result of net proceeds of $8.9 million received from our issuance of our Series A and Series A-2 convertible preferred stock and proceeds of $0.5 million from our issuance of convertible promissory notes, which were converted to Series A convertible preferred stock.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing development activities related to SER-109, which is still in clinical development, and our follow-on therapeutics and other programs. In addition, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. We anticipate that our expenses will increase substantially if and as we:

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

We expect that our existing cash, cash equivalents and investments, together with anticipated net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements through at least the first quarter of 2017. 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 or our follow-on programs and because the extent to which we may enter into collaborations with third parties for development of these product candidates is unknown, 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 or our other programs will depend on many factors, including:

- the progress and results of our Phase 2 clinical study of 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-287, SER-262 and SER-155;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;

- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates, although we currently have no commitments or agreements to complete any such transactions.

Identifying potential product candidates and conducting pre-clinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Additional debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute your ownership interest.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, 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 following table summarizes our contractual obligations at March 31, 2015 and the effect such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less Than 1 Year	1 - 3 Years	4 - 5 Years	More Than 5 Years
	(in thousands)				
Operating lease commitments[1]	$2,277	$ 986	$1,291	$ —	$ —
Debt obligations[2]	2,606	1,311	1,295	—	—
Total	$4,883	$ 2,297	$2,586	$ —	$ —

(1) Amounts in the table reflect payments due for our laboratory and office space in Cambridge, Massachusetts under two operating lease agreements that expire in February 2016 and January 2018. In April 2015, we entered into an additional lease for office and laboratory space in Cambridge, Massachusetts with a term expiring in April 2020. Future payments due under this lease are $0.3 million during the year ending December 31, 2015, $0.4 million during the years ending December 31, 2016 and 2017, $0.4 million during the years ending December 31, 2018 and 2019, and $0.1 million thereafter. Such amounts are not reflected in the table.

(2) Reflects the contractually required principal and interest payments payable pursuant to our loan and security agreement.

We enter into contracts in the normal course of business with CROs for clinical trials, pre-clinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

Recently Issued Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-10, *Development Stage Entities*. The amendments in this update removed all incremental financial reporting requirements, including inception-to-date information and certain other disclosures currently required under GAAP, in the financial statements of development stage companies. The amendments are effective for annual reporting periods beginning after December 15, 2014 and interim reporting periods beginning after December 15, 2015. Early adoption is permitted. We elected to early adopt this guidance and, therefore, have not presented inception-to-date and other related disclosures in our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The amendments in this update will explicitly require a company's management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The new standard will be effective in the first annual period ending after December 15, 2016. Early application is permitted. We are currently evaluating the potential impact of the adoption of this standard, but we believe its adoption will have no impact on our financial position, results of operations or cash flows.

In February 2015, the FASB issued ASU No. 2015-02, *Consolidation: Amendments to the Consolidation Analysis*, or ASU 2015-02, which modifies existing consolidation guidance for reporting organizations that are required to evaluate whether they should consolidate certain legal entities. ASU 2015-02 will be effective for annual periods beginning after December 15, 2015, and for interim periods within those fiscal years, and requires either a retrospective or a modified retrospective approach to adoption. Early adoption is permitted. We are currently evaluating the impact of the adoption of ASU 2015-02, but believe its adoption will have no material impact on our financial position, results of operations or cash flows.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on our consolidated financial statements upon adoption.

Quantitative and Qualitative Disclosure about Market Risk

Interest Rate Fluctuation Risk

We are exposed to market risk related to changes in interest rates. As of March 31, 2015, our cash, cash equivalents and investments consisted of cash, money market accounts and investments in corporate bonds and commercial paper 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.

As of March 31, 2015, we had $2.2 million of borrowings outstanding under term loans pursuant to our loan and security agreement with Comerica Bank. These term loans bear interest at an annual rate equal to 3.0% plus the greater of (1) the bank's prime rate and (2) the LIBOR rate plus 2.5%, thereby exposing us to interest rate risk. Based on the $2.2 million of principal outstanding as of March 31, 2015, an immediate 10% change in the bank's prime rate or the LIBOR rate would not have a material impact on our debt-related obligations, financial position or results of operations.

BUSINESS

Overview

We are a microbiome therapeutics platform company developing a novel class of biological drugs, which we refer to as Ecobiotic microbiome therapeutics. The human microbiome is an ecology of microorganisms, including bacteria, fungi and viruses, that, when unhealthy, or dysbiotic, can leave the body more susceptible to infections, metabolic disorders, allergies, autoimmune disease, inflammation and other conditions. Our drugs are designed to restore health by repairing the function of a dysbiotic microbiome. We are initially focused on implementing our microbiome therapeutics platform to develop Ecobiotic microbiome therapeutics that treat dysbiosis in the colonic microbiome, one of the most diverse microbiomes in the human body. SER-109, our lead product candidate is designed to prevent further recurrences of *Clostridium difficile* infection, or CDI, a debilitating infection of the colon and, if approved by the U.S. Food and Drug Administration, or FDA, could be a first-in-field drug. In our Phase 1b/2 clinical study of SER-109 in recurrent CDI patients, 97% of patients achieved a clinical cure, which we defined as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing. SER-109 has been granted Breakthrough Therapy designation by the FDA. Breakthrough Therapy designation is intended to expedite the development and review of drugs or biologics that treat serious or life-threatening diseases or conditions and that preliminary clinical evidence indicates may be a substantial improvement over existing therapies. We initiated a Phase 2 clinical study of SER-109 for recurrent CDI and dosed the first patient in May 2015. We expect study results in the middle of 2016.

The human microbiome is one of the richest and most diverse ecosystems on earth, with a population of more than 100 trillion microorganisms that live in our intestines, mouth, skin and elsewhere in the body. Among the microbiomes in the human body, the colonic microbiome is one of the most diverse microbial communities. In a healthy, symbiotic state the colonic microbiome plays an important role in human health, helping the body digest food, resist pathogens, regulate the metabolic systems and synthesize essential nutrients and vitamins. However, the colonic microbiome may change in composition for a variety of reasons, including in response to long-term or high-dose antibiotics and following gastrointestinal infection. These changes in composition result in the loss of key microbes, resulting in a state of dysbiosis. Dysbiosis of the colonic microbiome is associated with a wide range of disease and infections, such as gastrointestinal infection and inflammatory and metabolic diseases.

While the study of the human microbiome is not new, the scientific community's understanding of the microbiome, and the colonic microbiome in particular, has been significantly advanced through genomics, which has enabled the broader understanding of the human microbiome at the organismal, functional and community level. Recently published scientific research has correlated dysbiosis in the colonic microbiome with numerous diseases and conditions in humans and in animal models, including: infections, metabolic disorders, allergies, autoimmune disease, inflammation and other non-specific conditions, such as irritable bowel syndrome, or IBS. Information regarding the impact of the colonic microbiome on various disease states is still emerging, although an increasing number of publications are appearing in leading scientific journals. There are currently no FDA-approved therapeutics that are designed to restore the microbiome to a healthy state.

We are developing a new approach to treating disease by restoring a dysbiotic colonic microbiome to a healthy state using our Ecobiotic microbiome therapeutics. Our approach is premised on the hypothesis that the proximal cause of many diseases is a dysbiosis in the natural state of the colonic microbiome that perpetuates the conditions that allow disease to take hold and flourish. We believe that the restoration of a dysbiotic colonic microbiome using rationally designed therapeutics represents a paradigm shift in the approach to treating the underlying disease. Our Ecobiotic microbiome therapeutics, which are derived from our microbiome therapeutics platform, are rationally designed ecological compositions, consisting of discrete combinations of beneficial microorganisms with targeted functional properties that provide the ability to re-establish keystone features of a functional microbiome in settings of disease.

Our approach to discovery and design is based on an iterative bedside-to-bench-to-bedside drug discovery strategy that begins with data on the human microbiome that we gather from clinical studies. From this data, we identify the ecological differences between a healthy and a diseased microbiome, which we then use to rationally design potential Ecobiotic microbiome therapeutics. After further in-lab testing, selected Ecobiotic microbiome therapeutic candidates are moved back into the clinic for testing with humans. We apply a comparative genomic systems biology framework that leverages proprietary computation, microbiology and screening capabilities to design lead candidates targeted at these ecological deficiencies. We are able to apply this framework and experience to existing clinical data sets, as well as to the proprietary clinical data set we have generated through our SER-109 clinical trial. We believe we can utilize our knowledge and data to design Ecobiotic microbiome therapeutics to treat various medical conditions, such as non-*Clostridium difficile* infection and inflammatory and metabolic diseases. We also have advanced capabilities in the fermentation of colonic bacteria and the formulation of vegetative and spore forms of bacteria into therapeutics. We believe that the combination of experience, proprietary data and proprietary know-how that comprise our microbiome therapeutics platform provides us with a competitive advantage in the design and development of microbiome therapeutics. Further, our approach and platform, which enable the rational design, testing, optimization, formulation and manufacturing of Ecobiotic microbiome therapeutics, provide a framework that we believe can significantly reduce the time typically required to advance therapeutics to the clinic.

Using our microbiome therapeutics platform, we are developing our lead clinical product candidate, SER-109, which is designed to durably repair dysbiosis in the colonic microbiome in the setting of recurrent CDI. CDI is caused by the use of broad spectrum antibiotics which induce dysbiosis of the microbiome resulting in a colonization by *Clostridium difficile,* or *C. difficile,* a spore forming bacterium. CDI leads to severe and persistent diarrhea in infected individuals, but can also lead to more severe outcomes, such as inflammation of the colon, toxic megacolon and death. The U.S. Centers for Disease Control, or CDC, has identified CDI as one of the top three most urgent antibiotic-resistant bacterial threats in the United States. It is the most common cause of hospital acquired infection in the United States and has overtaken methicillin-resistant *Staphylococcus aureus*, or MRSA. CDI is responsible for the deaths of approximately 29,000 Americans each year. We estimate the incidence of primary CDI in the United States is between 640,000 and 820,000 patients per year. While the epidemiological data are varied outside the United States, we believe that, due to the widespread use of antibiotics, CDI is a growing global disease. The standard of care for CDI is to treat with antibiotics. In many cases, antibiotic treatments may resolve the acute infection caused by *C. difficile*. However, these antibiotic treatments kill bacteria indiscriminately, inducing a dysbiosis of the microbiome and potentially making patients more susceptible to a recurrence of CDI. For those patients who experience a recurrence of their CDI, we believe it is this dysbiosis of the microbiome, not the presence of *C. difficile*, which is the proximal cause of disease. Research suggests that the risk of recurrence is approximately 25% after the primary occurrence of CDI, 40% after a first recurrence and greater than 60% for those experiencing two or more recurrences. In addition, a recent randomized trial comparing two antibiotics for the treatment of primary CDI indicated that 8% of patients receiving fidaxomicin and 9% of patients receiving vancomycin did not respond to these antibiotics two days after completing their antibiotic regimen. Based on this information, we estimate that the addressable population of patients in the United States with recurrent CDI, defined as patients who have experienced at least three occurrences of CDI in the past nine months, is between 85,000 and 110,000 patients per year.

SER-109 is a bacterial spore ecology consisting of an average of 50 bacterial species derived from healthy donors' fecal matter that is designed to prevent further recurrences of CDI in patients suffering from recurrent CDI by restoring the dysbiotic microbiome to a state of health. In our recently completed open label Phase 1b/2 clinical study, 29 of 30 patients, or 97%, achieved a clinical cure, which we defined as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing. The study demonstrated that SER-109 is well-tolerated and has a favorable safety profile with no serious adverse events considered by the investigators to be attributable to SER-109 treatment. We also

performed an analysis of the microbiome using next-generation sequencing technology and microbiological analysis. These studies demonstrated a re-establishment of keystone organisms and a rapid increase in bacterial diversity, which enable the restoration of the microbiome to a healthy state. SER-109 has been granted Breakthrough Therapy designation by the FDA. We initiated a Phase 2 clinical study of SER-109 for recurrent CDI and dosed the first patient in May 2015. We expect study results in the middle of 2016. We are conducting manufacturing process pre-validation studies of SER-109 to support a Phase 3 clinical trial and a potential biologics license application and commercial launch.

We believe the results of our open label Phase 1b/2 clinical study of SER-109 provide validation of the hypothesis underlying our microbiome therapeutics platform, supporting its further use to develop additional Ecobiotic microbiome therapeutics. Using the data we obtained from the SER-109 clinical trial, we are developing SER-262 as an Ecobiotic microbiome therapeutic designed to be used following antibiotic treatment of primary CDI to prevent the initial recurrence of CDI. SER-262 consists of bacteria that are a subset of the bacterial ecology comprising SER-109. Unlike SER-109, SER-262 strains are clonally isolated and produced in fermenters and do not require donations from human sources. Pre-clinical studies of SER-262 have demonstrated efficacy in preventing the initial recurrence of CDI in mouse and hamster models. We intend to initiate clinical studies of SER-262 in the middle of 2016.

In addition to our CDI product candidates, we are utilizing our microbiome therapeutics platform to develop SER-287 to treat inflammatory bowel disease, or IBD, including ulcerative colitis, and SER-155 to treat enteric pathogens, such as antibiotic-resistant bacteria. We are also researching Ecobiotic microbiome therapeutics for the treatment of metabolic diseases, such as early-stage, non-insulin dependent diabetes; other inflammatory diseases, such as Crohn's disease; and infections related to antibiotic use, cancer chemotherapy and immune suppression.

The following chart summarizes our current product pipeline:

(1) We are developing SER-262 to be used following antibiotic treatment of primary CDI to prevent initial recurrence of CDI.

We have assembled a world class group of scientists, clinicians, directors and investors, who have established our leadership in the field of microbiome therapeutics. We were co-founded by Drs. Noubar Afeyan, David Berry and Geoffrey von Maltzahn of Flagship VentureLabs, the innovation foundry of Flagship Ventures, which has founded 27 life sciences companies. Through Flagship VentureLabs' contribution of foundational scientific concepts and intellectual property, assembly of our management team and critical early-stage support, we launched as the first company focused on the ecological nature of the microbiome. Led by Dr. Roger Pomerantz, our Chairman, President and Chief Executive Officer, our experienced management team possesses core capabilities in microbiome therapeutics, infectious disease, drug development, commercialization, chemistry, manufacturing and controls, or CMC, public company management and finance. Dr. Pomerantz, an infectious disease physician-scientist, has extensive experience in infectious disease drug development and commercialization, licensing and acquisitions gained over a 10-year career in senior executive positions at Merck & Co, Johnson & Johnson and Tibotec Pharmaceuticals. Dr. Pomerantz led the development and commercialization of eight FDA-approved infectious disease drugs in his career. In addition to Dr. Pomerantz, our management team includes Mr. Eric Shaff, Dr. David Cook, Dr. John Aunins, Dr. Michele Trucksis and Dr. Matthew Henn. Collectively, our management team has successfully developed 18 approved pharmaceutical drugs in infectious disease and other indications. Our management team has extensive experience in microbial ecology, microbiology and live biologicals, with a collective 23 years studying the microbiome and over 60 published papers on the science of the microbiome. Additionally, our team has extensive experience in building out commercial capabilities in specialty diseases and has a track record for success in launching vaccine products, which have analogous manufacturing processes to that of Ecobiotic microbiome therapeutics. In November and December 2014, we completed two preferred stock financings, which included as investors several prominent mutual funds and healthcare dedicated funds, as well as an affiliate of Nestlé Health Science.

Our Strategy

Our goal is to become the leading biopharmaceutical company developing and commercializing microbiome therapeutics to address significant unmet medical needs. The critical components of our strategy include:

- ***Rapidly advancing the development of our lead product candidate, SER-109, for the prevention of further recurrences of CDI in patients with recurrent CDI***. SER-109 has been granted Breakthrough Therapy designation by the FDA, which provides for intensive guidance from the FDA in an effort to expedite the drug development process. Based on the results from our recently completed Phase 1b/2 clinical study of SER-109, we dosed the first patient in a Phase 2 clinical study in May 2015 in patients with three or more occurrences of CDI within the previous nine months. We expect to enroll 87 patients in a double-blinded and placebo-controlled clinical trial, with patients randomized in a ratio of 2:1 into a SER-109 arm or placebo arm. The primary endpoint of the trial will be the absence of CDI recurrence requiring antibiotic treatment during the eight-week follow-up period after dosing. We also plan to follow patients for an additional 16 weeks to document the safety profile of SER-109 compared to placebo. Secondary endpoints include the time to CDI recurrence and the proportion of patients experiencing CDI recurrence at four weeks, 12 weeks and 24 weeks. We also plan to compare changes in the composition of the colonic microbiome from baseline to Week 24 post-treatment using genomic analysis. In addition, subjects that recur in either arm of the study will have the option to enroll in a parallel open label safety study in which patients will receive SER-109. We expect results from the Phase 2 clinical study in the middle of 2016. Following the analysis of the data to come from our Phase 2 clinical study, we plan to meet with the FDA to present Phase 2 safety and efficacy results and a proposed protocol for the Phase 3 clinical trial. We plan to initiate the Phase 3 clinical trial in 2016.

- ***Advancing the clinical development of SER-262 to be used following antibiotic treatment of primary CDI to prevent an initial recurrence of CDI.*** We are developing SER-262 as a therapeutic to be used following antibiotic treatment of primary CDI to prevent an initial recurrence of CDI. SER-262 contains a subset of the bacterial ecology comprising SER-109, however, SER-262 is not derived from human stool and is made in bacterial fermenters in a rational *in vitro* design. Pre-clinical studies of SER-262 have demonstrated efficacy similar to SER-109 in mouse and hamster models of CDI. We intend to initiate clinical studies of SER-262 in the middle of 2016.
- **Initiating the clinical development of SER-287 for the treatment of IBD, including ulcerative colitis.** We have an active pre-clinical program to develop SER-287 for the treatment of IBD, including ulcerative colitis, which, based on current research and our experience with SER-109, we believe can be treated by restoring the underlying dysbiotic microbiome. We anticipate initiating a Phase 1b proof-of-concept clinical trial for SER-287 for ulcerative colitis by the end of 2015.
- ***Developing SER-155 for the treatment of antibiotic resistant bacteria.*** We are designing and developing SER-155, an Ecobiotic microbiome therapeutic that is expected to have activity against enteric bacterial pathogens. We expect SER-155 to be used for the treatment of antibiotic-resistant bacteria to eliminate colonization and prevent infection.
- ***Leveraging our leading microbiome therapeutics platform to develop additional innovative and novel Ecobiotic microbiome therapeutics across a range of medical conditions with high unmet need.*** We believe that the combination of experience, proprietary data and proprietary know-how related to the microbiome and of the production of microbial strains provides us a competitive advantage in the design and development of microbiome therapeutics. Our platform enables us to build upon our existing and growing clinical experience to rationally approach the treatment of acute and complex chronic diseases. We intend to leverage this advantage to develop additional innovative Ecobiotic microbiome therapeutics.
- ***Commercializing our Ecobiotic microbiome therapeutics, including SER-109, directly in the United States and with collaborators outside the United States.*** We have retained the worldwide rights to SER-109 and SER-262 and expect to initially maintain similar rights with respect to other Ecobiotic microbiome therapeutics we develop. We believe the market for recurrent CDI is sufficiently concentrated to permit us to effectively commercialize SER-109 in the United States with a direct sales force of less than 100 individuals. We intend to leverage the experience gained by commercializing SER-109 in the United States to further build our direct sales force to address the larger patient population to be addressed by SER-262. Outside the United States and for chronic diseases in larger populations, we expect to rely on collaborators to commercialize our Ecobiotic microbiome therapeutics.
- ***Developing manufacturing capabilities sufficient to support commercialization of any approved Ecobiotic microbiome therapeutic candidates.*** If approved by the FDA, we believe SER-109 could be a first-in-field drug, which will require manufacturing capabilities that are distinct from other biologic drugs. We intend to make strategic investments in manufacturing capabilities to help ensure that we maintain control of our know-how and also because we believe these capabilities will be necessary and highly advantageous for the development of future Ecobiotic microbiome therapeutics such as SER-262. Our bioprocess and manufacturing personnel are focused on creating a platform of manufacturing expertise that will set the stage for further advances in the emerging field of microbiome therapeutics.

Understanding the Microbiome and Its Impact on Disease

The human microbiome is one of the richest and most diverse ecosystems on earth with a population of more than 100 trillion microorganisms that live in our intestines, mouth, skin and elsewhere in the body. These microbiomes have numerous beneficial functions necessary to supporting health, such as digesting food, preventing disease-causing bacteria from invading the body, regulating our immune system and synthesizing essential nutrients and vitamins. Among the various microbiomes in the human body, the colonic microbiome is one of the most diverse microbial communities. At up to 100 billion to one trillion cells per milliliter, it is among the densest microbial ecosystems ever observed. In a healthy, symbiotic state the colonic microbiome enables the body to function normally. However, we believe the colonic microbiome can change in composition, such as in response to long-term or high-dose exposure to antibiotics or following a gastrointestinal infection. As a result, there is a loss of key microbes that results in a state of dysbiosis. Dysbiosis of the microbiome is associated with a wide range of disease and infections.

Although bacteria are often associated with infection and disease, much of the bacteria that colonize the human body are essential for life. Until recently, few scientific studies existed that focused on the benefits of the bacteria comprising the microbiome. In 2005, the National Institutes of Health funded the Human Microbiome Project, or HMP, which had as one of its goals the characterization of the microbiome with enough specificity to enable the study of variations in the microbiome and their influence on disease.

Historically, researchers studied microbes in patients by isolating pathogens and growing them in culture. This process typically identifies only a limited diversity of microbial species. The HMP used genomic sequencing technologies to analyze 5,000 samples, representing more than 3.5 terabases of genome sequence data, to identify specific genetic signals found only in bacteria. HMP researchers calculate that more than 10,000 microbial species occupy the human ecosystem, and these researchers believe they have characterized the normal range of microbial variation in the U.S. population. Importantly, HMP researchers have discovered that different consortia of microbes may accomplish the same metabolic activity, and the presence of those metabolic activities is more important than the exact species of microbe providing the function. Results from the HMP have provided a robust baseline microbiome against which disease states can be compared.

With data developed by the HMP, numerous scientific studies are emerging in both animals and humans, suggesting that many human diseases can be correlated with dysbiosis of the microbiome. These include infections and diseases, such as CDI or vancomycin-resistant *Enterococcus*, or VRE; metabolic disorders, such as early-stage, non-insulin dependent diabetes, obesity and non-alcoholic fatty liver disease; allergies; autoimmune disease; inflammatory diseases, such as ulcerative colitis, Crohn’s disease and pouchitis; and other non-specific conditions such as irritable bowel syndrome. Examples of some studies include:

- The results of a study published in *PLOS Pathogens* in 2012 suggested that a mixture of six different bacteria found naturally in the gastrointestinal system of mice, when isolated from stool and reintroduced into the infected mice, was effective at suppressing CDI. Researchers in the study found that a single treatment of the bacteria was sufficient and that the suppression lasted for months.
- An article published in the *Annals of the New York Academy of Sciences* in 2011 reviewed data from various animal and human studies linking alterations in the colonic microbiome with type 1 diabetes. The article concluded, among other things, that the microbiota in the gastrointestinal tract, through their impact on the development of the immune system and the structure of the intestine, are vital to the pathogenesis of type 1 diabetes, though the mechanisms by which this occurred were still unclear.

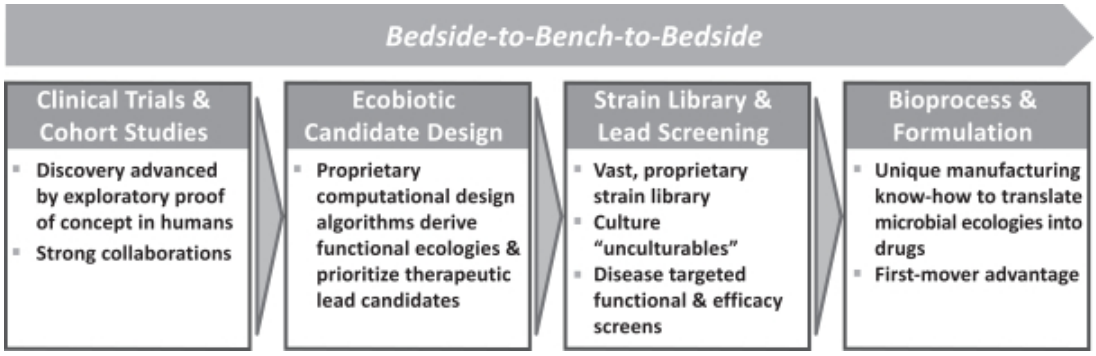
- A study published in *Nature* in 2006 suggested that the microbiome of obese mice demonstrated an increased capacity to harvest energy from the diet. Additionally, the study suggested this trait was transmissible, and the colonization of germ-free mice with the microbiota from obese mice resulted in significantly greater total body fat than colonization with microbiota from a lean mouse. These results suggest the microbiome of the gastrointestinal tract is a contributing factor to the pathophysiology of obesity.
- An article published in *Science* in 2011 suggested that a bacterium found in the gastrointestinal tract of humans appeared to keep mice safe from food allergies. The study noted that mice given antibiotics early in life were far more susceptible to peanut sensitization, a model of human peanut allergy. When these mice were given a solution containing Clostridia, a common class of bacteria found in the gastrointestinal tract, the animals' peanut sensitization disappeared. The same reaction was not obtained when another common type of bacteria, *Bacteroides*, was introduced to similarly situated mice. Researchers concluded that the Clostridia were operating in the gastrointestinal tract to keep peanut proteins that caused allergic reactions out of the blood stream.

There are currently no microbiome therapeutics approved by the FDA. We believe that the ability to develop drugs that are able to modulate the microbiome and return a dysbiotic microbiome to its healthy state presents a significant opportunity to improve human health.

Our Microbiome Therapeutics Platform

We are developing a new approach to restoring health in settings of microbiome dysbiosis by using our microbiome therapeutics platform to develop Ecobiotic microbiome therapeutics. Our microbiome therapeutics platform is premised on the hypothesis that the proximal cause or significant contributor to multifactorial diseases is a dysbiosis of the colonic microbiome. We believe this represents a paradigm shift in approaching the way the underlying disease is defined and can be treated. Our microbiome therapeutics are a novel class of biological drugs designed to treat disease by restoring a dysbiotic microbiome to a state of health. They represent rationally defined ecological compositions, consisting of discrete combinations of beneficial microorganisms with targeted functional properties that provide the ability to re-establish keystone features of a functional microbiome in settings of disease.

Our microbiome therapeutics platform integrates genomic and related data sets, proprietary algorithms and computational analysis, sequencing and screening and clinical insights. This platform allows us to rationally design, test, optimize, formulate and manufacture Ecobiotic microbiome therapeutics. Our microbiome therapeutics platform provides a framework that we believe can significantly reduce the time typically required to advance therapeutics to the clinic. The following diagram depicts the steps in our fully end-to-end microbiome therapeutics platform:

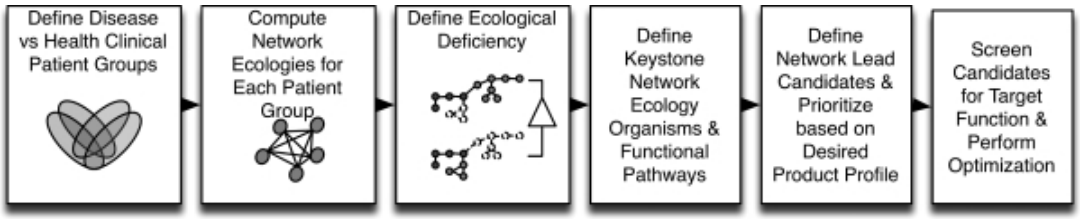


Clinical Trials and Cohort Studies

Our discovery process begins with human data derived from clinical trials and cohort studies, which we use as a basis for designing our Ecobiotic microbiome therapeutics. This allows us to compare the colonic microbiome of healthy normal individuals to those in a dysbiotic state, revealing the ecological signatures of microbiome differences that we target using our Ecobiotic microbiome therapeutics. Additionally, our experience with SER-109 serves as a critical dataset for humans, instructing us on how the introduction of certain keystone microbes can facilitate and augment the restoration of a dysbiotic colonic microbiome for other indications. Using these proprietary insights and tools we can evaluate emerging data sets that link a change in the microbiome with various diseases and define therapeutic lead candidates. A study conducted with fecal transplantation in the setting of insulin resistance suggested that lean donor microbiomes can increase insulin sensitivity in subjects with metabolic syndrome. By using our genomic data sets and our proprietary tools combined with our experience with SER-109, we integrate clinical results into bench research to design our Ecobiotic microbiome therapeutics.

Ecobiotic Candidate Design

We have developed a candidate design program to assist us in identifying the keystone structural and functional elements of healthy microbiomes, the deficiencies present in disease states and the functional profile of a microbial ecological network that can return the microbiome to a healthy state. The following diagram depicts the steps in our candidate design program:



Our candidate design program applies computational comparative genomics and systems biology methods to analyze existing clinical data sets, such as those derived from the SER-109 Phase 1b/2 clinical study, to elucidate the structure and function of a healthy microbiome relative to a microbiome in a disease state. The structure is defined in terms of the organisms that comprise the ecology of the microbiome while the function is defined in terms of the genes and metabolic pathways inherent to the organisms that comprise that ecology. Structure and functional properties of a microbiome are determined using our proprietary algorithms that derive actual ecological networks that characterize the microbiome of subjects with a particular disease or that are in a state of health. Our algorithms define those organisms that impact the structure of the microbial communities and the health of the microbiome, which we refer to as keystone organisms, and their associated critical, functional biological pathways. Keystone organisms and their associated critical, functional biological pathways may exist in low, moderate, or high abundance in an ecology of microbes, but are often missing or at reduced levels in an individual with disease. By comparing the ecologies in healthy and disease states, we are able to identify the ecological deficiencies and missing keystone components that characterize the disease state and are the target of our Ecobiotic microbiome therapeutics.

Ecobiotic microbiome therapeutics are rationally designed to solve for the microbiome ecological deficiencies identified between disease and health states. Rational design involves the determination, prioritization and optimization of microbial network ecologies with the greatest therapeutic potential based on critical factors, such as the evolutionary relationships of the microbes, theoretical and empirically defined functional capabilities, safety profile of strains and various bioprocessing parameters. We maintain a proprietary design and discovery database that captures and integrates

key information about microbial strains. Our design algorithms in combination with our functional screening capabilities enable us to identify lead candidate compositions that possess the necessary functional profile to restore the ecological deficiency that causes the dysbiosis.

Strain Library and Lead Screening

To facilitate the screening of network ecologies and individual strains, we have developed and maintain proprietary know-how on the isolation, cultivation and fermentation of a host of microbial strains. Using information from our strain library, we develop and execute moderate- to high-throughput *in vitro* and *ex vivo* screens that evaluate the efficacy and functional properties of lead candidates and individual microbial strains that comprise the lead candidate ecologies. Once we have a lead candidate we screen the therapeutic to evaluate its efficacy and functional properties in disease relevant models. We conduct experiments in specific *in vivo* models on a reduced set of candidates that are relevant to the disease indications we are investigating.

Bioprocess and Formulation

Our Ecobiotic microbiome therapeutics in development consist of combinations of bacteria or bacterial spores rather than single strains. As a result, we must be able to produce, purify and formulate multiple strains of bacteria economically and be able to test the composition of a combination product for quality control. Our bioprocess development and manufacturing processes are designed to address each of these elements.

- *Fermentation:* We employ platform fermentation processes as starting conditions for current good manufacturing processes, or cGMP, production schemes and, when required, plan to develop strain specific process parameters.
- *Purification:* Similar to fermentation, we use small-scale purification operations to complete bench-scale manufacturing and quickly assess the final process yield, quality and robustness.
- *Formulation:* Our Ecobiotic microbiome therapeutics are combinations of cells and bacterial spores and can be administered by a number of methods and by different routes to effect the primary goal of delivering the bacteria to the intended location in a condition where they are able to replicate and correct dysbiosis. Currently, our Ecobiotic microbiome therapeutics are designed to be administered in oral form.
- *Analytical:* We intend to address quality control requirements for our Ecobiotic microbiome therapeutics using proprietary microbiological and sequence-based testing schemes, including high-throughput quantitative analytics to assess the identity, potency and purity of the final product.

Pre-clinical and Clinical Testing

One of the key competitive advantages of microbiome therapeutics is that we believe they will not need to undergo the same pre-clinical testing that other modalities such as small molecules require. Because the components of our Ecobiotic microbiome therapeutics are found naturally in the body, we do not expect to need carcinogenicity studies or studies designed to evaluate how our Ecobiotic microbiome therapeutics interact with other drugs. Further, we expect that we will not need to conduct traditional Phase 1 pharmacokinetic studies. Clinical pharmacokinetic studies are performed to examine the absorption, distribution, metabolism and excretion of a drug under investigation. Because our Ecobiotic microbiome therapeutics are not absorbed and, therefore, remain in the colonic microbiome, we believe such trials will not be necessary and we expect to proceed directly to patients with the disease that we are studying. These pre-clinical and clinical studies are costly and time-consuming and the ability to proceed in development without them provides an advantage as compared to traditional drug development. For example, based on our correspondence with the FDA, further pre-clinical studies will not be needed by the FDA for SER-109. In addition, we have confirmed

with the FDA that we do not need Phase 2 dose ranging studies. While we expect to file INDs for our future product candidates, we have not yet discussed with the FDA what testing will be required, but we believe the same requirements for SER-109 will apply across our other product candidates.

Our Management Team

We were co-founded by Drs. Noubar Afeyan, David Berry and Geoffrey von Maltzahn of Flagship VentureLabs, the innovation foundry of Flagship Ventures, which has founded 27 life sciences companies. Through Flagship VentureLabs' contribution of foundational scientific concepts and intellectual property, assembly of our management team and critical early-stage support, we launched as a company focused on the ecological nature of the microbiome. We are led by a team of experienced pharmaceutical industry executives and recognized experts in infectious diseases, microbiome therapeutics and biological manufacturing.

Our management team includes Dr. Roger Pomerantz, our Chairman, President and Chief Executive Officer, who has extensive experience in infectious disease, drug development and commercialization, licensing and acquisitions gained over a 10-year career in senior executive positions at Merck & Co, Johnson & Johnson and Tibotec Pharmaceuticals. Mr. Eric Shaff, our Chief Financial Officer and Executive Vice President, has over 10 years of corporate finance and accounting experience in the biotechnology industry, including as Vice President of Finance at Genzyme Corporation and, most recently, Vice President of Corporate Finance at Momenta Pharmaceuticals. Mr. Shaff was responsible for overall financial management at Momenta, including public company reporting, accounting and risk management. Dr. David Cook, our Chief Scientific Officer and Executive Vice President of Research & Development, has served in a variety of executive positions in his 22-year career including as the Chief Operating Officer for the International AIDS Vaccine Initiative and the founding Chief Executive Officer at Anza Therapeutics, a biotechnology start-up developing a novel microbial vaccine platform. Dr. John Aunins, our Chief Technology Officer and Executive Vice President of Bioprocess Development, has worked in the biotechnology field for 24 years. Dr. Aunins has deep experience in bioprocess development, manufacturing support and project leadership. He led process and product development teams at Merck Research Laboratories for Vaqta, Varivax, Zostavax, ProQuad, Rotateq and Gardasil. Dr. Michele Trucksis, our Chief Medical Officer, has over 25 years of clinical research and medical experience focused in infectious diseases. Prior to joining our company, Dr. Trucksis was Executive Director, Team Leader & Clinical Lead at Merck Research Laboratories, where she was responsible for medical, clinical and global product development and strategy in antibacterials and antifungals. Dr. Matthew Henn, our Head of Drug Discovery & Bioinformatics and Vice President, has over 16 years of combined research experience in microbial ecology, genomics and bioinformatics. Prior to joining our company, he was the Director of Viral Genomics and Assistant Director of the Genome Sequencing Center for Infectious Diseases at the Broad Institute of Harvard and MIT.

Our Product Pipeline

We believe our Ecobiotic microbiome therapeutics represent a novel approach with potential application across a broad range of human diseases. Our most advanced drug development programs are focused on the area of gastrointestinal infections, where the causal link between dysbiosis of the microbiome and susceptibility to disease has been established. In addition to our CDI product candidates, SER-109 and SER-262, we are utilizing our microbiome therapeutics platform to develop Ecobiotic microbiome therapeutics to treat IBD, including ulcerative colitis, and enteric pathogens, such as antibiotic-resistant bacteria. We are also researching Ecobiotic microbiome therapeutics for the treatment of metabolic diseases, such as early-stage, non-insulin dependent diabetes; other inflammatory diseases, such as Crohn's disease; and infections related to antibiotic use, cancer chemotherapy and immune suppression.

The following chart summarizes our current product pipeline:

(1) We are developing SER-262 to be used following antibiotic treatment of primary CDI to prevent initial recurrence of CDI.

Our CDI Product Candidates

We are developing SER-109 as an Ecobiotic microbiome therapeutic designed to prevent further recurrences of CDI in patients suffering from recurrent CDI, defined as at least three occurrences of CDI in a nine-month period, by restoring the dysbiotic microbiome to a healthy state. In our recently completed Phase 1b/2 clinical study, 26 of 30 patients, or 87% of patients, achieved the primary efficacy endpoint of experiencing no diarrhea associated with a positive *C. difficile* test during the eight weeks post-treatment. Additionally, 29 of 30 patients, or 97% of patients, achieved a clinical cure, which we defined as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing. The results of the trial suggest a favorable safety profile with no serious adverse events considered by the investigators to be attributable to SER-109. We also performed an analysis of the microbiome using next-generation sequencing technology and microbiological analysis. These studies demonstrated a re-establishment of keystone organisms and a rapid increase in bacterial diversity, which enable the restoration of the microbiome towards a healthy state. SER-109 has been granted Breakthrough Therapy designation by the FDA. We initiated a Phase 2 clinical study of SER-109 for recurrent CDI and dosed the first patient in May 2015. We expect study results in the middle of 2016. We are conducting manufacturing process pre-validation studies of SER-109 to support a Phase 3 clinical trial and a potential biologics license application and commercial launch.

We are also developing SER-262 to be used following antibiotic treatment of primary CDI to prevent an initial recurrence of CDI. Pre-clinical studies of SER-262 have demonstrated efficacy similar to SER-109 in mouse and hamster models of CDI. We intend to initiate clinical studies of SER-262 in the middle of 2016.

If approved, we believe these two product candidates will enable us to provide a more effective and safer treatment for preventing the recurrence of CDI than the current standard of care.

Clostridium difficile Infection, or CDI

C. difficile is a Gram-positive, toxin-producing, spore forming bacterium that causes severe and persistent diarrhea in infected individuals, but can also lead to more severe outcomes, such as pseudomembraneous colitis, toxic megacolon and death. *C. difficile* bacteria express toxins that disrupt the structural architecture of cells causing leakage of fluids through the gastrointestinal epithelium. The cells disrupted by these toxins eventually undergo apoptosis and die, releasing their contents into the colon, resulting in inflammation of the colon, severe and persistent diarrhea and, in the most serious cases, death.

CDI is generally not present in healthy adults, although approximately 1% to 5% of adults may carry low levels of *C. difficile* without clinical symptoms. CDI is most often associated with the prior use of antibiotics, although age and poor immune status are important risk factors as well. Antibiotics are thought to decrease resistance to CDI by causing dysbiosis in the microbiome. Since *C. difficile* spores are able to survive for long periods of time outside the body, and because healthcare settings are often sites of significant antibiotic use, CDI transmission rates in hospitals, long-term acute care facilities and nursing homes have been increasing. CDI is also a cause of morbidity and mortality among hospitalized cancer patients and bone marrow transplant patients as their immune systems are suppressed by cytotoxic drugs, which are drugs that inhibit or prevent the function of cells, and they may be heavily treated with antibiotics to treat infections. More recently, the rise of community-acquired CDI has been recognized as a growing problem.

The CDC has identified *C. difficile* as one of the top three most urgent antibiotic-resistant bacterial threats in the United States. It is the most common cause of hospital acquired infection in the United States, having overtaken MRSA. CDI is responsible for the deaths of approximately 29,000 Americans each year. CDI is also very costly to the healthcare system. According to a study published in *Clinical Infectious Diseases*, the economic burden of CDI in 2008 in U.S. acute care facilities alone was estimated to be as much as $4.8 billion. In addition, a summary of studies published in 2009 in *The Journal of Hospital Infection*, calculated that the treatment cost per episode of primary CDI was as much as $5,000 and as much as $18,000 per recurrence of CDI. The CDC estimates the incidence of primary CDI by focusing on 10 catchment areas covering 11 million residents. Based on this analysis, it is estimated that there are approximately 453,000 new cases of primary CDI per year. Further, according to a 2014 article in the *American Journal of Infection Control*, from 2001 to 2010, incidence of CDI per 1,000 patients discharged increased from 4.5 to 8.2 with an average hospital stay of eight days. We believe the CDC method underestimates incidence based on several factors. First, residents who are diagnosed outside of their catchment area are not included in estimates. Second, many of the CDC diagnostic labs use a lower sensitivity test, which results in about 20% lower detection rates than the current most sensitive method. In addition, the CDC approach misses community cases, which are estimated to account for 30% to 40% of total cases. As a result, we estimate the incidence of primary CDI in the United States is between 640,000 and 820,000 patients per year. Additional research suggests that the risk of recurrence is approximately 25% after primary CDI, 40% after a first recurrence and greater than 60% for those experiencing two or more recurrences. In addition, in a recent randomized trial comparing two antibiotics for primary CDI, 8% of patients receiving fidaxomicin and 9% of patients receiving vancomycin did not respond two days after completing their antibiotic regimen. Based on this information, we estimate that the addressable population of patients in the United States with recurrent CDI, defined as patients who have experienced at least three occurrences of CDI in the past nine months, is between 85,000 and 110,000 patients per year.

Outside of the United States, it is difficult to estimate the incidence of CDI, primarily given the lack of standardized national surveillance schemes. However, data from the recently completed EUCLID study, the largest ever prevalence study of CDI across Europe, were presented at the 2014 European Congress of Clinical Microbiology and Infectious Diseases. The study results suggest that the incidence of CDI in Europe has increased from 4.1 to 7.9 cases per 10,000 patient bed days between 2008 and 2012-13.

Current and developing treatment alternatives and their limitations

The treatment alternatives for patients with CDI include antibiotics, fecal microbiota transplantation, or FMT, over-the-counter probiotics, antibodies and vaccines.

Antibiotics

The current standard of care for CDI is to treat with antibiotics, such as metronidazole and vancomycin. Metronidazole has been found to be effective for primary CDI, but approximately 29% of patients experience recurrence. It is not recommended for severe disease, nor is it used beyond first recurrence due to side effects. Vancomycin is more expensive, but has a lower relapse rate of 25%. In addition, fidaxomicin, a recently approved antibiotic for CDI, may have higher initial efficacy compared to metronidazole, but it does not have a label claim to reduce or prevent CDI recurrence. No antibiotic therapeutics are currently approved for treatment of recurrence of CDI.

Recurrent CDI, defined as three or more occurrences of CDI in a nine-month period, is not well addressed by any of the available antibiotics. When a patient has recurred two or more times after the initial occurrence, antibiotic relapse rates are greater than 60% and the probability of additional relapse increases with successive cycles. Some physicians resort to pulse-taper regimens of vancomycin lasting six weeks or more, but there are no well-controlled clinical studies that show such regimens are effective. In extreme cases, patients are treated continuously for years with vancomycin, even while they continue to experience gastrointestinal symptoms including diarrhea and abdominal discomfort.

The primary limitation of antibiotics is that their use appears to exacerbate dysbiosis. Recent research in animal models has shown that antibiotic use not only eliminates many healthy bacteria in the gastrointestinal tract, but also leads to the release of nutrients that facilitate the growth of *C. difficile.* Antibiotics have also been shown to change the ratio of primary versus secondary bile acids in the colon by killing bacteria required to metabolize bile acids. This shift to a predominance of primary bile acids further facilitates the growth of *C. difficile*, as it requires primary bile acids for germination of its spores. As a result, antibiotic use may induce a lasting dysbiosis that makes it possible for *C. difficile* to colonize a person and then cause, or further perpetuate, disease.

Fecal microbiota transplantation

FMT, also known as a stool transplantation, is a procedure during which donated stool, including fecal microbes, is typically instilled via colonoscopy into a patient with CDI. We believe that the impressive efficacy of FMT, which has resulted in cure rates for recurrent CDI ranging from 81% to 93%, essentially confirms the role of dysbiosis as a cause of the disease. However, FMT presents several challenges for effective treatment of the disease. FMT has the potential to transmit infectious or allergenic agents between hosts, involves the transmission of potentially hundreds of unknown strains of bacteria, fungi and viruses from donor to subject, and is difficult to perform on a mass scale. Additionally, FMT is inherently non-standardized so that different desired and/or undesired material may be transmitted in any given donation. FMT is not approved by the FDA and we believe it may be unable to gain such approval since the product, to our knowledge, cannot be standardized and characterized according to current regulatory requirements for identity, potency, purity and safety.

Probiotic therapies

Probiotics represent a group of products typically available over the counter in supplements and in some foods, which contain a smaller number of species of bacteria. However, to date there have been no clinical studies that have established the ability of probiotics to repair a dysbiosis of the microbiome. Further, there is neither a legally recognized definition of, nor a standard of identity for, the term probiotic in the United States or Europe. Recently, the European Food Safety Authority rejected many of the claims of health benefits associated with probiotics because the microbes had not been

sufficiently characterized, the claimed effect was not considered beneficial and human studies in support of the claims had not been made available. As a result, after December 14, 2012, food and nutritional supplements companies were no longer allowed to communicate health benefits for their products on account of probiotic content in the European Union.

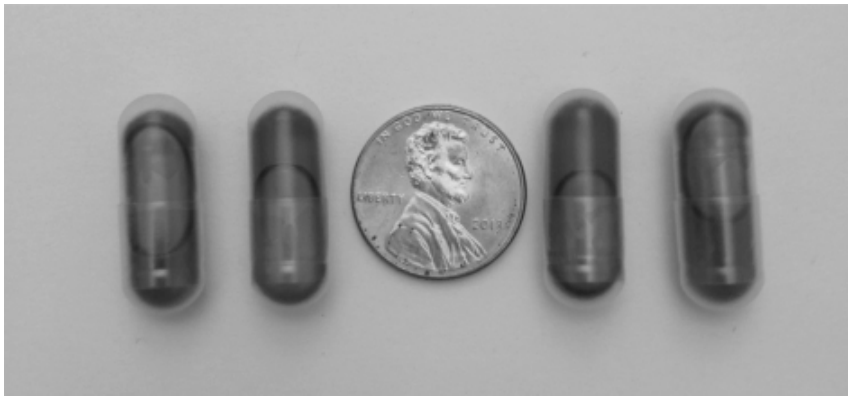
Antibodies and vaccines

Antibodies and vaccines are also in development to treat CDI. Antibodies suppress toxins to alleviate the symptoms of CDI, but they do not address the underlying dysbiosis of the microbiome, which we believe is the cause of recurrent CDI. Antibodies also require intravenous infusion and are more costly to produce relative to other treatments, such as antibiotics. The efficacy of vaccines in treating CDI in humans currently remains unproven. In addition, it is difficult to define a target population for a CDI vaccine, given that the at-risk patient population is largely elderly individuals who typically respond less robustly to vaccination therapies.

SER-109

SER-109 is a bacterial spore ecology consisting of an average of 50 bacterial species derived from healthy donors' fecal matter that is designed to prevent further recurrences of CDI in patients suffering from recurrent CDI by restoring a dysbiotic microbiome to a state of health. In our open label Phase 1b/2 clinical study of SER-109, we evaluated the effect of treatment with SER-109 in patients with three or more occurrences of CDI in a 12-month period. Of the 30 patients enrolled in the trial, 29, or 97%, achieved a clinical cure, which we defined as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing. The trial demonstrated that SER-109 is well-tolerated and suggested a favorable safety profile with no serious adverse events considered by the investigators to be attributable to the SER-109 treatment. We also performed an analysis of the microbiome using next-generation sequencing technology and microbiological analysis. These studies demonstrated a re-establishment of keystone organisms and a rapid increase in bacterial diversity, which enable the restoration of the microbiome to a healthy state.

SER-109 is formulated as oral capsules for single-dose administration after completion of antibiotics. A single dose of SER-109 comprises 100 million spores that we anticipate delivering in four small oral capsules. The spores in SER-109 are intended to germinate in the gastrointestinal tract and immediately compete for the same nutrients required by *C. difficile*. The spore forming organisms from SER-109 are also intended to shift the balance of bile acids toward secondary acids that are less efficient for promoting germination of *C. difficile* spores. The following picture is a commercial prototype of a single dose of SER-109 (and is not necessarily a single dose of SER-109 for our Phase 2 clinical study):



Phase 1b/2 clinical study design

The Phase 1b/2 clinical study was a two part trial designed to evaluate the safety and efficacy of SER-109 in approximately 30 patients with recurrent CDI, defined as three or more occurrences of CDI in the previous 12 months.

Part 1 of the study evaluated a single dose of SER-109 administered orally in 30 capsules over two days, with the dose derived from approximately 75 grams of stool. Part 2 of the study evaluated a single dose of SER-109 administered orally in a range of one to 12 capsules over one day. The dose in Part 2 was based on spore count, as opposed to fecal mass, which is expected to allow for a more precise dosing regimen. The target dose in Part 2 was $1x10^8$ spores per dose, which was approximately 17-fold lower than the mean dose in Part 1. The SER-109 doses were derived from seven different healthy human donors. Prior to receiving treatment with SER-109, patients were on antibiotic therapy consisting of either fidaxomicin, vancomycin or metronidazole to control their CDI symptoms. At least 24 hours prior to starting treatment with SER-109, antibiotic therapy was discontinued.

The trial was designed to enroll patients between the ages of 18 and 90 years, with relapsed, laboratory-confirmed CDI with three or more occurrences in the previous 12 months. Enrolled patients must have undergone treatment for CDI with at least three courses of antibiotic therapy in the last 12 months and have a life expectancy of greater than three months. Patients with acute leukemia, recent bone marrow transplant or recent chemotherapy, as well as patients with a history of IBD or IBS with diarrhea, total colectomy or liver cirrhosis were excluded from the trial. The following table identifies patient demographics following enrollment in the trial:

Cohort	Mean Dose (spore units)	Male/Female	Age Median (Range)	Number of CDI Recurrences in Prior 12 months Median (Range)
1	$1.7x10^9$	5 / 10	71 years (22 – 88)	3 (2 – 6)
2	$1.0x10^8$	5 / 10	58 years (39 – 83)	3 (2 – 5)

The primary safety measures were an evaluation of adverse events, laboratory values, vital signs and physical examination of findings prior to and after dosing with SER-109 over a 24-week time period. Evaluations occurred by telephone calls, in-home assessments or clinic visits by qualified personnel. Patients were assessed at Days 2 and 4 and Weeks 1, 2, 4, 8 and 24 post-treatment. The primary efficacy measure was the absence of CDI (defined in this study as more than three unformed bowel movements in a 24-hour period with laboratory confirmation of the presence of *C. difficile* toxin in the stool) during the eight weeks after initiating therapy. Eight weeks was selected as the measurement period for the primary endpoint based on our clinical advisory board's experience that a significant majority of CDI recurrences occur within eight weeks. Secondary efficacy measures included minimum effective dose, time to CDI recurrence following SER-109, time without diarrhea during the follow-up period and change in diversity of the colonic microbiome at Day 4 and Weeks 1, 2, 4 and 8 as measured by deep sequencing of patient stool samples. Stool samples were collected pre-treatment and on Day 4 and Weeks 1, 2, 4, 8 and 24 post-treatment.

Phase 1b/2 clinical study results

Efficacy. Twenty-six of 30 patients, or 87% of patients, in the Phase 1b/2 clinical study achieved the primary efficacy endpoint of experiencing no recurrence of CDI during the eight weeks post-treatment. These 26 patients consisted of 13 patients in each of Part 1 and Part 2 of the study. Among the 26 patients was one patient who experienced an initial recurrence on Day 26 and was re-treated, per protocol, with a dose from the same donor. Following re-treatment, this patient also achieved the

primary efficacy endpoint. Efficacy results were not dependent upon the initial human donor or the dose over the range of $3.4x10^7$ to $2.3x10^{10}$ spores.

Of those patients who did not meet the primary efficacy endpoint, one patient had a recurrence of CDI on Day 5 and did not receive a second treatment with SER-109. The three other patients who failed the protocol-defined primary efficacy endpoint were determined by their attending investigator to be recovering from their diarrheal episode by the time they submitted their stool sample for CDI testing. In each case, the investigator advised the patient to refrain from antibiotic use and the patients' condition resolved without antibiotic therapy. All three patients were determined to be clinically CDI free at eight weeks. As a result, the clinical cure rate for the study, which we defined as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing, was 97%, or 29 of 30 patients.

We also tested a total of 27 patients at Week 8 for *C. difficile* carriage, where a patient carries the *C. difficile* bacterium but does not experience symptoms related to *C. difficile*. Of the 27 patients tested, 24 patients, or 89% of patients, tested negative for *C. difficile* carriage. Among the three patients who were not tested for *C. difficile* carriage, one patient did not continue with the study to Week 8 and samples were not collected for two patients at Week 8. In addition, 22 patients continued to participate in the Phase 1b/2 clinical study and did not receive additional antibiotics. Of these patients, 21, or 95% of patients, experienced no recurrence of CDI 24 weeks after treatment.

We also performed an analysis of the microbiome using next-generation sequencing technology and microbiological analysis to evaluate long-term changes in the microbiome, including the restoration of bacterial diversity in the colon of patients. These studies demonstrated a rapid increase in bacterial diversity and a restructuring of the microbiome towards a healthy state. Upon introduction, SER-109 appears to engraft its bacterial species into the microbiome, with some of these species persisting in the patient's gastrointestinal tract for at least 24 weeks after dosing. In addition, in some patients we noted the repopulation of organisms that were not in SER-109 and had not been detected in the patient prior to treatment. We believe this phenomenon, which we refer to as augmentation, is an important element for restoration of bacterial diversity and repair of dysbiosis. Engraftment and augmentation, as well as the clinical resolution of CDI, were not dependent on the dose of SER-109 administered.

We believe the engraftment and augmentation observed with SER-109 could have important medical implications for treating other infectious agents. For example, in the Phase 1b/2 clinical study, we observed that some patients were not only infected with *C. difficile*, but were also colonized with other harmful organisms at high levels. Importantly, after SER-109 treatment, levels of these organisms declined by as much as 100,000-fold. For example, we identified multiple patients in the trial with high levels of VRE, which are drug-resistant bacteria that colonize the gastrointestinal tract and can cause serious bloodstream infections. In patients identified with VRE, the VRE was reduced below the limit of detection of our assays after treatment.

Safety. In Part 1 of the study, 80% of the patients experienced at least one adverse event, all of which were treatment emergent adverse events, or TEAEs. A TEAE was defined as an adverse event that started or worsened at or during the time of or after the date of the first dose of SER-109 through the final follow-up visit. Five, or 33%, of the patients were judged by the investigator to have a TEAE attributable to SER-109 and all were mild or moderate. In Part 2, 100% of the patients experienced at least one adverse event, all of which were TEAEs. Nine, or 60%, of the patients were judged by the investigator to have a TEAE attributable to SER-109 and all were mild or moderate. The most common adverse events were gastrointestinal disorders and diarrhea. The majority of TEAEs were mild in severity and consistent with post-antibiotic recovery from CDI. One patient in Part 2 had a severe adverse event of chest pain, which was not considered related to SER-109. Two patients each in Part 1 and Part 2 had more than one serious adverse event, none of which was considered related to SER-109. There were no deaths in Part 1 or Part 2.

Clinical development plan

We initially proposed to the FDA a Phase 3 clinical trial and then a Phase 2/3 clinical trial, in each case in an effort to advance the clinical development of SER-109. However, in our subsequent interactions with the FDA, we determined that it would be more expedient to commence a Phase 2 study while we developed the final manufacturing requirements and analytic assay validation that would have been required before we could start a Phase 3 or combined Phase 2/3 clinical trial. Because the FDA cleared us to proceed with the Phase 2 clinical study, we were able to dose the first patient in this study in May 2015. We expect initial clinical study results in the middle of 2016. Following the analysis of the data to come from our Phase 2 clinical study, we plan to meet with the FDA to present Phase 2 safety and efficacy results and a proposed protocol for the Phase 3 clinical trial. We are conducting pre-validation studies of our manufacturing process for SER-109, and we expect to obtain sufficient data from these studies for a Phase 3 clinical trial. We plan to initiate the Phase 3 clinical trial in 2016.

The FDA has indicated that we do not need to conduct further pre-clinical studies of SER-109. We believe this conclusion is the result of several factors, including the following:

- gastrointestinal bacteria are host-specific and animal data would not be more representative than our human clinical data;
- SER-109's favorable safety profile in patients in the Phase 1b/2 clinical study;
- ecobiotic microbiome therapeutics are unlikely to result in systemic exposure because they are not absorbed outside of the gastrointestinal tract;
- engraftment of spores is not dependent on dose; and
- SER-109 comprises spores from microbes found in a healthy human gastrointestinal tract.

Taken together, we believe these parameters allow for rapid and inexpensive development relative to typical drug discovery and development.

Phase 2 clinical study design

The Phase 2 clinical study is a randomized, double-blinded, placebo-controlled, parallel-group trial with two treatment arms enrolling a total of 87 patients. We plan to enroll eligible patients at 35 sites in the United States. Patients will be randomized 2:1 to receive either a single oral dose of SER-109 in four capsules or a matching placebo in four capsules. Based on the assumptions we have made for the recurrence rate of CDI and assuming we conduct final analyses for a minimum of 78 patients, our Phase 2 clinical study is sufficiently large, with the power of the study over 90%, to demonstrate that SER-109 is superior to placebo. If our assumptions about the recurrence rate of CDI are incorrect, the statistical power of the Phase 2 clinical study will be affected, and it may be more difficult to show that SER-109 is superior to placebo. In preparation for the clinical study, we have refined the formulation of the inner capsule and changed the manufacturing process to enable production to meet commercial requirements. We believe that the manufacturing and formulation changes have resulted in a more pure form of SER-109 that is comparable in potency to that used in the Phase 1b/2 clinical study based on a pre-clinical mouse *C. difficile* model.

The Phase 2 clinical study is designed to enroll patients 18 years or older with a documented history of three or more occurrences of CDI in the previous nine months, as compared to 12 months in our Phase 1b/2 clinical study. Additionally, enrolled patients must have been clinically responsive to ten to 21 days of standard of care antibiotics and show no evidence of diarrhea for two or more consecutive days prior to randomization. In contrast, enrolled patients in our Phase 1b/2 clinical study were permitted to be on long-term antibiotic therapy. Inclusion and exclusion criteria for the Phase 2 clinical study are generally similar to our Phase 1b/2 clinical study, but are more restricted in some patient populations. For example, the criteria exclude patients on steroids or on maintenance

immunotherapy and those with a history of untreated celiac disease or gluten enteropathy. However, the inclusion and exclusion criteria for the Phase 2 clinical study is less restrictive in other patient populations. For example, the criteria exclude patients with IBS or IBD only if active within the past 24 months, as compared to patients with any history of these diseases in our Phase 1b/2 clinical study, and patients with an absolute neutrophil count, or ANC, less than 500/mm^3, as compared to patients with an ANC less than 1000/mm^3 in the Phase 1b/2 clinical study.

The primary efficacy objective in the Phase 2 clinical study will be to demonstrate the superiority of SER-109 compared to placebo in the prevention of recurrent CDI in adult patients up to eight weeks after treatment. In this study, an episode of recurrent CDI will be defined as three or more unformed stools per day over two days with a positive *C. difficile* stool test and requiring antibiotic treatment. By comparison, our Phase 1b/2 clinical study defined an episode of recurrent CDI as three unformed stools over one day with a positive *C. difficile* stool test and did not require antibiotic treatment. The decision to treat with antibiotics will be based on the physician's clinical assessment of the patient in accordance with the guidelines set forth in our Phase 2 clinical study protocol. The primary safety objective will be to evaluate the safety of SER-109 in these patients up to 24 weeks after treatment as determined by clinical and laboratory safety assessments. During the follow-up period (Weeks 9-12), patients will be contacted by phone weekly and asked about adverse events and diarrheal symptoms. If diarrheal symptoms meeting the definition of recurrent CDI occur during the follow-up period, patients will be asked to return to the clinic for a clinical evaluation and a *C. difficile* test. In addition, patients will return to the clinic at Week 12 for safety evaluations. Following the Week 12 visit, patients will be contacted by phone at Weeks 16, 20 and 24 and asked about adverse events and diarrheal symptoms.

We also plan to evaluate secondary objectives including the time to CDI recurrence, if any, in patients who receive SER-109 compared to those who receive placebo, and the proportion of patients experiencing clinical CDI recurrence up to four, 12 and 24 weeks post-treatment in patients who receive SER-109 compared to placebo. In addition, exploratory objectives include comparing the changes in the composition of the gastrointestinal microbiome from baseline to 24 weeks post-treatment using genomic analysis and measuring quality of life and health outcomes up to 24 weeks post-treatment.

After all enrolled patients complete the Phase 2 clinical study, which will occur 24 weeks following dosing of each patient, or have discontinued before that time point, an analysis of the efficacy and safety endpoints will be performed. Following the analysis of this data, we plan to meet with the FDA to present Phase 2 safety and efficacy results and a proposed protocol for the Phase 3 clinical trial. We plan to initiate the Phase 3 clinical trial in 2016.

Open label extension study. Patients in either arm of the Phase 2 clinical study who relapse and experience an episode of recurrent CDI within eight weeks of treatment will be permitted to enroll in an open label extension study in which they will receive a single dose of SER-109. Participation in the open label extension will be conditioned upon the patient's continued satisfaction of the inclusion and exclusion criteria. We believe that providing the open label extension will assist in facilitating enrollment in the Phase 2 clinical study by providing participants the opportunity to ultimately receive SER-109 if they are initially enrolled in the placebo group. In addition, we believe the open label study will provide additional safety data and may provide us with greater understanding of the impact of a second dose of SER-109.

Manufacturing

SER-109 is a purified ecology of spores produced through a process of extraction from a natural human stool source, obtained from qualified, highly tested donors. The donor raw material is collected in a controlled setting, under a protocol that stringently ensures that donors meet qualification criteria.

Donors are required to be in good health, and to possess a medical history and a lifestyle that minimizes the risk of infectious disease transmission. Donors are tested for infectious agents and screened for gastrointestinal and other health factors. After initial qualification, the donor is eligible to donate for a defined period of time, and donors are monitored periodically for health status changes during the donation period. In the middle, and at the end of the donation period, the qualification assessment is repeated to help ensure the donor has maintained their health status. After successful completion of an exit screening the donations are released from quarantine for use in manufacturing.

We initially process the donor material and then transfer a production intermediate to a contract manufacturing organization, or CMO, to isolate the spores and to concentrate them for conversion to the oral capsule dosage form. The purified, concentrated drug substance is tested for identity, potency and purity, and subsequently formulated and filled into capsules at a controlled potency. The final drug product dosage form is four hard capsules for oral administration. Steps are specifically built into the process to remove and kill non-spore microbes. We are conducting pre-validation studies demonstrating the ability of the process to inactivate and clear the potential pathogens of concern, and we expect to obtain sufficient data from these studies for a Phase 3 clinical trial.

Raw materials, intermediates, drug substance and drug product are tested using cGMP assays developed with our know-how to assess the key quality attributes of identity, potency and purity of the natural product. Identity testing has been developed to assure the presence of live spore forms in the product. Potency assays assure the dose of spores, and assess stability of the spores and the product form during storage. Proprietary microbiological purity assays have been developed to enable testing for microbial contaminants in the presence of the live spore product.

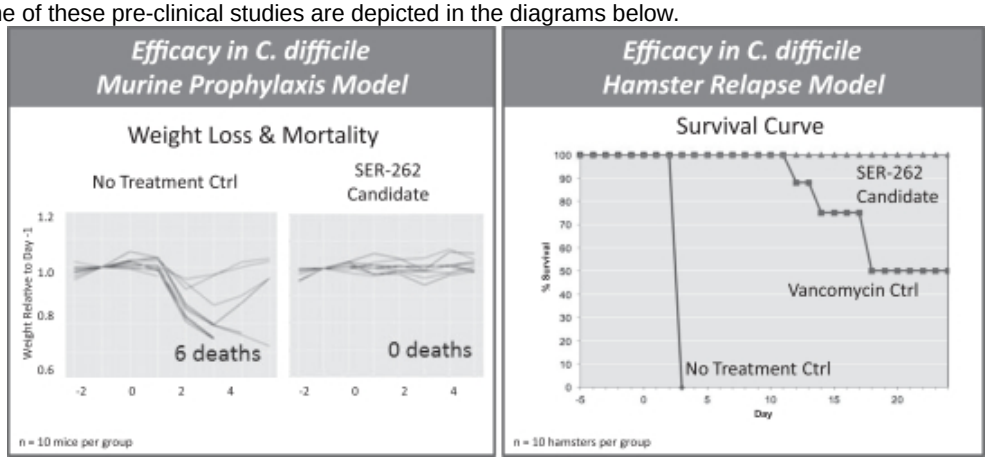
Once ingested, SER-109 spores administered to a patient multiply rapidly within the gastrointestinal tract. Therefore, the dosage required to treat a patient is modest. Moreover, based on the size of the recurrent CDI market, we expect the number of SER-109 doses necessary to meet expected market demand to also be modest. As a result, we believe we can address market demand with a relatively small-scale manufacturing process. Additionally, the need for donors to address anticipated market supply is also modest. If approved, we anticipate that we will be able to produce a sufficient commercial supply of SER-109 to meet estimated demand using donations from fewer than 20 human donors.

SER-262

We are developing SER-262, which is a multi-strain Ecobiotic microbiome therapeutic intended to be used following antibiotic treatment of primary CDI to prevent an initial recurrence of CDI. We are designing SER-262 to increase and improve diversity in the colonic microbiome after antibiotics following CDI. The results of our Phase 1b/2 clinical study of SER-109 provided multiple insights that we are employing in the spore ecology used in SER-262, which consists of a subset of bacteria found in SER-109. Pre-clinical studies of SER-262 candidates have demonstrated efficacy in mouse and hamster models of CDI.

As part of our pre-clinical development of SER-262 we have screened multiple SER-262 candidates for efficacy, compositional optimization and pre-clinical safety in animal models. SER-262 candidates provided significant protection against CDI with reduced mortality, minimum weight loss and clinical score measures of efficacy. Protection was observed using some candidates across a 100-fold dose range with the magnitude of the efficacy signal decreasing at lower doses. Through additional screening of various compositions, we intend to identify an optimal composition of SER-262. We plan to conduct additional mouse and hamster studies as well as conduct further *in vitro* characterization of individual strains, including whole genome sequencing, sporulation efficiency and fermentation requirements in preparation for filing an IND.

The results of some of these pre-clinical studies are depicted in the diagrams below.



We intend to file an IND to initiate clinical studies of SER-262 in the middle of 2016. Each of the strains used in our pre-clinical studies were purified from a qualified donor who participated in the SER-109 Phase 1b/2 clinical study. We believe that the prior clinical use of these strains may ease concerns over their safety in humans and may also limit pre-clinical toxicological studies that might otherwise be required. Additionally, given our ability to grow the spores in bacterial fermenters we will not require any additional donations from human donors for purposes of manufacturing SER-262.

SER-262 represents the continued evolution of our platform and capabilities, validating our ability to extend our technology to new indications. SER-262, unlike SER-109, is made in bacterial fermenters and in a rational *in vitro* design similar to a fixed dose combination of small or large molecules. We intend to use this approach going forward for future Ecobiotic microbiome therapeutics, which will eliminate the need for ongoing human donors in the CMC process.

Manufacturing

To manufacture SER-262, bacterial components for formulation will be fermented and purified as spores. The bacterial components will originate from cGMP master cell banks that will be manufactured and released starting from proprietary research cell banks. Research cell banks have been made for each strain by clonal isolation and multiple rounds of purification, followed by banking. We expect these banks will be ready for transfer to cGMP manufacturing for master cell banking following testing for identity and microbiological purity. The strains have been cultured in controlled fermentations with above-target yields on average to meet projected initial clinical testing needs. Optimization is on-going to define cultivation conditions that promote spore formation. We expect that subsequent purification processing, and formulation chemistries and processes, will enable final drug products containing both purified spores and combinations of spores with vegetative bacteria.

Other Product Candidates and Products in Discovery

SER-287

We have an active pre-clinical program to develop an Ecobiotic microbiome therapeutic for IBD, including ulcerative colitis. Consistent with our approach to rational drug design, we based this program on clinical observations and hypotheses about the role of a dysbiotic microbiome as the proximal cause of disease.

Recent published third-party research reported changes in the microbiome in a cohort of patients with IBD, including ulcerative colitis, compared to healthy individuals. The changes include higher levels of *Enterobacteriaceae* and lower levels of *Clostridiales*. The changes in these organisms are a form of dysbiosis, and we believe that if we can repopulate keystone organisms and functional pathways we could restore the microbiome thereby treating ulcerative colitis.

Based on this research and our experience with SER-109, we believe that we can use a complex spore ecology to restore the underlying dysbiosis of ulcerative colitis. SER-109 is comprised of organisms in the class of *Clostridiales*, which engraft after treatment with SER-109. SER-109 has also been shown to reduce the colonization of *Enterobacteriaceae* in CDI patients. We are developing SER-287 to treat ulcerative colitis. To derive SER-287, we will use data generated in our studies of SER-109. We are currently researching SER-287 and anticipate initiating a Phase 1b proof-of-concept clinical trial for SER-287 for ulcerative colitis by the end of 2015.

SER-155

We have an active pre-clinical program to develop Ecobiotic microbiome therapeutics for other infectious diseases. The Phase 1b/2 clinical study of SER-109 provided initial evidence suggesting that Ecobiotic microbiome therapeutics have the potential to eliminate colonization by microbial pathogens, such as VRE and Gram-negative *Enterobacteriaceae*. *Enterobacteriaceae*, such as *Klebsiella*, *Morganella* and *Proteus*, normally are present at low levels in the healthy colon, but like *C. difficile*, they can overgrow after antibiotic use. *Enterobacteriaceae* can include multidrug resistant organisms, or MDROs, that represent significant public health concerns. For example, carbapenem resistant *Enterobacteriaceae*, or CRE, is a significant problem in the United States. VRE, CRE and other MDROs colonize the gastrointestinal tract after antibiotic use and can spread through contact with patients and healthcare workers both in institutional and in community settings.

We are currently designing and developing SER-155, an Ecobiotic microbiome therapeutic that is expected to have activity against Gram-positive and Gram-negative enteric bacterial pathogens. We expect SER-155 to be used for the treatment of antibiotic-resistant bacteria to eliminate colonization and prevent infection. The selection of indication will be based on pre-clinical screening efforts, and the assessment of clinical development plan, regulatory path and market opportunities. We plan to conduct additional mouse and hamster studies as well as conduct further *in vitro* characterization of individual strains, including whole genome sequencing, sporulation efficiency and fermentation requirements in preparation for filing an IND.

Sales and Marketing

In light of our stage of development, we have not yet established a commercial organization. If SER-109 is approved in the United States, we plan to commercialize it with our own focused specialty sales force. We believe we can effectively commercialize SER-109 with a commercial team of 100 or fewer sales representatives that will target gastrointestinal and infectious disease physicians, which are the two primary groups of physicians who treat multiple recurrent CDI patients.

In addition, we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize SER-109 and SER-262 in markets outside the United States.

Manufacturing

The production of live bacterial products is highly specialized. Owing to their hardiness and environmental persistence, production of spore-forming organisms poses unique considerations for product, personnel and facility protection. Manufacturing activities with spores are subject to additional regulations. We believe that many of the challenges associated with manufacturing bacterial combinations are overcome by the low dose requirements of our product. For example, we expect that a typical fermentation will yield thousands of doses per liter. Additionally, because a given total dose is split between several strains, the per-strain requirements for production may be even lower. As a result, we believe the high productivity relative to the dose level will enable production scales for both clinical and commercial supply to be modest.

We have developed a supply chain for producing and testing materials to ensure the availability of future clinical trial supplies. Our development processes are designed to provide that all raw materials, process technologies and analytical tests we use are scalable and transferable to a cGMP manufacturing environment. These include the following core elements:

- *Fermentation*. We believe that microscale screening is possible for optimization of the bacterial cultures of interest in our current and foreseeable candidates. These screens will focus a given strain on the fermentation platform that is best-suited for optimization and scale-up. Small-scale fermentation systems (0.1 L to 20 L) enable the optimization of a wide variety of culture conditions and have been demonstrated to be scalable to commercial fermentation processes and enable technology transfer to clinical and final manufacturing scales. We employ platform fermentation processes as starting conditions for cGMP production schemes, and when required, will develop strain specific process parameters. To develop master cell banks and bulk drug substance for commercial product, we plan to use bacterial strains originating from the research cell bank, so we expect the research cell banks and final drug product will be genetically and physiologically similar.
- *Purification*. Similar to fermentation, we believe small-scale purification, formulation, filling and dosage preparation operations are available to complete bench-scale manufacturing and/or spores, which quickly assess the final process yield, quality and robustness.
- *Formulation*. Our Ecobiotic microbiome therapeutics are combinations of live bacteria and can be administered by a number of methods and by different routes. The primary goal in developing formulation is to deliver the bacteria to the intended location in a condition where they are able to replicate and correct dysbiosis. Formulation development will generally use approved excipients and preservatives, and will include screening of both liquid and solid formulations to maximize the opportunity for extended stability with minimal cold-chain requirements.
- *Analytical*. We intend to address quality control requirements for our Ecobiotic microbiome therapeutics using proprietary microbiological and sequence-based testing schemes. We have available and are further developing quality control and in-process analytical tools that can quantitatively measure the composition of spore, vegetative microbe and spore/vegetative combinations, which we believe enable a wide variety of drug substances to be manufactured. Throughout the bioprocess and formulation development platform we plan to use high-throughput quantitative analytics to assess the identity, potency and purity of the final product.

We currently have a pilot manufacturing facility at our Cambridge location where we conduct process development, scale-up activities and a portion of the cGMP manufacture of Ecobiotic microbiome therapeutics. We currently intend to establish a manufacturing facility for our product candidates for production at a commercial scale which we may do by expanding our current facility or building additional facilities.

Intellectual Property

We strive to protect the proprietary technology that we believe is important to our business, including seeking and, if granted, maintaining patents intended to cover our product candidates and compositions, their methods of use and processes for their manufacture and any other aspects of inventions that are commercially important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

We plan to continue to expand our intellectual property estate by filing patent applications directed to compositions, methods of treatment, methods of manufacture and methods for patient selection created or identified from our ongoing development of our product candidates. Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce any patents that we may obtain, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on know-how and continuing technological innovation to develop and maintain our proprietary position and, in the future, may rely on or leverage in-licensing opportunities. We seek to obtain domestic and international patent protection, and endeavor to promptly file patent applications for new commercially valuable inventions.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent may be challenged in courts after issuance. Moreover, many jurisdictions permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or at all, whether the claims of any patent applications, should they issue, will cover our product candidates, or whether the claims of any issued patents will provide sufficient protection from competitors or otherwise provide any competitive advantage.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially even longer, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries and patent application filings, we cannot be certain of the priority of inventions covered by pending patent applications. Accordingly, we may not have been the first to invent the subject matter disclosed in some of our patent applications or the first to file patent applications covering such subject matter, and we may have to participate in interference proceedings or derivation proceedings declared by the United States Patent and Trademark Office, or USPTO, to determine priority of invention.

Our patent portfolio includes patent applications in the early stages of prosecution and three issued patents. For our pending applications, we anticipate determining, in advance of the applicable deadlines, whether to pursue these applications and if so will pursue them in the United States and selected ex-U.S. jurisdictions. Substantive patent prosecution before the USPTO was begun in four applications from two patent families, and three of these have issued as patents. We believe that issued claims will provide protection for SER-109, SER-262, SER-287 and SER-155.

Our patent estate leverages both offensive and defensive strategies. As of May 31, 2015, we owned a total of nine patent application families that include Patent Cooperation Treaty, or PCT, applications and/or U.S. patent applications, and some of these families are described briefly below. We also own two additional patent application families that include only U.S. provisional applications that will not themselves be examined and for which the deadline to file PCT applications and/or U.S.

non-provisional applications has not yet expired. The pending patent applications as of May 31, 2015 in six of the patent application families in our portfolio are described briefly below. We expect to pursue additional applications in these families over time.

- A family related to binary combinations of microbes that includes the following issued and pending applications: (i) an issued U.S. patent, which claims therapeutic compositions that include selected binary combinations of microbes; (ii) an issued U.S. patent, which claims methods of using such compositions to treat or prevent CDI; (iii) a continuation U.S. patent application and (iv) a PCT application claiming similar methods and compositions. We have initiated the filing of national stage applications based on this PCT application in 11 ex-U.S. jurisdictions. Patents issuing from or based on these applications, if any, are expected to expire in 2033, assuming all required maintenance fees are paid and absent any applicable patent term extension or patent term adjustment. We expect this patent application family to provide patent protection for SER-109, SER-262, SER-287 and SER-155.
- A family related to combinations of bacterial spores that includes the following issued and pending applications: (i) one issued U.S. patent and one U.S. application that claim certain methods of treatment of gastrointestinal diseases, including Crohn's disease and colitis, using combinations of bacterial spores and (ii) a PCT application claiming similar methods, as well as related compositions. The time period for electing to pursue foreign patent protection by filing national stage applications in individual jurisdictions based on this PCT application has not yet expired, and we will need to decide whether and where to pursue ex-U.S. protection before expiration of the applicable deadlines. Patents issuing from or based on these applications, if any, are expected to expire in 2034, assuming all required maintenance fees are paid and absent any applicable patent term extension or patent term adjustment. We expect this patent application family to provide patent protection for SER-109, SER-262, SER-287 and SER-155.
- A family that includes a pending PCT application related to compositions of matter and methods for new combinations of microbes for treating gastrointestinal diseases. The time period for electing to pursue US and foreign patent protection by filing national stage applications in individual jurisdictions based on this PCT application has not yet expired, and we will need to decide whether and where to pursue U.S. and ex-U.S. protection before expiration of the applicable deadlines. If we do pursue protection in one or more jurisdictions, patents based on this application, if granted, are expected to expire in 2034, assuming all required maintenance fees are paid and absent any applicable patent term extension or patent term adjustment.
- A family that includes a pending PCT application related to Ecobiotic quality control and characterization methods. The time period for electing to pursue U.S. and foreign patent protection by filing national stage applications in individual jurisdictions based on this PCT application has not yet expired, and we will need to decide whether and where to pursue US and ex-US protection before expiration of the applicable deadlines. If we do pursue protection in one or more jurisdictions, patents based on this application, if granted, are expected to expire in 2034, assuming all required maintenance fees are paid and absent any applicable patent term adjustment.
- A family that includes a pending PCT application related to methods of restructuring of a host microbiome using microbial populations identified using our network-based discovery platforms. The time period for electing to pursue U.S. and foreign patent protection by filing national stage applications in individual jurisdictions based on this PCT application has not yet expired, and we will need to decide whether and where to pursue U.S. and ex-U.S. protection before expiration of the applicable deadlines. If we do pursue protection in one or more jurisdictions, patents based on this application, if granted, are expected to expire in 2034, assuming all required maintenance fees are paid.

- A family that includes a pending PCT application related to compositions of matter and methods of treating disorders with compositions that include, for example, ternary combinations of microbes. The time period for electing to pursue U.S. and foreign patent protection by filing national stage applications in individual jurisdictions based on this PCT application has not yet expired, and we will need to decide whether and where to pursue U.S. and ex-U.S. protection before expiration of the applicable deadlines. If we do pursue protection in one or more jurisdictions, patents based on this application, if granted, are expected to expire in 2034, assuming all required maintenance fees are paid and absent any applicable patent term extension or patent term adjustment.

Patent term

The base term of a U.S. patent is 20 years from the filing date of the earliest-filed non-provisional, patent application from which the patent claims priority. The term of a U.S. patent can be lengthened by patent term adjustment, which compensates the owner of the patent for administrative delays at the USPTO. In some cases, the term of a U.S. patent is shortened by terminal disclaimer that reduces its term to that of an earlier-expiring patent.

The term of a U.S. patent may be eligible for patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act, to account for at least some of the time the drug is under development and regulatory review after the patent is granted. With regard to a drug for which FDA approval is the first permitted marketing of the active ingredient, the Hatch-Waxman Act allows for extension of the term of one U.S. patent that includes at least one claim covering the composition of matter of such an FDA-approved drug, an FDA-approved method of treatment using the drug and/or a method of manufacturing the FDA-approved drug. The extended patent term cannot exceed the shorter of five years beyond the non-extended expiration of the patent or fourteen years from the date of the FDA approval of the drug, and a patent cannot be extended more than once or for more than a single product. During the period of extension, if granted, the scope of exclusivity is limited to the approved product for approved uses. Some foreign jurisdictions, including Europe and Japan, have analogous patent term extension provisions, which allow for extension of the term of a patent that covers a drug approved by the applicable foreign regulatory agency. In the future, if and when our product candidates receive FDA approval, we expect to apply, if appropriate, for patent term extension on patents covering those product candidates, their methods of use and/or methods of manufacture.

Trade secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. We typically rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We protect trade secrets and know-how by establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and collaborators. These agreements provide that all confidential information developed or made known during the course of an individual or entities' relationship with us must be kept confidential during and after the relationship. These agreements also provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties.

Competition

The development and commercialization of new drug and biologic products is highly competitive and is characterized by rapid and substantial technological development and product innovations. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. We are aware of a number of large pharmaceutical and biotechnology companies, including Merck, Shire, Sanofi, Pfizer and Novartis, as well as smaller, early-stage companies, that are pursuing the development of products, including microbiome therapeutics, for the prevention of CDI and other disease indications we are targeting. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others may be based on entirely different approaches. For example, FMT is a procedure that has resulted in high cure rates for recurrent CDI and our competitors and physicians may continue to seek to standardize and implement this procedure. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors.

These third parties compete with us in recruiting and retaining qualified scientific, sales and marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The key competitive factors affecting the success of SER-109 and any other product candidates that we develop, if approved, are likely to be their efficacy, safety, convenience, price, the level of competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market, especially for any competitor developing a microbiome therapeutic which will likely share our same regulatory approval requirements. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of lower cost products.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs and biologics such as those we are developing. We, along with our contract manufacturers, will be required to navigate the various pre-clinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies

or seek approval for our product candidates. The process of obtaining regulatory approvals and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, the FDA regulates drug and biologic products under the Federal Food, Drug and Cosmetic Act, its implementing regulations and other laws, including, in the case of biologics, the Public Health Service Act. Our product candidates are subject to regulation by the FDA as biologics. Biologics require the submission of a biologics license application, or BLA, and approval by the FDA before being marketed in the United States. None of our product candidates has been approved by the FDA for marketing in the United States, and we currently have no BLAs pending. If we fail to comply with applicable FDA or other requirements at any time during product development, clinical testing, the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, suspension or revocation of approved applications, warning letters, product recalls, product seizures, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution. Any FDA enforcement action could have a material adverse effect on us.

The process required by the FDA before our biologic product candidates may be marketed in the United States generally involves the following:

- completion of pre-clinical laboratory tests and animal studies performed in accordance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before clinical trials in the United States may begin;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication, conducted in accordance with the FDA's good clinical practice, or GCP, regulations;
- submission to the FDA of a BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP regulations; and
- FDA review and approval of the BLA prior to any commercial marketing, sale or shipment of the product.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Pre-clinical and Clinical Trials

Once a product candidate is identified for development, it enters the pre-clinical testing stage. Pre-clinical studies include laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which must be conducted in accordance with GLP requirements. The results of the pre-clinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing clinical trials to commence on the terms

originally specified in the IND. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development, and the FDA must grant permission, either explicitly or implicitly by not objecting, before each clinical trial can begin.

Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol must be submitted to the FDA as part of the IND. An independent institutional review board, or IRB, for each medical center proposing to participate in a clinical trial must also review and approve the clinical trial before it can begin at that center, and the IRB must monitor the clinical trial until it is completed. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP requirements, including requirements for informed consent.

For purposes of BLA approval, clinical trials are typically conducted in three sequential phases, which may overlap or be combined.

- *Phase 1* — Phase 1 clinical trials involve initial introduction of the investigational product into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- *Phase 2* — Phase 2 clinical trials involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.
- *Phase 3* — Phase 3 clinical trials involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may condition approval of a BLA on the sponsor's agreement to conduct additional clinical trials to further assess the biologic's safety and effectiveness after BLA approval. Such post-approval clinical trials are typically referred to as Phase 4 clinical trials.

Although most clinical research performed in the United States in support of a BLA must be authorized in advance by the FDA, under the IND regulations and procedures described above, there are certain circumstances under which clinical trials can be conducted without submission of an IND. For example, a sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. Similarly, the FDA may exercise enforcement discretion to permit sponsors to conduct certain types of clinical investigations without an IND. Pursuant to the FDA guidance document "Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies" (July 2013), the FDA currently exercises enforcement discretion regarding the IND requirements for the use of FMT to treat CDI not responsive to standard therapies, provided that the treating physician obtains adequate informed consent from the patient or his or her legally authorized representative for the use of FMT products. The FDA provided confirmation that it intends to exercise enforcement discretion with respect to our Phase 1b/2 clinical study of SER-109, a modified FMT product, and accordingly, we did not conduct

this trial under an IND. However, the guidance document states that the FDA will continue to work with any sponsors who wish to submit INDs for this use of FMT, and we intend to conduct all future clinical studies of SER-109, including our Phase 2 clinical study and our planned Phase 3 clinical trial, under an IND.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the biologic and finalize a process for manufacturing the biologic in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and manufacturers must develop, among other things, methods for testing the identity, strength, quality and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and FDA Review

The results of pre-clinical studies and clinical trials, together with other detailed information, including extensive manufacturing information and information on the composition of the biologic, are submitted to the FDA in the form of a BLA requesting approval to market the biologic for one or more specified indications. The submission of a BLA requires payment of a substantial user fee unless a waiver is granted. Each BLA submitted to the FDA is reviewed for administrative completeness and reviewability within 60 days of the FDA's receipt of the application. If the BLA is found to be complete, the FDA will file the BLA, triggering a full review of the application. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission.

Once a BLA has been accepted for filing, by law the FDA has 180 days to review the application and respond to the applicant. However, the review process is often significantly extended by FDA requests for additional information or clarification. Under the Prescription Drug User Fee Act, the FDA has a goal of reviewing BLAs within ten months of the 60-day filing date for standard review or six months for priority review, but the overall timeframe is often extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether the biological product is safe, pure and potent and whether the facility or facilities in which it is manufactured meet standards designed to assure the product's continued safety, purity and potency. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving a BLA, the FDA will inspect the facility or the facilities at which the biologic product is manufactured, and will not approve the product unless cGMP compliance is satisfactory. The FDA may also inspect the sites at which the clinical trials were conducted to assess their compliance with GCP requirements, and will not approve the biologic unless compliance with such requirements is satisfactory.

The FDA may deny approval of a BLA if the applicable statutory and regulatory criteria are not satisfied, or it may require additional pre-clinical or clinical data. Even if such data are submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than sponsors. Once the FDA approves a BLA, such approval may limit the indicated uses for which the biologic may be marketed. The FDA may also require implementation of a Risk Evaluation and Mitigation Strategy, or REMS, which can include a medication guide, communication plan, or elements to assure safe use, such as restricted distribution methods, physician training, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling claims or the development of adequate controls and specifications. Once approved, the FDA may

withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the market. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing based on the results of these post-marketing studies.

The biologic testing and approval processes require substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all. Even if we believe a clinical trial has demonstrated safety and efficacy of one of our product candidates for the treatment of a disease or condition, the results may not be satisfactory to the FDA. Pre-clinical and clinical data may be interpreted by the FDA in different ways, which could delay, limit or prevent regulatory approval. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals which could delay or preclude us from marketing our product candidates. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of our products. After approval, certain changes to the approved biologic, such as adding new indications, manufacturing changes or additional labeling claims, are subject to further FDA review and approval. Depending on the nature of the change proposed, a BLA supplement must be filed and approved before the change may be implemented. For many proposed post-approval changes to a BLA, the FDA has up to 180 days to review the application. As with new BLAs, the review process is often significantly extended by the FDA requests for additional information or clarification.

Expedited Development and Review Programs

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs and biologics to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include fast track designation, breakthrough therapy designation, priority review designation and accelerated approval, and the purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

A new drug or biologic is eligible for fast track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast track designation provides increased opportunities for sponsor meetings with the FDA during pre-clinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, as well as priority review, discussed below. In addition, a new drug or biologic may be eligible for breakthrough therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation provides all the features of fast track designation in addition to intensive guidance on an efficient drug development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with fast track or breakthrough therapy designation, may also be eligible for additional FDA programs intended to expedite the review process, including priority review designation and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. The FDA aims

to review applications for new products designated for priority review within six months, compared to ten months under standard review. Additionally, products intended to treat serious or life-threatening diseases or conditions may receive accelerated approval. Products are eligible for accelerated approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Accelerated approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. In addition, the FDA currently requires, as a condition for accelerated approval, pre-approval of all promotional materials intended for dissemination or publication within 120 days following marketing approval, which could adversely impact the timing of commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review designation and accelerated approval do not change the standards for approval but may expedite the development or review process. We have received Breakthrough Therapy designation for SER-109, and we may apply for one or more of the FDA's expedited programs for our other product candidates. The FDA may disagree that our product candidates satisfy the criteria for such programs, such programs may fail to result in expedited development or review timelines, or the FDA may ultimately refuse to approve our product candidates despite their inclusion in any expedited programs. In addition, if the Breakthrough Therapy designation for SER-109 is no longer supported by subsequent data, FDA may rescind the designation.

Post-Approval Requirements

Approved biologics that are manufactured or distributed in the United States are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product distribution, advertising and promotion and reporting of adverse experiences with the product. There also are continuing, annual user fee requirements for products and the establishments at which such products are manufactured, as well as new application fees for certain supplemental applications.

Any biologics manufactured or distributed by us or our contract manufactures pursuant to FDA approvals would be subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences associated with the product. Manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our contract manufacturers. Failure to comply with statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a product from distribution or withdraw approval of the BLA for that product.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of

distribution or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the internet and social media. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Physicians may prescribe legally available biologics for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Biosimilars

We believe that any of our product candidates approved under a BLA should qualify for a 12-year period of exclusivity against biosimilar competition currently permitted by the Biologics Price Competition and Innovation Act, or BPCIA. Specifically, as part of the Patient Protection and Affordable Care Act enacted in 2010, as amended by the Health Care and Education Affordability Reconciliation Act, collectively the Affordable Care Act, the BPCIA established an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The new abbreviated regulatory pathway provides legal authority for the FDA to review and approve biosimilar biologics based on their similarity to an existing brand product, referred to as a reference product, including the possible designation of a biosimilar as interchangeable with a brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original brand product was approved under a BLA. There is a risk that, as proposed by President Obama, Congress could amend the BPCIA to significantly shorten this exclusivity period or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological drug products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. The BPCIA is complex and is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning is subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes that operate to limit the scope or length of exclusivity afforded by the BPCIA could have a material adverse effect on the future commercial prospects for our biological products. In addition, the period of exclusivity provided by the BPCIA only operates against third parties seeking approval via the abbreviated pathway, but would not prevent third parties from pursuing approval via the traditional approval pathway. In addition, foreign regulatory authorities may also provide for exclusivity periods for approved biological products. For

example, biological products in the European Union may be eligible for at least a ten-year period of exclusivity.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the product available in the United States for the disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting a BLA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan products are eligible for certain incentives, including tax credits for qualified clinical testing and waiver of application fees.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity during which the FDA may not approve any other applications to market the same therapeutic agent for the same indication, except in limited circumstances, such as a subsequent product's showing of clinical superiority over the product with orphan exclusivity. Competitors, however, may receive approval of different therapeutic agents for the indication for which the orphan product has exclusivity or obtain approval for the same therapeutic agent for a different indication than that for which the orphan product has exclusivity. Orphan product exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for the same therapeutic agent for the same indication before we do, unless we are able to demonstrate that our product is clinically superior. Further, if a designated orphan product receives marketing approval for an indication broader than the rare disease or condition for which it received orphan designation, it may not be entitled to orphan exclusivity.

We may seek orphan designation for one or more of our product candidates, but the FDA may disagree with our analysis of the prevalence of a disease or condition or other criteria for designation and refuse to grant orphan status. We cannot guarantee that we will obtain designation or approval for any product candidate, or that we will be able to secure orphan product exclusivity if we do obtain approval.

Other Healthcare Laws

Although we currently do not have any products on the market, if our product candidates are approved and we begin commercialization, we will be subject to healthcare regulation and enforcement by the federal government and the states in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations.

The federal Anti-Kickback Statute prohibits the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal healthcare programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts and free or reduced price items and services. The government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham research or consulting and other financial arrangements with physicians. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute

constitutes a false or fraudulent claim for purposes of the False Claims Act (discussed below). Many states have similar laws that apply to their state healthcare programs as well as private payors.

The False Claims Act, or FCA, imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. Actions under the FCA may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the FCA can result in significant monetary penalties and treble damages. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi–billion dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. In addition, companies have been forced to implement extensive corrective action plans, and have often become subject to consent decrees or corporate integrity agreements, severely restricting the manner in which they conduct their business. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Affordable Care Act, among other things, imposed new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers were required to begin collecting data on August 1, 2013 and submit reports on aggregate payment data to the government for the first reporting period (August 1, 2013 – December 31, 2013) by March 31, 2014, and to report detailed payment data for the first reporting period and submit legal attestation to the accuracy of such data by June 30, 2014. Thereafter, drug manufacturers must submit reports by the 90th day of each subsequent calendar year. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The shifting commercial compliance environment and the need to build and maintain robust systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In both domestic and foreign markets, sales and reimbursement of any approved products will depend, in part, on the extent to which third-party payors, such as government health programs, commercial insurance and managed healthcare organizations provide coverage, and establish adequate reimbursement levels for, such products. Third-party payors are increasingly challenging the prices charged for medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Additionally, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. If third-party payors do not consider our products to be cost-effective compared to other therapies, the payors may not cover our products as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis.

The containment of healthcare costs also has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results.

Outside the United States, ensuring adequate coverage and payment for our products will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. Conducting such a clinical trial could be expensive and result in delays in our commercialization efforts. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly approved healthcare products. Recent budgetary pressures in many countries are also causing governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates. If budget pressures continue, governments may implement additional cost-containment measures. Cost-control initiatives could decrease the price we might establish for products that we may develop or sell, which would result in lower product revenues or royalties payable to us. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products.

Healthcare Reform

In the United States, there have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biological products, government control and other

changes to the healthcare system. It is uncertain what legislative proposals will be adopted or what actions federal, state or private payors for medical goods and services may take in response to any healthcare reform proposals or legislation. We cannot predict the effect medical or healthcare reforms may have on our business, and no assurance can be given that any such reforms will not have a material adverse effect.

By way of example, in March 2010, the Affordable Care Act was signed into law, which, among other things, includes changes to the coverage and payment for drug products under government health care programs. Among other things, the Affordable Care Act:

- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of ''average manufacturer price,'' or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- extended Medicaid drug rebates, previously due only on fee-for-service utilization, to Medicaid managed care utilization, and created an alternate rebate formula for new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs;
- expanded the types of entities eligible for the 340B drug discount program that mandates discounts to certain hospitals, community centers and other qualifying providers. With the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, because 340B pricing is determined based on AMP and Medicaid drug rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discounts to increase; and
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals. Adoption of other new legislation at the federal or state level could further limit reimbursement for pharmaceuticals, including our product candidates if approved.

Employees

As of May 31, 2015, we had 46 full-time permanent employees. Eleven employees work in administration and operations and 35 work in research and development.

Facilities

Research and Offices

Our corporate headquarters are located in Cambridge, Massachusetts, where we currently sublease approximately 7,461 square feet of office space under a sublease that expires in February 2016. We also maintain a research and development facility in Cambridge, Massachusetts, where we lease approximately 13,568 square feet of space for office and laboratory facilities under a lease that expires in January 2018 and approximately 7,484 square feet under a lease that expires in April 2020.

Manufacturing

We currently conduct part of our manufacturing business in our leased laboratory facilities in Cambridge, Massachusetts. We believe our current laboratory facilities are sufficient to meet our bioprocess development and manufacturing needs through mid-2015, after which we expect to require purpose-built or renovated space to prepare for commercialization of SER-109. SER-262, SER-287, SER-155 and other product candidates may be brought into the SER-109 facilities for economies of operation, or may remain external with contract manufacturing organizations, depending on business dynamics and development needs.

In preparation for commercial production of SER-109, we intend to bring raw material donor qualification and management and donation processing into a new facility operated by us that will meet commercial requirements. The location of this facility is yet to be determined. We estimate that capital costs for setting up such a facility will be approximately $2.0 million, and that it will be operated by our staff.

We plan to control the production of SER-109 under cGMP by making strategic investments in manufacturing, which may include collaborations with third parties, the design and renovation of existing facilities and the construction of new facilities.

Legal Proceedings

We are not party to any material legal proceedings.

MANAGEMENT

Executive Officers, Key Employees and Directors

The following table sets forth the name, age and position of each of our executive officers, key employees and directors as of May 31, 2015.

Name	Age	Position
Executive Officers		
Roger J. Pomerantz, M.D.	58	President and Chief Executive Officer and Chairman of the Board
John G. Aunins, Ph.D.	54	Chief Technology Officer and Executive Vice President of Bioprocess Development
David N. Cook, Ph.D.	57	Chief Scientific Officer and Executive Vice President of Research & Development
Eric D. Shaff.	39	Chief Financial Officer and Executive Vice President
Michele Trucksis, Ph.D., M.D.	62	Chief Medical Officer and Executive Vice President
Other Key Employees		
Matthew Henn, Ph.D.	40	Head of Drug Discovery & Bioinformatics and Vice President
Directors		
Noubar B. Afeyan, Ph.D.(2)	52	Director
Dennis A. Ausiello, M.D.(3)	69	Director
Grégory Behar	45	Director
Werner Cautreels, Ph.D.(1)	62	Director
Peter Barton Hutt(2)(3)	80	Director
Richard N. Kender(1)(2)	59	Director
Lorence H. Kim, M.D.(1)(3)	41	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

Executive Officers and Other Key Employees

Roger J. Pomerantz, M.D., has served as our President and Chief Executive Officer since June 2014 and as Chairman of our board of directors since November 2013. Since July 2014, Dr. Pomerantz has been a Senior Partner at Flagship Ventures, an early-stage venture capital firm. From January 2011 to September 2013, Dr. Pomerantz was Worldwide Head of Licensing and Acquisitions and Senior Vice President at Merck & Co., Inc., or Merck, a pharmaceutical company, where he oversaw licensing and acquisitions for Merck Research Laboratories, the research and development division of Merck. From February 2010 to February 2013, Dr. Pomerantz served as Global Head of Infectious Diseases and Senior Vice President at Merck, where he oversaw pharmaceutical development and discovery of antibiotics, antivirals, antifungals and antiparasitic agents. Prior to Merck, Dr. Pomerantz was Global Head of Infectious Diseases for the pharmaceutical division of Johnson & Johnson, Inc., a multinational medical device, consumer goods and pharmaceutical corporation, where he was responsible for anti-infective agents worldwide. He joined Johnson & Johnson, Inc. in August 2005 as President of Tibotec Pharmaceuticals, Inc., now Janssen Therapeutics and a subsidiary of Johnson & Johnson, Inc., a pharmaceutical company focused on the treatment of infectious diseases. Dr. Pomerantz has developed eight approved infectious disease drugs for diseases including HIV, HCV and tuberculosis. He also serves on the board of directors of Contrafect Corporation, a biotechnology company. Dr. Pomerantz received his B.A. in Biochemistry from The Johns Hopkins University and his M.D. from The Johns Hopkins School of Medicine. We believe Dr. Pomerantz's extensive academic and clinical experience, as well as his knowledge of the pharmaceutical industry, qualifies him to serve on our board of directors.

John G. Aunins, Ph.D., has served as our Chief Technology Officer and Executive Vice President of Bioprocess Development since December 2012. Prior to joining our company, Dr. Aunins served on our Scientific Advisory Board from February 2012 to December 2012. From April 1989 to November 2011, Dr. Aunins served in various roles at Merck, most recently as Executive Science Director. At Merck, Dr. Aunins led process and product development teams for six licensed vaccines and multiple vaccine candidates. He is a Fellow of the American Institute for Medical and Biological Engineering and an adjunct Full Professor at the Instituto de Tecnologia Quimica e Biologica in Oeiras, Portugal. Dr. Aunins received his B.S. from the University of Kansas and his Ph.D. in Chemical Engineering from the Massachusetts Institute of Technology.

David N. Cook, Ph.D., has served as our Chief Scientific Officer and Executive Vice President of Research & Development since October 2012. From February 2010 to October 2012, Dr. Cook was the Chief Operating Officer at the International AIDS Vaccine Initiative, a global not-for-profit, research and development organization focused on the development of a safe and accessible vaccine for HIV. As Chief Operating Officer, Dr. Cook acted as the head of operations, overseeing seven international offices and research facilities. Dr. Cook received his A.B. from Harvard College and his Ph.D. in Chemistry from the University of California, Berkeley.

Matthew Henn, Ph.D., has served as our Head of Drug Discovery & Bioinformatics since December 2014 and as Vice President since May 2015. From June 2012 to December 2014, Dr. Henn served as our Head of Product Design. From April 2010 to June 2012, Dr. Henn was Director of Viral Genomics and, from May 2009 to April 2010, Assistant Director of the Genome Sequencing Center for Infectious Diseases at the Broad Institute of Harvard and MIT, a biomedical research organization. Dr. Henn has over 60 peer-reviewed publications in microbiology and bioinformatics. He is a scientific advisor for the National Institutes of Health's Viral Pathogen Bioinformatics Resource Center and served on the editorial board of *Genome Medicine* from 2010 to 2015. Dr. Henn received his B.S. from the University of New Hampshire and his Ph.D. in Ecosystem Sciences from the University of California, Berkeley.

Eric D. Shaff has served as our Chief Financial Officer and Executive Vice President since November 2014. From January 2012 to November 2014, Mr. Shaff was Vice President of Corporate Finance for Momenta Pharmaceuticals, a biotechnology company. From June 2004 to December 2011, Mr. Shaff held a number of corporate development and finance positions with Genzyme Corporation, a biotechnology company, most recently as Vice President of Finance/Controller for the Personalized Genetic Health division. Mr. Shaff received his B.A. from the University of Pennsylvania and his MBA from Cornell University.

Michele Trucksis, Ph.D., M.D., has served as our Chief Medical Officer and Executive Vice President since January 2015. Dr. Trucksis has been an Associate Clinical Professor at Harvard Medical School since January 2005. From December 2006 to December 2014, Dr. Trucksis held various positions of increasing seniority at Merck Research Laboratories, the research and development division of Merck. Most recently, from June 2014 to December 2014, Dr. Trucksis served as Executive Director, Team Leader & Clinical Lead, Antifungals and Antibacterials where she was responsible for medical, clinical and global product development and strategy. From July 2011 to June 2014, Dr. Trucksis was Project Leader, Antifungals and Antibacterials, and from December 2006 to July 2011, she was Director in Clinical Pharmacology. Dr. Trucksis received her B.S. in Medical Technology from Youngstown State University, her Ph.D. in Biochemistry from Kent State University and her M.D. from Case Western Reserve University School of Medicine.

Directors

Noubar B. Afeyan, Ph.D., has served as a member of our board of directors since October 2010. Since 1999, Dr. Afeyan has served as the Managing Partner and Chief Executive Officer of Flagship Ventures, an early-stage venture capital firm that he co-founded. Dr. Afeyan is serving or has served

on the board of directors of several public and private companies, including BG Medicine, Inc., BIND Therapeutics, Inc., Eleven Biotherapeutics, Inc., Helicos Biosciences, Moderna Therapeutics, Inc. and Pronutria Biosciences, Inc. Dr. Afeyan received a B.S. from McGill University and a Ph.D. in Biochemical Engineering from the Massachusetts Institute of Technology. We believe Dr. Afeyan is qualified to serve on our board of directors because of his extensive investment experience and his knowledge of the biotechnology industry.

Dennis A. Ausiello, M.D., has served as a member of our board of directors since April 2015. Dr. Ausiello serves as the Director of the Center for Assessment Technology and Continuous Health (CATCH), Jackson Distinguished Professor of Clinical Medicine at Harvard Medical School and Physician-in-Chief Emeritus at Massachusetts General Hospital. From 1996 to April 2013, Dr. Ausiello served as the Chief of Medicine at Massachusetts General Hospital. Dr. Ausiello is a member of the Institute of Medicine of the National Academy of Sciences and a fellow of the American Academy of Arts and Sciences. Dr. Ausiello has also served on the board of directors of Pfizer Inc. since December 2006 and Alnylam Pharmaceuticals since April 2012, each a pharmaceutical company. Dr. Ausiello received his undergraduate degree from Harvard College and an M.D. from the University of Pennsylvania. We believe that Dr. Ausiello is qualified to serve on our board of directors because of his extensive experience as a physician and as a director of pharmaceutical companies.

Grégory Behar has served as a member of our board of directors since December 2014. Mr. Behar has served as Chief Executive Officer of Nestlé Health Science S.A., a health sciences company, since October 2014. From July 2011 to July 2014, Mr. Behar was President and Chief Executive Officer of Boehringer Ingelheim Pharmaceuticals Inc. (USA), a pharmaceutical company. From 2010 to July 2011, Mr. Behar was Corporate Vice President Region NECAR (North European Union, Canada and Australasia) for Boehringer-Ingelheim GmbH, a pharmaceutical company. Mr. Behar received his B.S. from the University of California, Los Angeles, a M.S. in Mechanical Engineering and Manufacturing from EPFL in Switzerland and an MBA from INSEAD in France. We believe that Mr. Behar is qualified to serve on our board of directors because of his extensive business experience in the health sciences and pharmaceutical industries.

Werner Cautreels, Ph.D., has served as a member of our board of directors since March 2013. Dr. Cautreels has served as President and Chief Executive Officer of Selecta Biosciences, a biotechnology company, since June 2010. From May 1998 to June 2010, Dr. Cautreels worked for Solvay Pharmaceuticals, the pharmaceutical division of the Solvay Group, which was acquired by Abbot Laboratories. Since 2009, Dr. Cautreels has served on the board of directors of Galapagos NV, a biotechnology company. Dr. Cautreels received a B.S. and M.S. and a doctorate in Chemistry from the University of Antwerp and an eMBA from Harvard Business School. We believe Dr. Cautreels is qualified to serve on our board of directors because of his extensive experience in the biotechnology industry.

Peter Barton Hutt has served as a member of our board of directors since May 2013. Mr. Hutt is senior counsel at Covington & Burling LLP, specializing in food and drug law. Mr. Hutt has served as a member of the board of directors of Q Therapeutics, Inc. since 2002, Xoma Corporation since 2005, Concert Pharmaceuticals since 2006, BIND Therapeutics, Inc. since 2008 DBV Technologies since 2009 and Flex Pharma, Inc. since 2014. Mr. Hutt previously served on the board of directors of Momenta Pharmaceuticals, Inc., Celera Corporation, which was acquired by Quest Diagnostics in 2011, and ISTA Pharmaceuticals, which was acquired by Bausch & Lomb in 2012. Mr. Hutt received a B.A. from Yale University, an LL.B. from Harvard Law School and an LL.M. from the New York University School of Law. We believe that Mr. Hutt is qualified to serve on our board of directors because of his experience serving as a director of biotechnology companies and his legal and regulatory knowledge.

Richard N. Kender has served as a member of our board of directors since October 2014. From October 1978 to September 2013, Mr. Kender held positions in a variety of corporate areas at Merck,

most recently serving as Senior Vice President of Business Development and Corporate Licensing. Mr. Kender serves on the board of directors of INC Research Holdings, Inc., a contract research organization. Mr. Kender received a B.S. from Villanova University and an MBA from Fairleigh Dickinson University. We believe Mr. Kender is qualified to serve on our board of directors because of his extensive business experience and his knowledge of the pharmaceutical industry.

Lorence H. Kim, M.D., has served as a member of our board of directors since October 2014. Since April 2014, Dr. Kim has been the Chief Financial Officer of Moderna Therapeutics, a biotechnology company. From July 2000 to April 2014, Dr. Kim held a number of positions at Goldman, Sachs & Co., an investment bank, most recently as Managing Director and Co-Head of Biotechnology Investment Banking. Dr. Kim received an A.B. from Harvard University, an MBA in Healthcare Management from the Wharton School of the University of Pennsylvania and an M.D. from the University of Pennsylvania's School of Medicine. We believe Dr. Kim is qualified to serve on our board of directors because of his investment experience and knowledge of the biotechnology industry.

Board Composition and Election of Directors

Director Independence

Our board of directors currently consists of eight members. Our board of directors has determined that, of our eight directors, Drs. Noubar B. Afeyan, Dennis A. Ausiello, Werner Cautreels and Lorence H. Kim and Messrs. Grégory Behar, Peter Barton Hutt and Richard N. Kender do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of The NASDAQ Stock Market LLC, or NASDAQ. There are no family relationships among any of our directors or executive officers.

Classified Board of Directors

In accordance with our restated certificate of incorporation and amended and restated bylaws that will go into effect upon the closing of this offering, our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Effective upon the closing of this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be Dennis A. Ausiello, Werner Cautreels and Roger J. Pomerantz, and their terms will expire at our first annual meeting of stockholders following this offering;
- the Class II directors will be Peter Barton Hutt, Richard N. Kender and Lorence H. Kim, and their terms will expire at our second annual meeting of stockholders following this offering; and
- the Class III directors will be Noubar B. Afeyan and Grégory Behar, and their terms will expire at the third annual meeting of stockholders following this offering.

Our restated certificate of incorporation that will go into effect upon the closing of this offering will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control of our company. Our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of our outstanding voting stock entitled to vote in the election of directors.

In selecting board members, our board may consider many factors, such as personal and professional integrity, ethics and values; experience in corporate management, such as serving as an officer or former officer of a publicly held company; experience as a board member or executive officer of another publicly held company; diversity of expertise and experience in substantive matters pertaining to our business relative to other board members; and diversity of background and perspective, including, but not limited to, with respect to age, gender, race, place of residence and specialized experience.

Board Leadership Structure

Our board of directors is currently chaired by our President and Chief Executive Officer, Dr. Roger J. Pomerantz. Our corporate governance guidelines provide that, if the chairman of the board is a member of management or does not otherwise qualify as independent, the independent directors of the board may elect a lead director. Dr. Noubar B. Afeyan currently serves as our lead director. The lead director's responsibilities include, but are not limited to: presiding over all meetings of the board of directors at which the chairman is not present, including any executive sessions of the independent directors; approving board meeting schedules and agendas; and acting as the liaison between the independent directors and the chief executive officer and chairman of the board. Our corporate governance guidelines further provide the flexibility for our board of directors to modify our leadership structure in the future as it deems appropriate.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. Our audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed through committee reports about such risks.

Board Committees

Our board of directors has established three standing committees—audit, compensation and nominating and corporate governance—each of which operates under a charter that has been approved by our board of directors. Upon the closing of this offering, each committee's charter will be available under the Corporate Governance section of our website at *www.serestherapeutics.com*. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

Audit Committee

The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- discussing our risk management policies;
- establishing policies regarding hiring employees from the registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our internal auditing staff, if any, registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by Securities Exchange Commission, or SEC, rules.

The members of our audit committee are Werner Cautreels, Richard N. Kender and Lorence H. Kim. Mr. Kender serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and NASDAQ. Our board of directors has determined that Mr. Kender and Mr. Cautreels meet the independence requirements of Rule 10A-3 under the Exchange Act and the applicable listing standards of NASDAQ. Since our board of directors has determined that Dr. Kim does not meet the requirements of Rule 10A-3 under the Exchange Act, we are relying on the independence phase-in rules for newly listed companies and plan to add a third independent director to the audit committee within one year of listing. Our board of directors has determined that Mr. Kender is an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable NASDAQ rules and regulations.

Compensation Committee

The compensation committee's responsibilities include:

- annually reviewing and approving corporate goals and objectives relevant to CEO compensation;
- determining our CEO's compensation;
- reviewing and approving, or making recommendations to our board with respect to, the compensation of our other executive officers;
- overseeing an evaluation of our senior executives;
- overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to our board of directors with respect to director compensation;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis"; and
- preparing the annual compensation committee report required by SEC rules.

The members of our compensation committee are Noubar B. Afeyan, Peter Barton Hutt and Richard N. Kender. Dr. Afeyan serves as the chairperson of the committee. Our board of directors has determined that each of Dr. Afeyan and Messrs. Hutt and Kender is independent under the applicable NASDAQ rules and regulations, is a “non-employee director” as defined in Rule 16b-3 promulgated under the Securities Exchange Act and is an “outside director” as that term is defined in Section 162(m) of the Internal Revenue Code of 1986, as amended.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee’s responsibilities include:

- identifying individuals qualified to become board members;
- recommending to our board of directors the persons to be nominated for election as directors and to each board committee;
- reviewing and making recommendations to our board of directors with respect to management succession planning;
- developing and recommending to our board of directors corporate governance principles; and
- overseeing an annual evaluation of our board of directors.

The members of our nominating and corporate governance committee are Dennis A. Ausiello, Peter Barton Hutt and Lorence H. Kim. Mr. Hutt serves as the chairperson of the committee. Our board of directors has determined that Mr. Hutt and Drs. Ausiello and Kim are independent under the applicable NASDAQ rules and regulations.

Compensation Committee Interlocks and Insider Participation

No member of our compensation committee is or has been our current or former officer or employee. None of our executive officers served as a director or a member of a compensation committee (or other committee serving an equivalent function) of any other entity, one of whose executive officers served as a director or member of our compensation committee during the fiscal year ended December 31, 2014.

Code of Ethics and Code of Conduct

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Upon the closing of this offering, our code of business conduct and ethics will be available under the Corporate Governance section of our website at *www.serestherapeutics.com*. In addition, we intend to post on our website all disclosures that are required by law or the listing standards of NASDAQ concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

EXECUTIVE AND DIRECTOR COMPENSATION

Executive Compensation

This section discusses the material components of the executive compensation program offered to our named executive officers, or NEOs, identified below. For 2014, our NEOs were:

- Roger J. Pomerantz, M.D., President and Chief Executive Officer;
- David A. Berry, M.D., Ph.D., former Interim President and Chief Executive Officer;
- Eric D. Shaff, Chief Financial Officer and Executive Vice President; and
- David N. Cook, Ph.D., Chief Scientific Officer and Executive Vice President of Research & Development.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the closing of this offering may differ materially from the currently planned programs summarized in this discussion.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and have elected to comply with the reduced compensation disclosure requirements available to emerging growth companies under the JOBS Act.

2014 Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)[4]	Option Awards ($)[5]	All Other Compensation ($)	Total ($)
Roger J. Pomerantz, M.D.[1] *President and Chief Executive Officer*	2014	247,917	233,750	6,567,603	69,393[6]	7,118,663
David A. Berry, M.D., Ph.D.[2]	2014	136,500	—	—	—	136,500
Former Interim President and Chief Executive Officer	2013	125,667	—	—	—	125,667
Eric D. Shaff[3] *Chief Financial Officer and Executive Vice President*	2014	35,192	12,205	1,413,756	—	1,461,153
David N. Cook, Ph.D.	2014	300,000	99,000	—	—	399,000
Chief Scientific Officer and Executive Vice President of Research & Development	2013	300,000	—	113,119	21,201	434,320

(1) We hired Dr. Pomerantz as our President and Chief Executive Officer effective June 1, 2014. Dr. Pomerantz's 2014 annual base salary was $425,000. Dr. Pomerantz also serves as Chairman of our board of directors but receives no additional compensation for this service.
(2) Dr. Berry served as our Interim President and Chief Executive Officer from March 29, 2013 through May 30, 2014. Dr. Berry is a Partner at Flagship Ventures and also served as a member of our board of directors during 2014. Dr. Berry received no compensation from us for his service as our Interim President and Chief Executive Officer or as a member of our board of directors during 2014. However, we paid Flagship Ventures Management, Inc., an affiliate of Flagship Ventures, a total of $136,500 for services provided to us by Dr. Berry during 2014. For a further discussion of the services agreement, refer to "Certain Relationships and Related Person Transactions—Services Agreement".
(3) We hired Mr. Shaff as our Chief Financial Officer and Executive Vice President effective November 19, 2014. Mr. Shaff's 2014 annual base salary was $300,000.
(4) Represents amounts paid under our annual cash bonus program. For additional information regarding these amounts, refer to "—Narrative Disclosure to Summary Compensation Table —Annual Cash Bonuses."
(5) Represents the aggregate grant date fair value of the option awards computed in accordance with FASB ASC Topic 718. For a description of the assumptions used in valuing these awards, see Note 10 to our audited consolidated financial statements included elsewhere in this prospectus.
(6) Represents reimbursement of travel and lodging costs associated with working in the Cambridge, Massachusetts area.

Narrative Disclosure to Summary Compensation Table

The primary elements of compensation for our NEOs are base salary, annual cash bonuses and long-term, equity-based compensation awards. The NEOs also participate in employee benefit plans and programs that we offer to our other full-time employees on the same basis.

Base Salary

Our NEOs receive base salary to compensate them for the satisfactory performance of duties to our company. The base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Dr. Pomerantz's and Mr. Shaff's 2014 annual base salaries were determined as a result of negotiations with the NEO in connection with his commencing employment. Dr. Cook did not receive a base salary increase during 2014. Our board of directors approved, effective February 1, 2015, an increase in Dr. Pomerantz's base salary to $439,875 and Mr. Cook's base salary to $310,500.

Annual Cash Bonuses

Our NEOs have the opportunity to earn annual performance bonuses based on the achievement of short-term performance goals. Each of Dr. Pomerantz and Mr. Shaff are entitled to receive an annual bonus with a target amount equal to 50% and 30%, respectively, of his annual base salary, except that Mr. Shaff's 2014 annual bonus was prorated to reflect his partial year of service.

In determining 2014 annual bonuses for our NEOs our board of directors considered our achievement of business development and financing milestones, completion of capital raising transactions and successful executive recruitment and hiring during 2014 and the individual NEO's contributions to these successes. The actual amounts that our board of directors elected to pay our NEOs under our annual cash bonus program are set forth in the "Bonus" column of the Summary Compensation Table above.

Equity-Based Compensation

We generally offer stock options to our employees, including our NEOs, as the long-term incentive component of our compensation program. We typically grant options to employees when they commence employment with us and may thereafter grant additional options in the discretion of our board of directors or its compensation committee. Our stock options allow employees to purchase shares of our common stock at a price equal to the fair market value of our common stock on the date of grant, as determined by our board of directors, and may be intended to qualify as "incentive stock options" under the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code.

Our stock options typically vest as to 25% of the shares subject to the option on the first anniversary of the grant date (or service commencement date for initial grants) and as to 6.25% of the shares subject to the option every third month during the three-year period thereafter, subject to the holder's continued service with us. From time to time, our board of directors may also construct alternate vesting schedules as it determines are appropriate to motivate particular employees. Stock options granted to our employees may be subject to accelerated vesting in certain circumstances, as described in the section titled "Employment Agreements."

In connection with Dr. Pomerantz's hire as our President and Chief Executive Officer, in August 2014, we granted him an option to purchase 1,675,751 shares of our common stock at an exercise price per share of $0.71, which our board of directors determined to be the fair market value of our common stock on the date of grant. The option is subject to our standard vesting terms described above. In connection with Mr. Shaff's hire as our Chief Financial Officer and Executive Vice

President, in December 2014, we granted him an option to purchase 262,692 shares of our common stock at an exercise price per share of $7.79, which our board of directors determined to be the fair market value of our common stock on the date of grant. The option is subject to our standard vesting terms described above. Dr. Cook did not receive an equity award grant during 2014.

In connection with this offering, we intend to adopt a new incentive plan to facilitate the grant of cash and equity incentives to our directors, employees and consultants and to enable our company to obtain and retain the services of these individuals. Additional information about our new incentive plan is provided in the section titled "Incentive Plans—2015 Incentive Award Plan" below.

In addition, effective upon the effectiveness of the registration statement of which this prospectus is a part, we granted Mr. Shaff an option to purchase 100,000 shares of our common stock and Dr. Cook an option to purchase 90,000 shares of our common stock, each at an exercise price per share equal to the initial public offering price of our common stock in this offering. These options will vest as to 25% of the underlying shares on the first anniversary of the grant date and as to 6.25% of the underlying shares on the last day of each calendar quarter during the three-year period thereafter, subject to the holder's continued service with us and potential accelerated vesting as described in the section titled "Employment Agreements."

Retirement, Health, Welfare and Additional Benefits

Our NEOs are eligible to participate in our employee benefit plans and programs, including medical and dental benefits and life insurance, to the same extent as our other full-time employees, subject to the terms and eligibility requirements of those plans. We also sponsor a 401(k) defined contribution plan in which our NEOs may participate, subject to limits imposed by the Internal Revenue Code, to the same extent as all of our other full-time employees. We do not currently, nor did we during 2014, match contributions made by participants in the 401(k) plan or make other contributions to participant accounts. We do not typically provide any perquisites or special personal benefits to our NEOs, but have from time to time reimbursed commuting and relocation expenses for our NEOs.

Outstanding Equity Awards at 2014 Fiscal Year-End

	Option Awards				
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable[1]	Option Exercise Price ($)	Option Expiration Date
Roger J. Pomerantz, M.D.	6/1/2014	—	1,675,751	0.71	8/6/2024
	9/9/2013	82,500	137,500	0.48	11/5/2023
David A. Berry, M.D., Ph.D.	—	—	—	—	—
Eric D. Shaff	11/17/2014	—	262,692	7.79	12/8/2024
David N. Cook, Ph.D.	10/24/2012	184,218	143,282	0.48	5/16/2023

(1) All options vest as to 25% of the total shares subject to the option on the first anniversary of the vesting commencement date, and as to 6.25% of the shares subject to the option on the last day of each calendar quarter during the three-year period thereafter, subject to the holder's continued employment with us through the applicable vesting date and potential accelerated vesting as described in the section titled "Employment Agreements."

Employment Agreements

We have entered into employment agreements with each of our NEOs that will become effective on the closing of this offering. Certain key terms of these agreements are described below.

Roger J. Pomerantz, M.D.

The employment agreement with Dr. Pomerantz entitles him to an initial annual base salary of $464,100, subject to periodic review and adjustment by our board of directors, and an annual target bonus opportunity of 50% of his annual base salary.

In the event Dr. Pomerantz's employment is terminated by us without cause or he resigns for good reason, subject to his timely executing a release of claims in our favor, he is entitled to receive 12 months of continued base salary and up to 12 months of continued medical, dental or vision coverage pursuant to COBRA, if elected. If the termination occurs within 60 days prior to or 12 months following a change in control, Dr. Pomerantz is also entitled to accelerated vesting of his time-based equity awards.

Dr. Pomerantz has agreed to refrain from disclosing our confidential information during or at any time following his employment with us and from competing with us or soliciting our employees or consultants for 12 months following termination of his employment.

For purposes of the employment agreement:

- "Cause" generally means Dr. Pomerantz's (i) failure to substantially perform his duties with us (other than due to disability) or materially comply with our policies; (ii) material failure to carry out or comply with any lawful and reasonable directive of our board of directors; (iii) breach of a material provision of his employment agreement; (iv) conviction, plea of no contest or imposition of unadjudicated probation for any felony or crime involving moral turpitude; (v) unlawful use (including being under the influence) or possession of illegal drugs on our (or our affiliate's) premises or while performing his duties and responsibilities under his employment agreement or (vi) commission of an act of fraud, embezzlement, misappropriation, willful misconduct or breach of fiduciary duty against us or any of our affiliates.
- "Good reason" generally means, subject to certain notice requirements and cure rights, without Dr. Pomerantz's consent, (i) a reduction in his base salary (except for a reduction of less than 10% contemporaneously affecting other senior executives); (ii) a material reduction in his authority or areas of responsibility or (iii) a relocation his primary office more than 50 miles outside of the Boston metropolitan area.

Eric D. Shaff and David N. Cook, Ph.D.

The employment agreements with Mr. Shaff and Dr. Cook entitle them to initial annual base salaries of $324,500 and $355,900, respectively, subject to periodic review and adjustment by our board of directors, and annual target bonus opportunities of 35% of their annual base salaries.

In the event either of Mr. Shaff or Dr. Cook is terminated by us without cause or he resigns for good reason, subject to his timely executing a release of claims in our favor, he is entitled to receive six months of continued base salary and up to six months of continued medical, dental or vision coverage pursuant to COBRA, if elected. If either of Mr. Shaff's or Dr. Cook's termination occurs within 60 days prior to or 12 months following a change in control, he is also entitled to accelerated vesting of his time-based equity awards.

Each of Mr. Shaff and Dr. Cook has agreed to refrain from disclosing our confidential information during or at any time following his employment with us and from competing with us or soliciting our employees or consultants for 12 months following termination of his employment.

For purposes of the employment agreements, “cause” and “good reason” have the same meanings as in Dr. Pomerantz’s employment agreement.

Incentive Plans

2015 Incentive Award Plan

In June 2015, our board of directors adopted and our stockholders approved the 2015 Incentive Award Plan, or the 2015 Plan, effective the day prior to the public trading date of our common stock, under which we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which we compete. The material terms of the 2015 Plan are summarized below.

Eligibility and Administration

Our employees, consultants and directors, and employees, consultants and directors of our subsidiaries, will be eligible to receive awards under the 2015 Plan. Following our initial public offering, the 2015 Plan will generally be administered by our board of directors with respect to awards to non-employee directors and by our compensation committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to certain limitations that may be imposed under the 2015 Plan, Section 16 of the Securities Exchange Act and/or stock exchange rules, as applicable. The plan administrator will have the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2015 Plan, subject to its express terms and conditions. The plan administrator will also set the terms and conditions of all awards under the 2015 Plan, including any vesting and vesting acceleration conditions.

Limitation on Awards and Shares Available

An aggregate of 2,200,000 shares of our common stock will initially be available for issuance under awards granted pursuant to the 2015 Plan. The number of shares initially available for issuance will be increased by (i) the number of shares represented by awards outstanding under our 2012 Plan (defined below) that are forfeited, lapse unexercised or are settled in cash and (ii) an annual increase on January 1 of each calendar year beginning in 2016 and ending in 2025, equal to the lesser of (a) 4% of the shares of common stock outstanding on the final day of the immediately preceding calendar year and (b) such smaller number of shares as determined by our board of directors. No more than 17,200,000 shares of common stock may be issued upon the exercise of incentive stock options. Shares issued under the 2015 Plan may be authorized but unissued shares, or shares purchased in the open market or treasury shares.

If an award under the 2015 Plan is forfeited, expires or is settled for cash, any shares subject to such award may, to the extent of such forfeiture, expiration or cash settlement, be used again for new grants under the 2015 Plan. Awards granted under the 2015 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by an entity with which we enter into a merger or similar corporate transaction will not reduce the shares available for grant under the 2015 Plan.

Awards

The 2015 Plan provides for the grant of stock options, including incentive stock options, or ISOs, and nonqualified stock options, or NSOs, restricted stock, dividend equivalents, stock payments, restricted stock units, or RSUs, stock appreciation rights, or SARs, and other stock- or cash-based awards. Certain awards under the 2015 Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Internal Revenue Code, which may impose additional requirements on the terms and conditions of such awards. All awards under the 2015 Plan will be set forth in award agreements, which will detail the terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. Awards other than cash awards generally will be settled in shares of our common stock, but the plan administrator may provide for cash settlement of any award. A brief description of each award type follows.

- *Stock Options*. Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Internal Revenue Code are satisfied. The exercise price of a stock option generally will not be less than 100% of the fair market value of the underlying share on the date of grant (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders). Vesting conditions determined by the plan administrator may apply to stock options and may include continued service, performance and/or other conditions.
- *SARs.* SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a SAR will generally not be less than 100% of the fair market value of the underlying share on the date of grant (except with respect to certain substitute SARs granted in connection with a corporate transaction), and the term of a SAR may not be longer than ten years. Vesting conditions determined by the plan administrator may apply to SARs and may include continued service, performance and/or other conditions.
- *Restricted Stock and RSUs*. Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met, and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on shares of our common stock prior to the delivery of the underlying shares. Delivery of the shares underlying RSUs may be deferred under the terms of the award or at the election of the participant, if the plan administrator permits such a deferral. Conditions applicable to restricted stock and RSUs may be based on continuing service, the attainment of performance goals and/or such other conditions as the plan administrator may determine.
- *Other Stock- or Cash-Based Awards.* Other stock- or cash-based awards are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock. Other stock- or cash-based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of base salary, bonus, fees or other cash compensation otherwise payable to any individual who is eligible to receive awards. The plan administrator will determine the terms and conditions of other stock- or cash-based awards, which may include vesting conditions based on continued service, performance and/or other conditions.

Performance Awards

Performance awards include any of the foregoing awards that are granted subject to vesting and/or payment based on the attainment of specified performance goals or other criteria the plan administrator may determine, which may or may not be objectively determinable. Performance criteria upon which performance goals are established by the plan administrator may include but are not limited to: (i) net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization and non-cash equity-based compensation expense); (ii) gross or net sales or revenue or sales or revenue growth; (iii) net income (either before or after taxes) or adjusted net income; (iv) profits (including, but not limited to, gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; (v) budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); (vi) cash flow (including operating cash flow and free cash flow or cash flow return on capital); (vii) return on assets; (viii) return on capital or invested capital; (ix) cost of capital; (x) return on stockholders' equity; (xi) total stockholder return; (xii) return on sales; (xiii) costs, reductions in costs and cost control measures; (xiv) expenses; (xv) working capital; (xvi) earnings or loss per share; (xvii) adjusted earnings or loss per share; (xviii) price per share or dividends per share (or appreciation in or maintenance of such price or dividends); (xix) regulatory achievements or compliance; (xx) implementation, completion or attainment of objectives relating to research, development, regulatory, commercial or strategic milestones or developments; (xxi) market share; (xxii) economic value or economic value added models; (xxiii) division, group or corporate financial goals; (xxiv) customer satisfaction/growth; (xxv) customer service; (xxvi) employee satisfaction; (xxvii) recruitment and maintenance of personnel; (xxviii) human resources management; (xxix) supervision of litigation and other legal matters; (xxx) strategic partnerships and transactions; (xxxi) financial ratios (including those measuring liquidity, activity, profitability or leverage); (xxxii) debt levels or reductions; (xxxiii) sales-related goals; (xxxiv) financing and other capital raising transactions; (xxxv) cash on hand; (xxxvi) acquisition activity; (xxxvii) investment sourcing activity; and (xxxviii) marketing initiatives.

Certain Transactions

In connection with certain transactions and events affecting our common stock, including a change in control, or change in any applicable laws or accounting principles, the plan administrator has broad discretion to take action under the 2015 Plan to prevent the dilution or enlargement of intended benefits, facilitate such transaction or event, or give effect to such change in applicable laws or accounting principles. This includes canceling awards, accelerating the vesting of awards, providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares available and replacing or terminating awards under the 2015 Plan. In addition, in the event of certain non-reciprocal transactions with our stockholders, or an "equity restructuring," the plan administrator will make equitable adjustments to the 2015 Plan and outstanding awards as it deems appropriate to reflect the equity restructuring.

Provisions of the 2015 Plan Relating to Director Compensation

The 2015 Plan provides that the plan administrator may establish compensation for non-employee directors from time to time subject to the 2015 Plan's limitations. Prior to commencing this offering, our stockholders approved the initial terms of our non-employee director compensation program, which is described below under the heading "—Director Compensation." Our board of directors or its authorized committee may modify the non-employee director compensation program from time to time in the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, provided that the sum of any cash compensation or other compensation and the grant date fair value of any equity awards granted as compensation for services as a non-employee director during any fiscal year may not

exceed $700,000. The plan administrator may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the plan administrator may determine in its discretion, provided that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation or in other compensation decisions involving non-employee directors.

Foreign Participants, Claw-Back Provisions, Transferability and Participant Payments

With respect to foreign participants, the plan administrator may modify award terms, establish subplans and/or adjust other terms and conditions of awards, subject to the share limits described above. All awards will be subject to the provisions of any claw-back policy implemented by our company to the extent set forth in such claw-back policy or in the applicable award agreement. With limited exceptions for estate planning, domestic relations orders, certain beneficiary designations and the laws of descent and distribution, awards under the 2015 Plan are generally non-transferable prior to vesting, and are exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2015 Plan, and exercise price obligations arising in connection with the exercise of stock options under the 2015 Plan, the plan administrator may, in its discretion, accept cash, wire transfer or check, shares of our common stock that meet specified conditions, a promissory note, a “market sell order”, such other consideration as it deems suitable or any combination of the foregoing.

Plan Amendment and Termination

Our board of directors may amend or terminate the 2015 Plan at any time; however, except in connection with certain changes in our capital structure, stockholder approval will be required for any amendment that increases the number of shares available under the 2015 Plan. The plan administrator will have the authority, without the approval of our stockholders, to amend any outstanding stock option or SAR to reduce its price per share. No award may be granted pursuant to the 2015 Plan after the tenth anniversary of the date on which our board of directors adopts the 2015 Plan.

2015 Employee Stock Purchase Plan

In June 2015, our board of directors adopted and our stockholders approved the 2015 Employee Stock Purchase Plan, or the ESPP, effective the day prior to the public trading date of our common stock. The material terms of the ESPP are summarized below.

Shares Available; Administration

A total of 365,000 shares of our common stock are initially reserved for issuance under our ESPP. In addition, the number of shares available for issuance under the ESPP will be annually increased on January 1 of each calendar year beginning in 2016 and ending in 2025, by an amount equal to the least of: (a) 400,000 shares, (b) 1% of the shares outstanding on the final day of the immediately preceding calendar year and (c) such smaller number of shares as is determined by our board of directors.

Our board of directors or its committee will have authority to interpret the terms of the ESPP and determine eligibility of participants. We expect that the compensation committee will be the initial administrator of the ESPP.

Eligibility

Our employees are eligible to participate in the ESPP if they are customarily employed by us or a participating subsidiary for more than 20 hours per week and more than five months in any calendar

year. However, an employee may not be granted rights to purchase stock under our ESPP if such employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our common or other class of stock.

Grant of Rights

The ESPP is intended to qualify under Section 423 of the Internal Revenue Code and stock will be offered under the ESPP during offering periods. The length of the offering periods under the ESPP will be determined by the plan administrator and may be up to 27 months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The purchase dates for each offering period will be the final trading day in each offering period. Offering periods under the ESPP will commence when determined by the plan administrator. The plan administrator may, in its discretion, modify the terms of future offering periods.

The ESPP permits participants to purchase common stock through payroll deductions of up to 25% of their eligible compensation, which includes a participant's gross base compensation for services to us, including overtime payments and excluding sales commissions, incentive compensation, bonuses, expense reimbursements, fringe benefits and other special payments. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period, which, in the absence of a contrary designation, will be 25,000 shares. In addition, no employee will be permitted to accrue the right to purchase stock under the ESPP at a rate in excess of $25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant will automatically be granted an option to purchase shares of our common stock. The option will expire at the end of the applicable offering period, and will be exercised at that time to the extent of the payroll deductions accumulated during the offering period. The purchase price of the shares, in the absence of a contrary designation, will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the purchase date, which will be the final trading day of the offering period. Participants may voluntarily end their participation in the ESPP at any time at least one week prior to the end of the applicable offering period, and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon a participant's termination of employment.

A participant may not transfer rights granted under the ESPP other than by will, the laws of descent and distribution or as otherwise provided under the ESPP.

Certain Transactions

In the event of certain transactions or events affecting our common stock, such as any stock dividend or other distribution, change in control, reorganization, merger, consolidation or other corporate transaction, the plan administrator will make equitable adjustments to the ESPP and outstanding rights. In addition, in the event of the foregoing transactions or events or certain significant transactions, including a change in control, the plan administrator may provide for (1) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (2) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, if any, (3) the adjustment in the number and type of shares of stock subject to outstanding rights, (4) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods or (5) the termination of all outstanding rights.

Plan Amendment

The plan administrator may amend, suspend or terminate the ESPP at any time. However, stockholder approval of any amendment to the ESPP will be obtained for any amendment which increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the ESPP, changes the corporations or classes of corporations whose employees are eligible to participate in the ESPP or changes the ESPP in any manner that would cause the ESPP to no longer be an employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code.

2012 Stock Incentive Plan

Our board of directors and stockholders have approved the 2012 Stock Incentive Plan, or the 2012 Plan, under which we may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards to employees, directors and consultants of our company. We have reserved a total of 4,309,653 shares of our common stock for issuance under the 2012 Plan.

Following the effectiveness of the 2015 Plan, we will not make any further grants under the 2012 Plan. However, the 2012 Plan will continue to govern the terms and conditions of the outstanding awards granted under it. As discussed above, shares of our common stock subject to outstanding awards granted under the 2012 Plan that are forfeited, lapse unexercised or are settled in cash and which following the effective date of the 2015 Plan are not issued under the 2012 Plan will be available for issuance under the 2015 Plan.

Administration

Our board of directors administers the 2012 Plan and has the authority to: (i) grant awards; (ii) adopt, amend and repeal administrative rules, guidelines and practices relating to the 2012 Plan; (iii) construe and interpret the 2012 Plan and any award agreements thereunder; and (iv) correct any defect, supply any omission or reconcile any inconsistency in the 2012 Plan or any award. The board of directors may delegate its authority under the 2012 Plan to one or more committees or subcommittees.

Types of Awards; Eligibility

The 2012 Plan provides for the grant of stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards to employees, officers, directors and consultants of our company and its qualifying parents and subsidiaries. As of the date of this prospectus, only awards of ISOs and NSOs are outstanding under the 2012 Plan.

Certain Transactions

If certain changes are made in, or events occur with respect to, our common stock, the 2012 Plan and outstanding awards will be appropriately adjusted in the class, number and, as applicable, exercise price of securities as determined by the board of directors. In the event of certain corporate transactions of our company, including a merger, consolidation, sale of our common stock, or our liquidation or dissolution, our board of directors may take the following actions as to options outstanding under the 2012 Plan: (i) provide that such awards will be assumed or substantially equivalent awards substituted, (ii) upon written notice to participants, provide that unexercised awards will terminate unless exercised, (iii) provide that outstanding awards will become exercisable, (iv) if the transaction involves cash payments in exchange for the sale of our common stock, terminate awards

for a cash payment equal to the excess of the transaction price of the underlying shares over the exercise price of the applicable award, (v) provide that, in connection with our liquidation or dissolution, awards will convert into a right to receive liquidation proceeds and (vi) any combination of the foregoing.

Amendment and Termination

The board of directors may amend outstanding awards under the 2012 Plan, including by reducing the exercise price per share of the award, without participant consent and may amend, suspend or terminate the 2012 Plan; provided in each case, that any amendment, suspension or termination does not materially or adversely affect the rights of participants holding outstanding awards under the 2012 Plan. Any modification or amendment that requires stockholder approval under applicable law or, with respect to ISOs, Section 422 of the Internal Revenue Code may not be effected without approval by the company's stockholders.

Director Compensation

We have not historically provided annual cash retainers or other compensation to our directors but have, from time to time, granted equity awards to certain directors as compensation for their service on our board of directors. In 2014, we granted each of Dr. Kim and Mr. Kender an option to purchase 75,000 shares of our common stock for their service on our board of directors. Their options have an exercise price per share of $3.14 and are subject to our standard vesting terms described in "Narrative Disclosure to Summary Compensation Table—Equity-Based Compensation" above. None of our other directors received compensation for serving on our board of directors during 2014.

Drs. Berry and Pomerantz each served as directors and executive officers of our company during 2014. Refer to the Summary Compensation Table and related narrative disclosure above for information regarding the compensation they received from us during 2014.

Effective upon the effectiveness of the registration statement of which this prospectus is a part, our board of directors granted Dr. Dennis Ausiello, who was elected to serve as a member of our board of directors in April 2015, an option to purchase 75,000 shares of our common stock at an exercise price per share equal to the initial public offering price of our common stock in this offering. These options will vest as to 25% of the underlying shares on April 17, 2016 and as to 6.25% of the underlying shares on the last day of each calendar quarter during the three-year period thereafter, subject to his continued service with us and accelerated vesting immediately prior to a change in control.

In addition, effective upon the effectiveness of the registration statement of which this prospectus is a part, our board of directors granted each of Drs. Afeyan, Cautreels and Kim, and Messrs. Behar, Hutt and Kender, an option to purchase 15,000 shares of our common stock at an exercise price per share equal to the initial public offering price of our common stock in this offering. These options will vest in a single installment on the earlier of the day before the next annual meeting of stockholders or the first anniversary of the grant date, subject to the director continuing to serve on our board of directors through that date and accelerated vesting immediately prior to a change in control.

2014 Director Compensation Table

Name	Option Awards ($)[1]	Total ($)
Noubar B. Afeyan, Ph.D.	—	—
Werner Cautreels, Ph.D.	—	—
Peter Barton Hutt	—	—
Lorence H. Kim, M.D.	407,302	407,302
Richard N. Kender	407,302	407,302
Grégory Behar	—	—

(1) Represents the aggregate grant date fair value of the option awards granted during 2014 computed in accordance with FASB ASC Topic 718. For a description of the assumptions used in valuing these awards, see Note 10 to our audited consolidated financial statements included elsewhere in this prospectus. The following table shows the number of option awards and unvested stock awards held as of December 31, 2014 by each of our directors who are not NEOs:

Name	Stock Options (#)	Restricted Shares (#)
Noubar B. Afeyan, Ph.D.	—	—
Werner Cautreels, Ph.D.	100,000	—
Peter Barton Hutt	50,000	6,250
Lorence H. Kim, M.D.	75,000	—
Richard N. Kender	75,000	—
Grégory Behar	—	—

In June 2015, our board of directors adopted and our stockholders approved a compensation program for our non-employee directors, effective upon the effectiveness of the registration statement of which this prospectus is a part, under which each non-employee director will receive the following amounts for their services on our board of directors:

- an option to purchase 30,000 shares of our common stock upon the director's initial election or appointment to our board of directors that occurs after our initial public offering;
- if the director has served on our board of directors for at least six months as of the date of an annual meeting of stockholders, an option to purchase 15,000 shares of our common stock on the date of the annual meeting;
- an annual director fee of $35,000, or if the director serves as chairman of our board of directors or lead director, an annual director fee of $20,000; and
- if the director serves on a committee of our board of directors, an additional annual fee as follows:
  - chairman of the audit committee—$15,000;
  - audit committee member other than the chairman—$7,500;
  - chairman of the compensation committee—$10,000;
  - compensation committee member other than the chairman—$5,000;
  - chairman of the nominating and corporate governance committee—$7,000; and
  - nominating and corporate governance committee member other than the chairman—$3,500.

Stock options granted to our non-employee directors under the program will have an exercise price equal to the fair market value of our common stock on the date of grant and will expire not later than ten years after the date of grant. The stock options granted upon a director's initial election or appointment will vest in four annual installments following the date of grant. The stock options granted annually to directors will vest in a single installment on the earlier of the day before the next annual meeting of stockholders or the first anniversary of the date of grant. In addition, all unvested stock options will vest in full upon the occurrence of a change in control.

Director fees under the program will be payable in arrears in four equal quarterly installments not later than the 15th day following the final day of each fiscal quarter, provided that the amount of each payment will be prorated for any portion of a quarter that a director is not serving on our board of directors and no fee will be payable in respect of any period prior to the effective date of the registration statement of which this prospectus is a part.

Each member of our board of directors is entitled to be reimbursed for reasonable travel and other expenses incurred in connection with attending meetings of the board of directors and any committee of the board of directors on which he or she serves.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following includes a summary of transactions since January 1, 2012 to which we have been a party in which the amount involved exceeded or will exceed $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and Director Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

Preferred Stock Financings

Series A Preferred Stock Financing. In June 2012, we issued and sold to entities affiliated with Flagship Ventures in private placements an aggregate of 6,329,114 shares of our Series A preferred stock at a purchase price of $0.79 per share, for aggregate consideration of approximately $5.0 million, and issued 1,901,883 shares of our Series A preferred stock upon the conversion of convertible debt and accrued interest totaling $1.5 million.

Series A-2 Preferred Stock Financing. In November 2012, we issued and sold to investors in a private placement an aggregate of 2,247,192 shares of our Series A-2 preferred stock at a purchase price of $1.78 per share, for aggregate consideration of approximately $4.0 million.

Series B Preferred Stock Financing. In May 2014, we issued and sold to investors in private placements an aggregate of 4,831,359 shares of our Series B preferred stock at a purchase price of $2.20 per share, for aggregate consideration of approximately $10.6 million.

The following table sets forth the aggregate number of these securities acquired by our directors, executive officers and the listed holders of more than 5% of our capital stock. Each share of our preferred stock identified in the following table will convert into one share of common stock in connection with this offering.

Participants[1]	Series A	Series A-2	Series B
5% or Greater Stockholders			
Entities affiliated with Flagship Ventures Funds[2]	8,230,997	1,123,596	2,272,727
Enso Ventures 2 Limited	—	1,123,596	681,818
Directors and Executive Officers			
Roger J. Pomerantz, M.D.	—	—	22,727
John Aunins, Ph.D.	—	—	34,090
David N. Cook, Ph.D.	—	—	45,454

(1) Additional details regarding these stockholders and their equity holdings are provided under the caption "Principal Stockholders."
(2) Flagship Ventures Funds consists of Flagship VentureLabs IV LLC, Flagship Ventures Fund IV, L.P., Flagship Ventures Fund IV-Rx, L.P. and Flagship Ventures Fund 2007 L.P.

The following directors are associated with our principal stockholders as indicated in the table below:

Director	Principal Stockholder
Noubar B. Afeyan, Ph.D.	Flagship Ventures Funds
David A. Berry, M.D., Ph.D[1].	Flagship Ventures Funds
Roger J. Pomerantz, M.D.	Flagship Ventures Funds

(1) Dr. Berry served on our board of directors from March 2012 to May 2015.

Services Agreement

In October 2010, we entered into a services agreement with Flagship Ventures Management, Inc., or Flagship Management, an affiliate of Flagship Ventures, under which Flagship Management provides us with personnel, advisory and administrative services on an as-needed basis. From October 19, 2010 to May 31, 2015, we paid Flagship Management an aggregate of $1.8 million for services provided under the services agreement, inclusive of the services provided by Dr. Berry, who served on our board of directors from March 2012 to May 2015 and as our Interim President and Chief Executive Officer from March 29, 2013 through May 30, 2014.

Standstill Agreement

In December 2014, in connection with the sale to Nestlé Health Science US Holdings, Inc., or Nestlé, of shares of our Series D preferred stock, Nestlé agreed that it would not increase its ownership of our securities or acquire our assets without the prior consent of our board of directors. Nestlé also agreed not to participate in any tender or exchange offer for our securities; any merger or other business combination involving us; any recapitalization, restructuring, liquidation, dissolution, or other extraordinary transaction involving us; or take action to seek representation on our board of directors or otherwise influence our management. Except for confidential discussions with our board of directors, Nestlé is also prohibited from entering into any discussions or arrangements with third parties regarding these restrictions. The restrictions under the standstill agreement terminate upon the earlier of December 19, 2019 or the third anniversary of the consummation of this offering. As long as no senior executive from Nestlé is serving on our board of directors at the time, these standstill provisions also terminate upon a public announcement by us of the initiation of a sale process or of an offer from, or public attempt by, a third party to acquire all or a substantial portion of our securities or assets.

Investors' Rights Agreement

We entered into an amended and restated investors' rights agreement in December 2014 with the holders of our preferred stock, including entities with which certain of our directors are affiliated. This agreement provides for certain rights relating to the registration of such preferred stockholders' shares of common stock and common stock issuable upon conversion of their preferred stock and a right of first refusal to purchase future securities sold by us. See "Description of Capital Stock — Registration Rights" for additional information.

Voting Agreement

We entered into an amended and restated voting agreement in December 2014, which was further amended in April 2015, by and among us and certain of our stockholders, pursuant to which the following directors were elected to serve as members on our board of directors and, as of the date of this prospectus, continue to so serve: Noubar B. Afeyan, Dennis A. Ausiello, Grégory Behar, Werner Cautreels, Peter Barton Hutt, Richard N. Kender, Lorence H. Kim and Roger J. Pomerantz. Pursuant to the voting agreement, Dr. Afeyan was initially selected to serve on our board of directors as the representative of holders of our preferred stock, as designated by Flagship Ventures Fund IV, L.P., Flagship Ventures Fund IV-Rx, L.P. and Flagship Ventures Fund 2007, L.P. Mr. Behar was initially selected to serve on our board of directors by Nestlé Health Science US Holdings, Inc. Dr. Pomerantz was initially selected to serve on our board of directors in his capacity as our Chief Executive Officer, and his employment agreement provides that he will serve as a director so long as he serves as our Chief Executive Officer. Drs. Ausiello, Cautreels and Kim and Messrs. Hutt and Kender were initially selected to serve on our board of directors as independent directors, as designated by the holders of preferred stock.

The voting agreement will terminate upon the closing of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by the holders of our common stock. The composition of our board of directors after this offering is described in more detail under “Management—Board Composition and Election of Directors.”

Employment Agreements

We have entered into employment agreements with our named executive officers. For more information regarding the agreements with our named executive officers, see “Executive and Director Compensation — Employment Agreements.”

Indemnification Agreements

We intend to enter into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses, such as attorneys’ fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person’s services as a director or executive officer.

Stock Option Grants to Executive Officers and Directors

We have granted stock options to our executive officers and certain of our directors as more fully described in the section titled “Executive and Director Compensation.”

Participation in this Offering

Nestlé Health Science US Holdings, Inc., or Nestlé, an existing stockholder affiliated with one of our directors, has indicated an interest to purchase $24.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, Nestlé may determine to increase or reduce the amount of its indication of interest, or otherwise elect not to purchase any shares. It is also possible that the number of shares allocated in this offering to Nestlé may be greater or smaller than the amount of its indication of interest, or no shares may be allocated to Nestlé.

Policies and Procedures for Related Person Transactions

Our board of directors has adopted a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were, are, or will be a participant, where the amount involved exceeds $120,000 in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm’s length transaction and the extent of the related person’s interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock, as of May 31, 2015, and as adjusted to reflect the sale of shares of common stock in this offering, by:

- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The number of shares beneficially owned by each stockholder is determined under rules issued by the Securities and Exchange Commission. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. Applicable percentage ownership is based on 30,403,502 shares of common stock outstanding as of May 31, 2015, assuming the conversion of all of our preferred stock into common stock in connection with this offering. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of May 31, 2015 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless noted otherwise, the address of all listed stockholders is 215 First Street, Cambridge, Massachusetts 02142. Each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Nestlé Health Science US Holdings, Inc., or Nestlé, an existing stockholder affiliated with one of our directors, has indicated an interest to purchase $24.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, Nestlé may determine to increase or reduce the amount of its indication of interest, or otherwise elect not to purchase any shares. It is also possible that the number of shares allocated in this offering to Nestlé may be greater or smaller than the amount of its indication of interest, or no shares may be allocated to Nestlé. The following table does not reflect any potential purchase by Nestlé, which purchase, if any, will increase the percentage of shares owned after this offering by Nestlé from that set forth in the table below. If Nestlé purchases $24.0 million in shares of our common stock at the initial public offering price of $18.00 per share, it will beneficially own 18.2% of the shares of our common stock after this offering.

Name of Beneficial Owner	Number of Shares Beneficially Owned Prior to Offering	Percentage of Shares Beneficially Owned	
		Prior to Offering	After Offering
5% or Greater Stockholders			
Entities affiliated with Flagship Ventures Funds(1)	16,627,320	54.7%	43.9%
Nestlé Health Science US Holdings, Inc.(2)	5,555,555	18.3%	14.7%
Entities affiliated with Fidelity Management & Research Company(3)	2,466,457	8.1%	6.5%
Enso Ventures 2 Limited	1,805,414	5.9%	4.8%
Named Executive Officers and Directors			
Roger J. Pomerantz, M.D.(4)	656,399	2.1%	1.7%
Noubar B. Afeyan, Ph.D.(1)	16,627,320	54.7%	43.9%
Dennis A. Ausiello, M.D.	—	—	—
Grégory Behar	—	—	—
Werner Cautreels, Ph.D.(5)	62,500	*	*
Peter Barton Hutt(6)	78,125	*	*
Richard N. Kender	—	—	—
Lorence H. Kim, M.D.	—	—	—
David N. Cook, Ph.D.(7)	270,610	*	*
Eric D. Shaff	—	—	—
All executive officers and directors as a group (12 persons)(8)	17,916,544	57.5%	46.4%

* Less than 1%.

(1) Consists of (a) 3,055,556 shares of common stock held by Flagship VentureLabs IV LLC (“Flagship VentureLabs”), (b) 1,944,444 shares of common stock held by Nestlé Health Science US Holdings, Inc. for which Flagship VentureLabs exercises voting control under certain circumstances, which voting control terminates upon the closing of the company’s initial public offering, (c) 8,822,420 shares of common stock held by Flagship Ventures Fund IV, L.P. (“Flagship Fund IV”), (d) 2,205,603 shares of common stock held by Flagship Ventures Fund IV-Rx, L.P. (“Flagship Fund IV-Rx”) and (e) 599,297 shares of common stock held by Flagship Ventures Fund 2007, L.P. (“Flagship Fund 2007” and together with Flagship VentureLabs, Flagship Fund IV and Flagship Fund IV-Rx, the “Flagship Funds”). Flagship Fund IV is a member of Flagship VentureLabs and also serves as its manager. The general partner of each of Flagship Fund IV and Flagship Fund IV-Rx is Flagship Ventures Fund IV General Partner LLC (“Flagship Fund IV GP”), and the general partner of Flagship Fund 2007 is Flagship Ventures 2007 General Partner LLC (“Flagship Fund 2007 GP” and together with Flagship Fund IV GP, the “Flagship General Partners”). Noubar Afeyan is a director of Seres Therapeutics and a member of the Flagship General Partners. In addition, Dr. Afeyan serves as a managing member of the Flagship General Partners and may be deemed to possess voting and investment control over the shares held by the Flagship Funds. Neither of the Flagship General Partners directly own any of the shares held by the Flagship Funds, and each of the Flagship General Partners and Dr. Afeyan disclaims beneficial ownership of such shares except to the extent of its or his pecuniary interest therein. The mailing address of the Flagship Funds is One Memorial Drive, 7th Floor, Cambridge, MA 02142.

(2) Nestlé Health Science US Holdings, Inc. is a wholly owned, indirect subsidiary of Nestlé S.A., a publicly traded company. The address for Nestlé Health Science US Holdings, Inc. is c/o Nestlé USA, Inc. 383 Main Ave, 5th Floor, Norwalk, CT 06851.

(3) Consists of (a) 1,292,035 shares of common stock held by Fidelity Select Portfolios: Biotechnology Fund, (b) 352,270 shares of common stock held by Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund, (c) 107,186 shares of common stock held by Fidelity Growth Company Comingled Pool, (d) 142,139 shares of common stock held by Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund and (e) 572,827 shares of common stock held by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund. These accounts are managed by direct or indirect subsidiaries of FMR LLC. Edward C. Johnson 3d is a Director and the Chairman of FMR LLC and Abigail P. Johnson is a Director, the Vice Chairman and the President of FMR LLC. Members of the family of Edward C. Johnson 3d, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B stockholders have entered into a stockholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Edward C. Johnson 3d nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act ("Fidelity Funds") advised by Fidelity Management & Research Company ("FMR Co"), a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. FMR Co carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees.

(4) Includes 633,672 shares of common stock which Dr. Pomerantz has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of May 31, 2015.

(5) Consists of 62,500 shares of common stock which Dr. Cautreels has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of May 31, 2015.

(6) Includes 28,125 shares of common stock which Mr. Hutt has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of May 31, 2015.

(7) Includes 40,937 shares of common stock which Dr. Cook has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of May 31, 2015.

(8) Consists of (a) 16,929,720 shares of common stock and (b) 765,234 shares of common stock which the holders have the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of May 31, 2015.

DESCRIPTION OF CAPITAL STOCK

General

The following description summarizes some of the terms of our restated certificate of incorporation and restated bylaws that will become effective upon the closing of this offering, our outstanding warrants, our amended and restated investors' rights agreement and of the General Corporation Law of the State of Delaware. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description, you should refer to our restated certificate of incorporation, restated bylaws, warrants and amended and restated investors' rights agreement, copies of which have been or will be filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the General Corporation Law of the State of Delaware. The description of our common stock and preferred stock reflects changes to our capital structure that will occur in connection with this offering.

Following the closing of this offering, our authorized capital stock will consist of 200,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share.

As of May 31, 2015, we had issued and outstanding:

- 7,536,515 shares of our common stock held of record by 23 stockholders;
- 8,230,997 shares of our Series A preferred stock that are convertible into 8,230,997 shares of our common stock as of such date;
- 2,247,192 shares of our Series A-2 preferred stock that are convertible into 2,247,192 shares of our common stock as of such date;
- 4,831,359 shares of our Series B preferred stock that are convertible into 4,831,359 shares of our common stock as of such date;
- 3,946,328 shares of our Series C preferred stock that are convertible into 3,946,328 shares of our common stock as of such date; and
- 3,611,111 shares of our Series D preferred stock that are convertible into 3,611,111 shares of our common stock as of such date.

In connection with this offering, all of the outstanding shares of our preferred stock will automatically convert into an aggregate of 22,866,987 shares of our common stock.

Common Stock

As of May 31, 2015, 30,403,502 shares of our common stock were held of record by 50 stockholders, assuming the conversion of all of our outstanding shares of preferred stock into shares of our common stock.

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our restated certificate of incorporation and restated bylaws also provide that our directors may be removed only for cause and

only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our restated certificate of incorporation. See below under "—Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws—Amendment of Restated Certificate of Incorporation." Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are, and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of our restated certificate of incorporation that will become effective upon the closing of this offering, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Options

As of May 31, 2015, options to purchase 3,977,746 shares of our common stock were outstanding under our 2012 Stock Incentive Plan.

Warrants

On June 6, 2014, we issued two warrants to the Mayo Foundation for Medical Education and Research, or the Mayo Foundation, in connection with our research and option agreement with the Mayo Foundation. In each case, the warrant, unless earlier exercised or terminated, terminates upon the closing of this offering. The first warrant provided the Mayo Foundation a right to purchase 454,545 shares of our common stock at a purchase price of $0.01 per share. On April 29, 2015, the Mayo Foundation exercised the first warrant and was issued 454,545 shares of our common stock. The second warrant is contingent upon the accomplishment of certain milestones. As of the date of this prospectus, the Mayo Foundation had not accomplished any of the milestones, and, therefore, there were no shares of our common stock exercisable pursuant to this warrant.

In connection with our loan and security agreement, we issued a warrant to Comerica Bank, or the Comerica Warrant, that is exercisable for 92,127 shares of Series A-2 preferred stock at an exercise price per share of $1.78. On May 16, 2014, Comerica Bank transferred this warrant to Comerica Ventures Incorporated. Upon the conversion of the Series A-2 preferred stock into common stock in connection with this offering, the warrant will become exercisable for 92,127 shares of common stock at an exercise price per share of $1.78. If unexercised, the warrant will expire on September 9, 2023.

Registration Rights

Upon the closing of this offering, holders of 22,959,114 shares of our common stock as of May 31, 2015, including shares issuable upon the exercise of the Comerica Warrant, or their transferees will be entitled to the following rights with respect to the registration of such shares for public resale under the Securities Act, pursuant to the amended and restated investors' rights agreement by and among us and certain of our stockholders, or the investors' rights agreement, until such shares can otherwise be sold without restriction under Rule 144, or until the rights otherwise terminate pursuant to the terms of the investors' rights agreement. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Demand Registration Rights

If at any time beginning 180 days after the effective date of the registration statement of which this prospectus is a part the holders of a majority of the registrable securities request in writing that we effect a registration with respect to all or part of their registrable securities, we may be required to register all or part of the registrable securities then outstanding. We are obligated to effect at most two registrations in response to these demand registration rights. If the holders requesting registration intend to distribute their shares by means of an underwriting, the managing underwriter of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

Piggyback Registration Rights

If at any time after this offering we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

Form S-3 Registration Rights

If the holders of at least 30% of the registrable securities then outstanding request in writing that we effect a registration with respect to registrable securities at an aggregate price to the public in the offering of at least $5,000,000, and we are entitled under the Securities Act to register our shares on a registration statement on Form S-3, we will be required to effect such registration. We will not be required to effect a registration pursuant to these Form S-3 registration rights if, within a given six-month period, we have already effected two registrations on Form S-3 for the holders of registrable securities.

Expenses

Ordinarily, other than underwriting discounts and commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements of a counsel for the selling security holders and blue sky fees and expenses.

Termination of Registration Rights

The registration rights terminate upon the earlier of five years after the closing of this offering, or, with respect to the registration rights of an individual holder, when the holder can sell all of such holder's registrable securities in a three-month period without restriction under Rule 144 under the Securities Act.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our restated certificate of incorporation and our restated bylaws could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interest, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to effect a change in control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

Our restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board, chief executive officer or president (in the absence of a chief executive officer), or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

Staggered Board

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see “Management—Board Composition and Election of Directors.” This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

Our restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits persons deemed to be “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this law may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our restated certificate of incorporation or restated bylaws; (4) any action to interpret, apply, enforce or determine

the validity of our restated certificate of incorporation or restated bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine. Our restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

Amendment of Restated Certificate of Incorporation

The amendment of any of the above provisions in our restated certificate of incorporation, except for the provision making it possible for our board of directors to issue preferred stock and the provision prohibiting cumulative voting, would require approval by holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote thereon.

The provisions of Delaware law, our restated certificate of incorporation and our restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interest.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be American Stock Transfer & Trust Company, LLC.

National Securities Exchange Listing

Our common stock has been approved for listing on The NASDAQ Global Select Market under the symbol “MCRB.”

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock.

Upon the closing of this offering, we will have outstanding an aggregate of 37,834,057 shares of common stock, based on our shares outstanding as of May 31, 2015 and including the issuance of 7,430,555 shares of common stock offered by us in this offering and the automatic conversion of all outstanding shares of our preferred stock into 22,866,987 shares of our common stock. Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining 30,403,502 shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. All of these shares are subject to the 180-day lock-up period under the lock-up agreements described below. Upon expiration of the lock-up period, all 30,403,502 shares will be available for sale in the public market, subject in some cases to applicable volume limitations under Rule 144.

In addition, of the 3,977,746 shares of our common stock that were subject to stock options outstanding as of May 31, 2015, options to purchase 516,388 shares of common stock were vested as of May 31, 2015 and, upon exercise, these shares will be eligible for sale subject to the lock-up agreements described below and Rules 144 and 701 promulgated under the Securities Act.

Lock-Up Agreements

We and each of our directors and executive officers and holders of substantially all of our outstanding capital stock, have agreed that, without the prior written consent of Goldman, Sachs & Co. and BofA Merrill Lynch, on behalf of the underwriters, we and they will not, subject to limited exceptions described below, during the period ending 180 days after the date of this prospectus:

- offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, or publicly disclose an intention to take any such actions with respect to, any shares of our common stock, or any options or warrants to purchase any shares of our common stock, or any securities convertible into, exchangeable for or that represent the right to receive shares of our common stock, whether now owned or hereinafter acquired, owned directly or indirectly; or
- request, make any demand for or exercise any right with respect to, the registration of any of our common stock or any security convertible into or exercisable or exchangeable for our common stock,

whether any transaction described above is to be settled by delivery of our common stock or such other securities, in cash or otherwise.

In the case of our officers, directors and stockholders, these lock-up restrictions are subject to certain exceptions, including transfers (i) made as bona fide gifts; (ii) to any immediate family member or a trust or other legal entity; (iii) by will or intestacy; (iv) to us upon the vesting or exercise of an option, other award granted under our stock incentive plans or stock purchase plan or the conversion

or exercise of warrants, in each case due to the net exercise of such option, award or warrant and/or to cover withholding tax obligations; (v) pursuant to our 2012 Stock Incentive Plan, to family members through gifts or domestic relations orders or to an executor or guardian upon death or disability; (vi) acquired in open market transactions; (vii) as part of a distribution, transfer or disposition without consideration to a holder's limited or general partners; (vii) due to repurchases by us in connection with the termination of employment or other service relationship or the failure to meet certain conditions; (ix) in connection with the conversion of any convertible security into, or the exercise of any option or warrant for, our common stock in connection with the consummation of this offering; (x) pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction involving a change of control; and (xii) in connection with the establishment of a trading plan pursuant to Rule 10b5-1 under the Securities Exchange Act.

In our case, these lock-up restrictions are subject to certain exceptions, including (i) the shares to be sold in this offering, (ii) grants of awards pursuant to equity incentive plans existing as of the date of this offering, (iii) the issuance of any shares of our common stock upon the exercise of options or equity-based awards granted under our equity incentive plans existing as of the date of this offering, (iv) the issuance of securities pursuant to employee stock purchase plans existing as of the date of this offering, (v) the issuance of securities upon the conversion or exchange of convertible or exchangeable securities or the vesting of restricted stock outstanding as of the date of this offering, (vi) the filing of any registration statement on Form S-8 relating to any benefit plans or arrangements disclosed in this prospectus and the issuance of securities registered pursuant thereto and (vii) the issuance of stock or securities convertible into or exercisable for shares of common stock in connection with any acquisition, collaboration, licensing or other joint venture or strategic transaction or any debt financing transaction involving us and an unaffiliated third party that includes a bona fide commercial relationship; provided that the issuance is not, in the aggregate, greater than 5% of our total outstanding shares of common stock immediately following the completion of this offering. In the case of issuances as described in (ii), (iii) and (vii) above, each recipient in the issuance must execute and deliver a lock-up agreement in connection with the securities received and we must enter stop transfer instructions with our transfer agent and registrar regarding the securities received.

Upon the expiration of the applicable lock-up periods, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 378,340 shares immediately after this offering; or
- the average weekly trading volume in our common stock on The NASDAQ Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the

seller must file a notice on Form 144 with the Securities and Exchange Commission and with the broker or the execution directly with a market maker. concurrently with either the placing of a sale order

Non-Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The Securities and Exchange Commission has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Securities Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Securities Exchange Act.

Equity Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our stock plans. We expect to file the registration statement covering shares offered pursuant to our stock plans shortly after the date of this prospectus, permitting the resale of such shares by nonaffiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144 and expiration of or release from the lock-up agreements described above.

Registration Rights

Upon the closing of this offering, the holders of 22,959,114 shares of common stock, which includes all of the shares of common stock issuable upon the automatic conversion of our preferred stock in connection with this offering and shares issuable upon the exercise of the Comerica Warrant, or their transferees will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration statement, except for shares purchased by affiliates. See "Description of Capital Stock—Registration Rights" for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax consequences. The consequences of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or IRS, in effect as of the date of this offering. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a non-U.S. holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to non-U.S. holders that hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a non-U.S. holder’s particular circumstances, including the impact of the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to non-U.S. holders subject to particular rules, including, without limitation:

- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies and other financial institutions;
- real estate investment trusts or regulated investment companies;
- brokers, dealers or traders in securities or currencies;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- S corporations, partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes, or investors in any such entities;
- tax-exempt or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons for whom our stock constitutes “qualified small business stock” within the meaning of Section 1202 of the Code; and
- tax-qualified retirement plans.

If a partnership (or other entity treated as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT INTENDED AS LEGAL OR TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER OTHER U.S. FEDERAL TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a "non-U.S. holder"

For purposes of this discussion, a "non-U.S. holder" is any beneficial owner of our common stock that is neither a "U.S. person," a partnership, or an entity disregarded as separate from its owner, each for U.S. federal income tax purposes. A U.S. person is any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code), or (2) has made a valid election under applicable Treasury Regulations to continue to be treated as a U.S. person.

Distributions

As described in the section titled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions on our common stock, such distributions of cash or property on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a non-U.S. holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "Sale or Other Taxable Disposition."

Subject to the discussion below on effectively connected income, dividends paid to a non-U.S. holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the non-U.S. holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A non-U.S. holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a non-U.S. holder are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such dividends are attributable), the non-U.S. holder will be exempt from the U.S. federal withholding tax

described above. To claim the exemption, the non-U.S. holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A non-U.S. holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

Subject to the discussions below on backup withholding and foreign accounts, a non-U.S. holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such gain is attributable);
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or a "USRPHC", for U.S. federal income tax purposes.

Gain described in the first bullet point above will generally be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates. A non-U.S. holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) of such effectively connected gain, as adjusted for certain items.

A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on any gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder (even though the individual is not considered a resident of the United States) provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we are not currently and do not anticipate becoming a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our other business assets and our non-U.S. real property interests, however, there can be no assurance we are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a non-U.S. holder of our common stock will not be subject to U.S. federal income tax if such class of stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such non-U.S. holder owned, actually or constructively, 5% or less of such class of our stock throughout the shorter of the five-year period ending on the date of the sale or other disposition or the non-U.S. holder's holding period for such stock; if the foregoing exception does not apply, then if we are or were to become a USRPHC a purchaser may be required to withhold 10% of the proceeds payable to a non-U.S. holder from a sale of our common stock and such non-U.S. holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code).

Non-U.S. holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding provided the applicable withholding agent does not have actual knowledge or reason to know such holder is a U.S. person and the holder either certifies its non-U.S. status, such as by providing a valid IRS Form W-8BEN, W-8BEN-E, or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the non-U.S. holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a U.S. person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of these information returns that are filed with the IRS may also be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the non-U.S. holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under the Foreign Account Tax Compliance Act, or FATCA, on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

The withholding provisions described above will generally apply to payments of dividends on our common stock and will apply to payments of gross proceeds from the sale or other disposition of such stock on or after January 1, 2017. Because we may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of these withholding rules we may treat the entire distribution as a dividend. Prospective investors should consult their tax advisors regarding the potential application of these withholding provisions.

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman, Sachs & Co. and Merrill Lynch, Pierce, Fenner & Smith Incorporated are the representatives of the underwriters.

Underwriters	Number of Shares
Goldman, Sachs & Co.	2,972,223
Merrill Lynch, Pierce, Fenner & Smith Incorporated	2,600,694
Leerink Partners LLC	1,263,194
Canaccord Genuity Inc.	594,444
Total	7,430,555

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional 1,114,583 shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid by us to the underwriters. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase 1,114,583 additional shares.

Paid by the Company	No Exercise	Full Exercise
Per Share	$ 1.26	$ 1.26
Total	$ 9,362,499	$ 10,766,874

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $0.756 per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We and our officers, directors and holders of substantially all of our outstanding capital stock have agreed with the underwriters, subject to certain exceptions, that we and they will not dispose of or hedge any of our or their capital stock or securities convertible into or exchangeable for shares of common stock during the period ending 180 days after the date of this prospectus, except with the prior written consent of the representatives. For more information, see "Shares Eligible for Future Sale—Lock Up Agreements."

Prior to the offering, there has been no public market for our shares. The initial public offering price will be negotiated among us and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

Our common stock has been approved for listing on The NASDAQ Global Select Market under the symbol “MCRB.”

In connection with the offering, the underwriters may purchase and sell shares of common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A “covered short position” is a short position that is not greater than the amount of additional shares for which the underwriters’ option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. “Naked” short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of the company’s stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on The NASDAQ Global Select Market, in the over-the-counter market or otherwise.

The underwriters do not expect sales to discretionary accounts to exceed five percent of the total number of shares offered.

We estimate that total expenses of this offering payable by us, excluding underwriting discounts and commissions, will be approximately $3.2 million. We have agreed to reimburse the underwriters for expenses relating to clearance of this offering with the Financial Industry Regulatory Authority (in an amount not to exceed $30,000).

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with the issuer. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

Selling Restrictions

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, or a Relevant Member State, each underwriter has represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, or the Relevant Implementation Date, it has not made and will not make an offer of shares to the public in that Relevant Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of shares to the public in that Relevant Member State at any time:

(a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

(b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;

(c) to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of the representatives for any such offer; or

(d) in any other circumstances which do not require the publication by the Issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer of shares to the public” in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

Each underwriter has represented and agreed that:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act, or FSMA) received by it in connection with the issue or sale of the shares in circumstances in which Section 21(1) of the FSMA does not apply to the Issuer; and

(b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

Hong Kong

The shares may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), or (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 by a relevant person which is: (a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired the shares under Section 275 except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; or (3) by operation of law.

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan, or the Financial Instruments and Exchange Law, and each underwriter has agreed that it will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Latham & Watkins LLP. Certain legal matters will be passed upon for the underwriters by Ropes & Gray LLP.

EXPERTS

The financial statements as of December 31, 2014 and 2013 and for each of the three years in the period ended December 31, 2014 included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. Upon the closing of this offering, we will be required to file periodic reports, proxy statements, and other information with the Securities and Exchange Commission pursuant to the Securities Exchange Act of 1934. You may read and copy this information at the Public Reference Room of the Securities and Exchange Commission, 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the public reference rooms by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission also maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the Securities and Exchange Commission. The address of that site is *www.sec.gov*.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Seres Therapeutics, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, of convertible preferred stock and stockholders' deficit and of cash flows present fairly, in all material respects, the financial position of Seres Therapeutics, Inc., formerly known as Seres Health, Inc., and its subsidiary at December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
April 8, 2015

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

	December 31, 2013	December 31, 2014	March 31, 2015 (unaudited)	Pro Forma March 31, 2015 (unaudited)
Assets				
Current assets:				
Cash and cash equivalents	$ 1,654	$114,185	$ 45,045	$ 45,045
Investments	—	—	59,271	59,271
Prepaid expenses and other current assets	51	58	768	768
Total current assets	1,705	114,243	105,084	105,084
Property and equipment, net	352	1,264	1,313	1,313
Restricted cash	37	139	139	139
Deferred offering costs	—	1,684	2,079	2,079
Deferred financing costs	31	15	13	13
Total assets	$ 2,125	$117,345	$108,628	$108,628
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)				
Current liabilities:				
Accounts payable	$ 393	$ 2,166	$ 1,109	$ 1,109
Accrued expenses and other current liabilities	263	1,737	1,126	1,126
Notes payable, current portion	400	1,200	1,200	1,200
Total current liabilities	1,056	5,103	3,435	3,435
Notes payable, net of discount	438	1,304	1,016	1,016
Preferred stock warrant liability	164	1,582	1,369	—
Total liabilities	1,658	7,989	5,820	4,451
Commitments and contingencies (Note 12)				
Convertible preferred stock (Series A, A-2, B, C, D and D-1), $0.001 par value; 11,806,272 shares authorized at December 31, 2013 and 24,348,003 shares authorized at December 31, 2014 and March 31, 2015 (unaudited); 10,478,189 shares issued and outstanding at December 31, 2013 and 22,866,987 shares issued and outstanding at December 31, 2014 and March 31, 2015 (unaudited); aggregate liquidation preference of $137,283 and $139,992 at December 31, 2014 and March 31, 2015 (unaudited), respectively; no shares issued or outstanding pro forma at March 31, 2015 (unaudited)	11,583	136,077	136,053	—
Stockholders' equity (deficit):				
Common stock, $0.001 par value; 24,500,000 shares authorized at December 31, 2013 and 38,000,000 shares authorized at December 31, 2014 and March 31, 2015 (unaudited); 6,855,000, 6,890,250 and 7,081,970 shares issued and outstanding at December 31, 2013 and 2014 and March 31, 2015 (unaudited), respectively; 29,948,957 shares issued and outstanding, pro forma at March 31, 2015 (unaudited)	7	7	7	30
Additional paid-in capital	—	1,104	2,520	139,919
Accumulated other comprehensive income	—	—	31	31
Accumulated deficit	(11,123)	(27,832)	(35,803)	(35,803)
Total stockholders' equity (deficit)	(11,116)	(26,721)	(33,245)	104,177
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 2,125	$117,345	$108,628	$108,628

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

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

	Year Ended December 31,			Three Months Ended March 31,	
	2012	2013	2014	2014	2015
				(unaudited)	
Revenue	$ —	$ —	$ —	$ —	$ —
Operating expenses:					
Research and development expenses	2,077	4,805	10,718	1,032	5,561
General and administrative expenses	956	1,247	4,364	640	2,606
Total operating expenses	3,033	6,052	15,082	1,672	8,167
Loss from operations	(3,033)	(6,052)	(15,082)	(1,672)	(8,167)
Other income (expense):					
Interest income (expense), net	(93)	(42)	(209)	(37)	(17)
Revaluation of preferred stock warrant liability	—	(8)	(1,418)	20	213
Total other income (expense), net	(93)	(50)	(1,627)	(17)	196
Net loss	(3,126)	(6,102)	(16,709)	(1,689)	(7,971)
Accretion of convertible preferred stock to redemption value	(276)	(875)	(1,291)	(233)	—
Net loss attributable to common stockholders	$ (3,402)	$ (6,977)	$ (18,000)	$ (1,922)	$ (7,971)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.59)	$ (1.09)	$ (2.67)	$ (0.29)	$ (1.15)
Weighted average common shares outstanding, basic and diluted	5,725,120	6,394,916	6,748,037	6,686,389	6,912,725
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)			$ (0.74)		$ (0.27)
Pro forma weighted average common shares outstanding, basic and diluted (unaudited)			20,683,511		29,779,712
Other comprehensive income:					
Unrealized gain on investments, net of tax of $0	—	—	—	—	31
Total other comprehensive income	—	—	—	—	31
Comprehensive loss	$ (3,126)	$ (6,102)	$ (16,709)	$ (1,689)	$ (7,940)

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

SERES THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share data)

	Series A, A-2, B, C, D and D-1 Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Deficit
	Shares	Amount	Shares	Par Value				
Balance at December 31, 2011	—	$ —	2,400,000	$ 2	$ —	$ (981)	$ —	$ (979)
Issuance of common stock	—	—	3,000,000	3	—	—	—	3
Issuance of Series A convertible preferred stock, net of issuance costs of $70	6,329,114	4,930	—	—	—	—	—	—
Conversion of promissory notes and accrued interest into Series A convertible preferred stock	1,901,883	1,502	—	—	—	—	—	—
Issuance of Series A-2 convertible preferred stock	2,247,192	4,000	—	—	—	—	—	—
Issuance of restricted common stock	—	—	2,440,000	2	—	—	—	2
Repurchase of unvested restricted common stock	—	—	(250,000)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	28	—	—	28
Accretion of convertible preferred stock to redemption value	—	276	—	—	(28)	(248)	—	(276)
Net loss	—	—	—	—	—	(3,126)	—	(3,126)
Balance at December 31, 2012	10,478,189	10,708	7,590,000	7	—	(4,355)	—	(4,348)
Repurchase of unvested restricted common stock	—	—	(735,000)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	209	—	—	209
Accretion of convertible preferred stock to redemption value	—	875	—	—	(209)	(666)	—	(875)
Net loss	—	—	—	—	—	(6,102)	—	(6,102)
Balance at December 31, 2013	10,478,189	11,583	6,855,000	7	—	(11,123)	—	(11,116)
Issuance of Series B convertible preferred stock, net of issuance costs of $71	4,831,359	10,558	—	—	—	—	—	—
Issuance of Series C convertible preferred stock, net of issuance costs of $187	3,946,328	47,813	—	—	—	—	—	—
Issuance of Series D and D-1 convertible preferred stock, net of issuance costs of $168	3,611,111	64,832	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	28,687	—	5	—	—	5
Issuance of common stock	—	—	6,563	—	5	—	—	5
Issuance of common stock warrant	—	—	—	—	317	—	—	317
Stock-based compensation expense	—	—	—	—	2,068	—	—	2,068
Accretion of convertible preferred stock to redemption value	—	1,291	—	—	(1,291)	—	—	(1,291)
Net loss	—	—	—	—	—	(16,709)	—	(16,709)
Balance at December 31, 2014	22,866,987	136,077	6,890,250	7	1,104	(27,832)	—	(26,721)
Series D convertible preferred stock issuance costs	—	(24)	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	191,720	—	89	—	—	89
Stock-based compensation expense	—	—	—	—	1,327	—	—	1,327
Unrealized gain on investments	—	—	—	—	—	—	31	31
Net loss	—	—	—	—	—	(7,971)	—	(7,971)
Balance at March 31, 2015 (unaudited)	22,866,987	$ 136,053	7,081,970	$ 7	$ 2,520	$ (35,803)	$ 31	$ (33,245)

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

SERES THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,			Three Months Ended March 31,	
	2012	2013	2014	2014	2015
				(unaudited)	
Cash flows from operating activities:					
Net loss	$(3,126)	$(6,102)	$ (16,709)	$(1,689)	$ (7,971)
Adjustments to reconcile net loss to net cash used in operating activities:					
Stock-based compensation expense	28	209	2,068	45	1,327
Depreciation and amortization expense	25	88	190	30	92
(Gain) loss from revaluation of preferred stock warrant liability	—	8	1,418	(20)	(213)
Licensing fees paid in common stock warrant	—	—	317	—	—
Non-cash interest expense	—	19	81	16	30
Changes in operating assets and liabilities:					
Prepaid expenses and other current assets	(29)	(21)	(7)	30	(710)
Accounts payable	103	281	810	99	(189)
Accrued expenses and other current liabilities	74	197	1,474	66	(706)
Net cash used in operating activities	(2,925)	(5,321)	(10,358)	(1,423)	(8,340)
Cash flows from investing activities:					
Purchases of property and equipment	(292)	(174)	(1,001)	(80)	(214)
Purchases of investments	—	—	—	—	(59,255)
Changes in restricted cash	(27)	(10)	(102)	—	—
Net cash used in investing activities	(319)	(184)	(1,103)	(80)	(59,469)
Cash flows from financing activities:					
Proceeds from issuance of convertible preferred stock, net of issuance costs	8,930	—	123,203	—	(24)
Proceeds from issuance of promissory notes	500	—	—	—	—
Proceeds from issuance of notes payable and preferred stock warrant, net of issuance costs	—	944	2,000	500	—
Proceeds from exercise of stock options	—	—	5	—	89
Proceeds from issuance of common stock and restricted common stock	5	—	5	—	—
Repayment of notes payable	—	—	(400)	—	(300)
Payments of initial public offering costs	—	—	(821)	—	(1,096)
Net cash provided by (used in) financing activities	9,435	944	123,992	500	(1,331)
Net increase (decrease) in cash and cash equivalents	6,191	(4,561)	112,531	(1,003)	(69,140)
Cash and cash equivalents at beginning of period	24	6,215	1,654	1,654	114,185
Cash and cash equivalents at end of period	$ 6,215	$ 1,654	$114,185	$ 651	$ 45,045
Supplemental disclosure of cash flow information:					
Cash paid for interest	$ —	$ 20	$ 122	$ —	$ 40
Supplemental disclosure of non-cash investing and financing activities:					
Conversion of promissory notes and accrued interest into shares of convertible preferred stock	$ 1,502	$ —	$ —	$ —	$ —
Accretion of convertible preferred stock to redemption value	$ 276	$ 875	$ 1,291	$ 233	$ —
Issuance of preferred stock warrant in connection with notes payable	$ —	$ 156	$ —	$ —	$ —
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ —	$ 863	$ —	$ 162
Property and equipment purchases included in accounts payable	$ —	$ —	$ 101	$ —	$ 28

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

SERES THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Information as of March 31, 2015 and for the three months ended March 31, 2014 and 2015 is unaudited)

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

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 designed 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, including SER-262 to prevent an initial recurrence of primary CDI and other product candidates to treat inflammatory bowel disease, including ulcerative colitis, and enteric pathogens, such as antibiotic-resistant bacteria. The Company is also conducting research on metabolic diseases, such as early-stage, non-insulin dependent diabetes; other inflammatory diseases, such as Crohn's disease; and infections related to antibiotic use, cancer chemotherapy and immune suppression.

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.

The Company's consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. The Company has experienced negative cash flows and had an accumulated deficit of $27,832 and $35,803 as of December 31, 2014 and March 31, 2015, respectively. The Company expects that its cash and cash equivalents at December 31, 2014 of $114,185 will enable it to fund its operating expense and capital expenditure requirements through at least December 31, 2015. The Company expects that its cash, cash equivalents and investments of $104,316 at March 31, 2015 will enable it to fund its operating expenses and capital expenditure requirements through at least March 31, 2016. The future viability of the Company is dependent on its ability to generate cash from operating activities or to raise additional capital to finance its operations. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies.

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The Company is seeking to complete an initial public offering of its common stock. Upon the closing of a qualified public offering, the Company's outstanding convertible preferred stock will automatically convert into shares of common stock (see Note 9).

In the event the Company does not complete an initial public offering, the Company expects to seek additional funding through private financings, debt financing, collaboration agreements or government grants. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaboration arrangements or obtain government grants. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company and its wholly owned subsidiary after elimination of all intercompany accounts and transactions.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual of research and development expenses and the valuation of common stock, stock-based awards and the preferred stock warrant liability. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Unaudited Interim Financial Information

The accompanying balance sheet as of March 31, 2015, the statements of operations and comprehensive loss and of cash flows for the three months ended March 31, 2014 and 2015, and the statement of convertible preferred stock and stockholders' deficit for the three months ended March 31, 2015 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2015 and the results of its operations and its cash flows for the three months ended March 31, 2014 and 2015. The financial data and other information disclosed in these notes related to the three months ended March 31, 2014 and 2015 are unaudited. The results for the three months ended March 31, 2015 are not necessarily indicative of results to be expected for the year ending December 31, 2015, any other interim periods, or any future year or period.

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Unaudited Pro Forma Information

The accompanying unaudited pro forma consolidated balance sheet as of March 31, 2015 has been prepared to give effect to the automatic conversion of all outstanding shares of convertible preferred stock into 22,866,987 shares of common stock and the warrant to purchase Series A-2 convertible preferred stock outstanding as of March 31, 2015 becoming a warrant to purchase 92,127 shares of common stock (see Note 8) as if the proposed initial public offering had occurred on March 31, 2015.

In the accompanying consolidated statements of operations, unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2014 and the three months ended March 31, 2015 have been prepared to give effect to the automatic conversion of all outstanding shares of convertible preferred stock into shares of common stock and the outstanding warrant to purchase Series A-2 convertible preferred stock becoming a warrant to purchase shares of common stock (see Note 8) as if the proposed initial public offering had occurred on the later of January 1, 2014 or the issuance date of the convertible preferred stock.

Cash Equivalents

The Company considers all short-term, highly liquid investments with original maturities of 90 days or less at acquisition date to be cash equivalents. Cash equivalents, which consist of money market accounts, corporate bonds and commercial paper purchased with original maturities of less than 90 days from the date of purchase, are stated at fair value.

Restricted Cash

The Company held cash of $37 as of December 31, 2013 and $139 as of December 31, 2014 and March 31, 2015 in a separate restricted bank account as a security deposit for the lease of the Company's facilities and as collateral for the Company's credit card program with Comerica Bank. The Company has classified these deposits as long-term restricted cash on its balance sheet.

Investments

The Company classifies its available-for-sale investments as current assets on the consolidated balance sheet if they mature within one year from the balance sheet date.

The Company classifies all of its investments as available-for-sale securities. The Company's investments are measured and reported at fair value using quoted prices in active markets for similar securities. Unrealized gains and losses on available-for-sale securities are reported as a separate component of stockholders' equity (deficit). The cost of securities sold is determined on a specific identification basis, and realized gains and losses are included in other income (expense) within the consolidated statement of operations and comprehensive loss. If any adjustment to fair value reflects a decline in the value of the investment that the Company considers to be "other than temporary', the Company reduces the investment to fair value through a charge to the consolidated statement of operations and comprehensive loss. No such adjustments were necessary during the periods presented.

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Concentration of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company has all cash and cash equivalents balances at one accredited financial institution, in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party manufacturers to supply products for research and development activities of its programs, including pre-clinical and clinical testing. These programs could be adversely affected by a significant interruption in the supply of such drug substance products.

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, investments and preferred stock warrant liability are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). 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 carrying value of the Company's outstanding debt as of December 31, 2014 and March 31, 2015 approximates fair value based on the variable interest rate for the borrowings outstanding as well as short duration of the term of the note (see Note 7). The fair value of the outstanding debt was estimated using a discounted cash flow analysis based on current market interest rates for debt issuances with similar remaining years to maturity, adjusted for credit risk, which represents a Level 3 measurement.

Deferred Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs (non-current) until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the

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offering. As of December 31, 2014 and March 31, 2015, the Company had recorded $1,684 and $2,079, respectively, of deferred offering costs in contemplation of a probable 2015 equity financing. Should the equity financing no longer be considered probable of being consummated, all deferred offering costs will be charged to operating expenses in the consolidated statement of operations. The Company did not record any deferred offering costs as of December 31, 2013.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the useful life of the asset. Laboratory equipment is depreciated over five years. Computer equipment and furniture and office equipment are depreciated over three years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the related asset. Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses include salaries, stock-based compensation and benefits of employees, third-party license fees and other operational costs related to the Company’s research and development activities, including allocated facility-related expenses and external costs of outside vendors engaged to conduct both pre-clinical studies and clinical trials.

Research Contract Costs and Accruals

The Company has entered into various research and development contracts with research institutions and other companies. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for

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estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Accounting for Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees and directors based on the fair value on the date of the grant and recognizes compensation expense of those awards, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues stock options and restricted stock awards with only service-based vesting conditions and records the expense for these awards using the straight-line method.

The Company measures stock-based awards granted to consultants and non-employees based on the fair value of the award on the date on which the related service is complete. Compensation expense is recognized over the period during which services are rendered by such consultants and non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of the Company's common stock and updated assumption inputs in the Black-Scholes option-pricing model.

The Company classifies stock-based compensation expense in its consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

The Company recognizes compensation expense for only the portion of awards that are expected to vest. In developing a forfeiture rate estimate, the Company has considered its historical experience to estimate pre-vesting forfeitures for service-based awards. The impact of a forfeiture rate adjustment will be recognized in full in the period of adjustment, and if the actual forfeiture rate is materially different from the Company's estimate, the Company may be required to record adjustments to stock-based compensation expense in future periods.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own

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traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Warrant to Purchase Convertible Preferred Stock

The Company classifies a warrant to purchase shares of its Series A-2 convertible preferred stock as a liability on its consolidated balance sheets as this warrant is a free-standing financial instrument that may require the Company to transfer assets upon exercise. The warrant was initially recorded at fair value on date of grant, and it is subsequently remeasured to fair value at each balance sheet date. Changes in fair value of the warrant are recognized as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant or the warrant becoming a warrant to purchase common stock instead of preferred stock.

The Company uses the Black-Scholes option-pricing model, which incorporates assumptions and estimates, to value the preferred stock warrant. The Company has assessed these assumptions and

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estimates on a quarterly basis as additional information impacting the assumptions is obtained. Estimates and assumptions impacting the fair value measurement include the fair value per share of the underlying Series A-2 convertible preferred stock, the remaining contractual term of the warrant, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying preferred stock. The Company determines the fair value per share of the underlying preferred stock by taking into consideration the most recent sales of its convertible preferred stock, results obtained from third-party valuations and additional factors that are deemed relevant. The Company historically has been a private company and lacks company-specific historical and implied volatility information of its stock. Therefore, it estimates its expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrant. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrant. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Segment Data

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is on developing Ecobiotic microbiome therapeutics to treat dysbiosis in the colonic microbiome. No revenue has been generated since inception, and all tangible assets are held in the United States.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. There was no difference between net loss and comprehensive loss for each of the years ended December 31, 2012, 2013 and 2014 and the three months ended March 31, 2014. For the three months ended March 31, 2015, other comprehensive income (loss) consisted of changes in unrealized gains (losses) from available-for-sale investments.

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 applies the two-class method to calculate its basic and diluted net loss per share attributable to common stockholders, 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 each of the periods presented and preferred stockholders do not participate in losses.

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The Company's convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Similarly, restricted stock awards granted by the Company entitle the holder of such awards to dividends declared or paid by the board of directors, regardless of whether such awards are unvested, as if such shares were outstanding common shares at the time of the dividend. However, the unvested restricted stock awards are not entitled to share in the residual net assets (deficit) of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Recently Issued and Adopted Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board (''FASB'') issued Accounting Standards Update (''ASU'') 2014-10, *Development Stage Entities*. The amendments in this update removed all incremental financial reporting requirements, including inception-to-date information and certain other disclosures currently required under GAAP, in the financial statements of development stage companies. The amendments are effective for annual reporting periods beginning after December 15, 2014 and interim reporting periods beginning after December 15, 2015. Early adoption is permitted. The Company elected to early adopt this guidance and, therefore, has not presented inception-to-date disclosures in its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The amendments in this update will explicitly require a company's management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The new standard will be effective in the first annual period ending after December 15, 2016. Early application is permitted. The Company is currently evaluating the potential impact of the adoption of this standard, but believes its adoption will have no impact on its financial position, results of operations or cash flows.

In February 2015, the FASB issued ASU No. 2015-02, *Consolidation: Amendments to the Consolidation Analysis (Topic 810)* ("ASU 2015-02"), which modifies existing consolidation guidance for reporting organizations that are required to evaluate whether they should consolidate certain legal entities. ASU 2015-02 will be effective for annual periods beginning after December 15, 2015, and for interim periods within those fiscal years, and requires either a retrospective or a modified retrospective approach to adoption. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of ASU 2015-02, but believes its adoption will have no material impact on its financial position, results of operations or cash flows.

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3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's assets and liabilities as of December 31, 2013 and 2014 and March 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:

	Fair Value Measurements as of December 31, 2013 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ —	$ 1,301	$ —	$ 1,301
	$ —	$ 1,301	$ —	$ 1,301
Liabilities:				
Liability for preferred stock warrant	$ —	$ —	$ 164	$ 164
	$ —	$ —	$ 164	$ 164

	Fair Value Measurements as of December 31, 2014 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Liability for preferred stock warrant	$ —	$ —	$ 1,582	$ 1,582
	$ —	$ —	$ 1,582	$ 1,582

	Fair Value Measurements as of March 31, 2015 Using:			
	Level 1	Level 2	Level 3	Total
		(unaudited)		
Assets:				
Cash equivalents	$ —	$ 29,078	$ —	$29,078
Investments	—	59,271	—	59,271
	$ —	$ 88,349	$ —	$88,349
Liabilities:				
Liability for preferred stock warrant	$ —	$ —	$ 1,369	$ 1,369
	$ —	$ —	$ 1,369	$ 1,369

As of December 31, 2013 and March 31, 2015, the Company's cash equivalents, which were invested in money market funds, corporate bonds and commercial paper with original maturities of less than 90 days from the date of purchase, were valued based on Level 2 inputs. The fair values of the Company's investments, which consisted of corporate bonds and commercial paper as of March 31, 2015, were determined using Level 2 inputs. During the years ended December 31, 2013 and 2014 and the three months ended March 31, 2014 and 2015, there were no transfers between Level 1, Level 2 and Level 3.

The warrant liability in the table above is comprised of the values of a warrant for the purchase of Series A-2 convertible preferred stock (see Note 8) and is based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

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4. Investments

As of March 31, 2015, the fair value of available-for-sale investments by type of security was as follows:

	March 31, 2015 (unaudited)			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Investments:				
Corporate bonds	$25,785	$ —	$ (8)	$25,777
Commercial paper	33,455	39	—	33,494
	$59,240	$ 39	$ (8)	$59,271

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. The Company did not hold any investments as of December 31, 2013 and 2014.

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

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,		March 31, 2015
	2013	2014	(unaudited)
Laboratory equipment	$ 402	$1,260	$ 1,271
Computer equipment	29	115	115
Furniture and office equipment	12	58	165
Leasehold improvements	22	114	114
Construction in progress	—	—	23
	465	1,547	1,688
Less: Accumulated depreciation and amortization	(113)	(283)	(375)
	$ 352	$1,264	$ 1,313

Depreciation and amortization expense was $25, $88 and $190 for the years ended December 31, 2012, 2013 and 2014, respectively, and $30 and $92 for the three months ended March 31, 2014 and 2015, respectively.

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6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31, 2013	December 31, 2014	March 31, 2015 (unaudited)
Development and manufacturing costs	$181	$ 598	$ 317
Payroll and payroll-related costs	22	547	304
Professional fees	45	314	234
Facility and other	15	278	271
	$263	$1,737	$ 1,126

7. Notes Payable

On September 9, 2013, the Company entered into a loan and security agreement with Comerica Bank, which provided for borrowings of up to $3,000 through August 2014. On September 9, 2013, the Company received $1,000 from borrowings under the agreement, and from March to August 2014, the Company received $2,000 from additional borrowings under the agreement. Through December 31, 2014, the Company borrowed the full $3,000 available under the loan and security agreement and had made $400 of scheduled principal repayments. During the three months ended March 31, 2015, the Company made $300 of scheduled principal repayments. Borrowings under the loan and security agreement are collateralized by substantially all of the Company's assets, except for its intellectual property.

In accordance with the terms of the loan and security agreement, the Company is obligated to make monthly, interest-only payments on any term loans funded under the agreement until August 1, 2014. Thereafter, the Company is obligated to pay 30 consecutive, equal monthly installments of principal and interest from September 1, 2014 through February 1, 2017, the maturity date. Term loans under the loan and security agreement bear interest at an annual rate equal to 3.0% plus the greater of (1) the bank's prime rate and (2) the LIBOR rate plus 2.5% (the greater of which equated to 6.25% at December 31, 2014). In addition, a final payment of $60 is due upon the earlier of the maturity date, acceleration of the term loans or prepayment of all or part of the term loans. That amount is being recorded as additional interest expense over the term of the loan and security agreement, using the effective interest method.

In connection with entering into the loan and security agreement, the Company granted to the lender a warrant to purchase 92,127 shares of Series A-2 convertible preferred stock at an exercise price of $1.78 per share (see Note 8). The Company recorded the grant date fair value of the warrant of $156 as a debt discount and as a preferred stock warrant liability on the grant date. The debt discount, which also reflected $26 of fees paid to the lender, is being accreted to the carrying value of the debt, using the effective interest method.

Accretion of the debt discount recorded as additional interest expense was $19 and $66 for the years ended December 31, 2013 and 2014, respectively, and $0 and $12 for the three months ended March 31, 2014 and 2015, respectively. As of December 31, 2013 and 2014 and March 31, 2015, the unamortized debt discount was $162, $96 and $84, respectively.

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There are no financial covenants associated with the loan and security agreement; however, there are negative covenants restricting the Company's activities, including limitations on dispositions, mergers or acquisitions, encumbering or granting a security interest in its intellectual property, incurring indebtedness or liens, paying dividends, making certain investments and engaging in certain other business transactions. The obligations under the loan and security agreement are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in the Company's business, operations or financial or other condition.

As of December 31, 2014, annual principal repayment requirements under the loan and security agreement were $1,200 during each of the years ending December 31, 2015 and 2016, and $200 during the year ending December 31, 2017.

8. 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 a loan and security agreement (see Note 7). 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 remeasures the fair value of the liability for this preferred stock warrant at each reporting date from its grant date, with any adjustments being recorded as a component of other income (expense), net in the Company's consolidated statement of operations and comprehensive loss. The Company recorded losses of $8 and $1,418 for the years ended December 31, 2013 and 2014, respectively, and gains of $20 and $213 for the three months ended March 31, 2014 and 2015, respectively, 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:

	Year Ended December 31,		Three Months Ended March 31,	
	2013	2014	2014	2015
			(unaudited)	
Risk-free interest rate	3.20%	2.17%	2.82%	1.83%
Expected term (in years)	9.7	8.7	9.5	8.5
Expected volatility	86.0%	84.0%	86.0%	80.0%
Expected dividend yield	0%	0%	0%	0%
Fair value of Series A-2 convertible preferred stock	$ 2.07	$ 17.18	$ 1.56	$ 14.87

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The following table provides a rollforward of the fair value of the Company's preferred stock warrant liability:

	Fair Value
Balance as of December 31, 2012	$ —
Issuance of Series A-2 preferred stock warrant	156
Loss on revaluation	8
Balance as of December 31, 2013	164
Loss on revaluation	1,418
Balance as of December 31, 2014	1,582
Gain on revaluation	(213)
Balance as of March 31, 2015 (unaudited)	$ 1,369

Upon the closing of an initial public offering in which the Series A-2 convertible preferred stock is converted into common stock, the preferred stock warrant will become exercisable for common stock instead of preferred stock, and the preferred stock warrant liability, remeasured at fair value at that time, will be reclassified to additional paid-in capital.

9. Convertible Preferred Stock

The Company has issued Series A, Series A-2, Series B, Series C, Series D and Series D-1 convertible preferred stock (collectively, the "Convertible Preferred Stock"). The Convertible Preferred Stock is classified outside of stockholders' equity (deficit) because the shares contain redemption features that are not solely within the control of the Company. As of December 31, 2014 and March 31, 2015, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 24,348,003 shares of $0.001 par value preferred stock.

In June 2012, the Company issued 3,797,468 shares of Series A convertible preferred stock at an issuance price of $0.79 per share for proceeds of $3,000, net of issuance costs of $70. At that same time, convertible promissory notes in the amount of $1,400 and accrued interest of $102 were converted into 1,901,883 shares of Series A convertible preferred stock.

In October 2012, the Company issued 2,531,646 shares of Series A convertible preferred stock at an issuance price of $0.79 per share for proceeds of $2,000.

In November 2012, the Company issued 2,247,192 shares of Series A-2 convertible preferred stock at an issuance price of $1.78 per share for proceeds of $4,000.

In May 2014, the Company issued 4,831,359 shares of Series B convertible preferred stock at an issuance price of $2.20 per share for proceeds of $10,558, net of issuance costs of $71.

In November 2014, the Company issued 3,946,328 shares of Series C convertible preferred stock at an issuance price of $12.1632 per share for proceeds of $47,813, net of issuance costs of $187.

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In December 2014, the Company issued 2,222,222 shares of Series D convertible preferred stock and 1,388,889 shares of Series D-1 convertible preferred stock at an issuance price of $18.00 per share for aggregate proceeds of $64,832, net of issuance costs of $168.

Convertible Preferred Stock consisted of the following:

	December 31, 2013				
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A convertible preferred stock	8,230,997	8,230,997	$ 7,231	$ 7,301	8,230,997
Series A-2 convertible preferred stock	3,575,275	2,247,192	4,352	4,352	2,247,192
	11,806,272	10,478,189	$ 11,583	$ 11,653	10,478,189

	December 31, 2014				
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A convertible preferred stock	8,230,997	8,230,997	$ 7,767	$ 7,861	8,230,997
Series A-2 convertible preferred stock	2,339,319	2,247,192	4,665	4,700	2,247,192
Series B convertible preferred stock	4,831,359	4,831,359	11,000	11,146	4,831,359
Series C convertible preferred stock	3,946,328	3,946,328	47,813	48,376	3,946,328
Series D convertible preferred stock	3,611,111	2,222,222	39,900	40,123	2,222,222
Series D-1 convertible preferred stock	1,388,889	1,388,889	24,932	25,077	—
	24,348,003	22,866,987	$ 136,077	$ 137,283	21,478,098

	March 31, 2015 (unaudited)				
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A convertible preferred stock	8,230,997	8,230,997	$ 7,767	$ 8,016	8,230,997
Series A-2 convertible preferred stock	2,339,319	2,247,192	4,665	4,793	2,247,192
Series B convertible preferred stock	4,831,359	4,831,359	11,000	11,366	4,831,359
Series C convertible preferred stock	3,946,328	3,946,328	47,813	49,331	3,946,328
Series D convertible preferred stock	3,611,111	3,611,111	64,808	66,486	3,611,111
Series D-1 convertible preferred stock	1,388,889	—	—	—	—
	24,348,003	22,866,987	$ 136,053	$ 139,992	22,866,987

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The holders of the Convertible Preferred Stock have the following rights and preferences:

Voting Rights

The holders of Convertible Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote and have the right to vote the number of shares equal to the number of shares of common stock into which such Convertible Preferred Stock could convert on the record date for determination of stockholders entitled to vote. In addition, holders of Series A, Series A-2, Series B and Series C convertible preferred stock, voting as separate class, are entitled to elect one director of the Company.

Dividends

The holders of Convertible Preferred Stock are entitled to receive dividends in preference to any dividend on common stock at the rate of 8% of the Original Issue Price (as defined below) per share, per annum compounded. Dividends are payable only when, as, and if declared by the board of directors. As of December 31, 2014 and March 31, 2015, no dividends had been declared or paid by the Company. The Original Issue Price is $0.79 per share for Series A convertible preferred stock, $1.78 per share for Series A-2 convertible preferred stock, $2.20 per share for Series B convertible preferred stock, $12.16 per share for Series C convertible preferred stock, $18.00 per share for Series D convertible preferred stock and $18.00 per share for Series D-1 convertible preferred stock, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Convertible Preferred Stock.

Liquidation Preference

In the event of any liquidation, voluntary or involuntary, dissolution or winding up of the Company or Deemed Liquidation Event (as defined below), holders of Convertible Preferred Stock are entitled to receive, in preference to all other stockholders, and to the extent available, an amount equal to the Original Issue Price per share, adjusted for any stock dividends, stock splits or reclassifications, plus any accruing dividends accrued but unpaid, whether or not declared, together with any other dividends declared but unpaid. In the event that proceeds are not sufficient to permit payment in full to these holders, the proceeds will be ratably distributed among the holders of Convertible Preferred Stock on a *pari passu* basis to the full preferential amount each such holder is otherwise entitled to receive.

After payments have been made in full to the holders of convertible preferred stock, then, to the extent available, holders of the common stock will receive the remaining amounts available for distribution ratably in proportion to the number of common shares held by them provided, however, if the holders of any series of Convertible Preferred Stock would receive a greater amount of the proceeds if they had converted their shares of Convertible Preferred Stock, then such holders shall not receive any proceeds under the preceding paragraph and will receive proceeds on an as converted to common stock basis.

Unless (i) the holders of at least 60% of the then outstanding shares of the Convertible Preferred Stock, voting together as a single class and (ii) the holders of the majority of the then outstanding shares of Series C convertible preferred stock, voting as a separate class, elect otherwise, a Deemed

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Liquidation Event shall include a merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company.

Conversion

Each share of Series A, Series A-2, Series B, Series C and Series D convertible preferred stock is convertible into common stock at the option of the stockholder at any time after the date of issuance. Each share of Series A, Series A-2, Series B, Series C and Series D convertible preferred stock will automatically be converted into shares of common stock, at the applicable conversion ratio of each series then in effect, upon a qualified public offering, defined as any listing of the Company's common stock on the NYSE or NASDAQ.

Except with respect to Series D-1 convertible preferred stock, the conversion ratio of each series of Convertible Preferred Stock is determined by dividing the Original Issue Price of each series of preferred stock by the Conversion Price of each series. The Conversion Price is $0.79 for Series A, $1.78 for Series A-2, $2.20 for Series B, $12.16 for Series C and $18.00 for Series D, each being subject to adjustment as set forth in the Company's certificate of incorporation, as amended and restated, unless the holders of at least 60% of the outstanding Series A, Series A-2, Series B, Series C and Series D convertible preferred stock agree that no such adjustment shall be made. As of December 31, 2014 and March 31, 2015, all outstanding shares of Series A, Series A-2, Series B, Series C and Series D convertible preferred stock were convertible into common stock on a 1-for-1 basis.

As of December 31, 2014, each share of Series D-1 convertible preferred stock was automatically convertible into Series D convertible preferred stock upon either (i) the expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended ("HSR Act"), such that a holder of Series D-1 convertible preferred stock could acquire shares of Series D preferred stock, or (ii) if applicable, a transfer of shares of Series D-1 convertible preferred stock to a person that would not be required to make a filing under the HSR Act to acquire shares of Series D convertible preferred stock. On January 23, 2015, the waiting period under the HSR Act expired and all outstanding shares of Series D-1 convertible preferred stock automatically converted into 1,388,889 shares of Series D convertible preferred stock.

Redemption Rights

In conjunction with the closing of the Series C convertible preferred stock financing, the redemption rights of the Series A, Series A-2 and Series B convertible preferred stock were removed at that time. As a result of the removal of the redemption rights, as of November 24, 2014, the Company ceased the periodic recording of adjustments to accrete the carrying values of Series A, Series A-2 and Series B convertible preferred stock to their respective redemption values through January 1, 2019. Prior to November 24, 2014, the carrying values of the Series A, Series A-2 and Series B convertible preferred stock were being accreted to their redemption values through January 1, 2019.

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Reissuance

Shares of any series of Convertible Preferred Stock that are redeemed or converted will be retired or canceled and cannot be reissued by the Company.

10. Stockholders' Equity (Deficit)

Common Stock

As of December 31, 2014 and March 31, 2015, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 38,000,000 shares of $0.001 par value common stock.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of the Convertible Preferred Stock. When dividends are declared on shares of common stock, the Company must declare at the same time a dividend payable to the holders of Convertible Preferred Stock equivalent to the dividend amount they would receive if each preferred share were converted into common stock. The Company may not pay dividends to common stockholders until all dividends accrued or declared but unpaid on the Convertible Preferred Stock have been paid in full. No dividends had been declared to date.

As of December 31, 2014 and March 31, 2015, the Company had reserved 27,277,091 shares and 27,786,995 shares, respectively, for the conversion of the outstanding shares of Convertible Preferred Stock (see Note 9), the exercise of outstanding stock options and the number of shares remaining available for future grant under the Company's 2012 Plan, the exercise of outstanding common stock warrants, and the exercise of an outstanding warrant to purchase Series A-2 convertible preferred stock assuming it becomes a warrant to purchase common stock (see Note 8).

Common Stock Warrants

In June 2014, the Company entered into a research agreement under which it acquired a license to intellectual property. In exchange for the license, the Company issued to the research institution a warrant to purchase 454,545 shares of common stock at an exercise price of $0.01 per share, which was immediately exercisable. Upon issuance of the warrant, the Company recorded research and development expense of $317 for the fair value of the warrant, determined using the following assumptions in the Black-Scholes option-pricing model: expected volatility of 86.0%, risk-free interest rate of 2.3%, expected term of seven years (equaling the contractual term of the warrant) and no expected dividends. Because this warrant is indexed to the Company's stock and can only be settled by gross physical delivery of shares or net share settlement, the Company has determined that this warrant qualifies for equity classification. Unless earlier exercised or terminated, the warrant will be automatically exercised upon the closing of an initial public offering by the Company in a cashless exercise, with shares issued being determined based on the initial public offering price.

Also in connection with the research agreement, in June 2014, the Company issued a warrant to purchase up to 284,090 shares of common stock at an exercise price equal to the per share price at

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which the Company most recently sold shares of its preferred stock (which was $18.00 as of December 31, 2014 and March 31, 2015), which is exercisable for a number of shares to be determined by the Company's board of directors from time to time, upon achieving specified milestones related to up to five indications. No portion of the warrant was exercisable as of March 31, 2015. Unless the milestones are achieved and the warrant is earlier exercised, this warrant will be terminated upon the closing of an initial public offering by the Company. Because achievement of the specified milestones was not deemed probable as of December 31, 2014, the Company did not record any expense for this warrant from date of issuance through March 31, 2015.

2012 Stock Incentive Plan

The Company's 2012 Stock Incentive Plan, as amended, (the "2012 Plan") provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors and consultants of the Company. The 2012 Plan is administered by the board of directors, or at the discretion of the board of directors, by a committee of the board. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or their committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years. The Company generally grants stock-based awards with service conditions only ("service-based" awards).

Stock options granted under the 2012 Plan generally vest over four years and expire after ten years, although options have been granted with vesting terms less than four years.

The total number of shares of common stock that may be issued under the 2012 Plan was 1,261,836 shares as of December 31, 2013. In May 2014, the Company effected an increase in the number of shares of common stock reserved for issuance under the 2012 Plan to 3,561,836 shares. In December 2014, the Company effected an increase in the number of shares of common stock reserved for issuance under the 2012 Plan to 3,608,029 shares. The total number of shares of common stock that may be issued under the 2012 Plan was 3,608,029 shares as of December 31, 2014, none of which remained available for future grant at December 31, 2014. In March 2015, the Company effected an increase in the number of shares of common stock reserved for issuance under the 2012 Plan to 4,309,653 shares. As of March 31, 2015, there were 100,000 shares available for future grant under the 2012 Plan.

As required by the 2012 Plan, the exercise price for stock options granted is not to be less than the fair value of common shares as determined by the Company as of the date of grant. The Company values its common stock by taking into consideration its most recently available valuation of common shares performed by management and the board of directors as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant.

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Stock Option Valuation

The assumptions that the Company used to determine the fair value of the stock options granted to employees and directors were as follows, presented on a weighted average basis:

	Year Ended December 31,			Three Months Ended March 31,
	2012	2013	2014	2015 (unaudited)
Risk-free interest rate	0.92%	1.27%	1.83%	1.57%
Expected term (in years)	6.0	6.0	6.0	6.0
Expected volatility	109.4%	85.9%	83.5%	76.0%
Expected dividend yield	0%	0%	0%	0%

The Company did not grant any stock options to employees and directors during the three months ended March 31, 2014.

Stock Options

The following table summarizes the Company's stock option activity since January 1, 2012:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2012	—	$ —	—	$ —
Granted	317,836	0.10		
Exercised	—	—		
Forfeited	—	—		
Outstanding as of December 31, 2012	317,836	$ 0.10	9.65	$ —
Granted	999,000	0.48		
Exercised	—	—		
Forfeited	(55,000)	0.10		
Outstanding as of December 31, 2013	1,261,836	$ 0.40	9.34	$ 100
Granted	2,361,943	1.88		
Exercised	(28,687)	0.16		
Forfeited	(15,750)	1.12		
Outstanding as of December 31, 2014	3,579,342	$ 1.38	9.21	$ 59,498
Granted	611,624	15.77		
Exercised	(191,720)	0.46		
Forfeited	(10,000)	0.10		
Outstanding as of March 31, 2015 (unaudited)	3,989,246	$ 3.63	9.17	$ 48,425
Options vested and expected to vest as of December 31, 2014	3,579,342	$ 1.38	9.21	$ 59,498
Options exercisable as of December 31, 2014	662,451	$ 0.38	8.27	$ 11,671
Options vested and expected to vest as of March 31, 2015 (unaudited)	3,989,246	$ 3.63	9.17	$ 48,425
Options exercisable as of March 31, 2015 (unaudited)	545,388	$ 0.36	8.01	$ 8,405

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The weighted average grant-date fair value of stock options granted during the years ended December 31, 2012, 2013 and 2014 and the three months ended March 31, 2015 was $0.09, $0.35, $4.25 and $10.50 per share, respectively. The total intrinsic value of stock options exercised during the year ended December 31, 2014 was $512 and during the three months ended March 31, 2015 was $2,941.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

During the year ended December 31, 2014, the Company granted performance-based stock options to employees for the purchase an aggregate of 60,000 shares of common stock with a grant date fair value of $3.92 per share. These stock options are exercisable only upon achievement of specified performance targets in each option agreement. As of December 31, 2014, none of these options were exercisable because none of the specified performance targets had been achieved. Because achievement of the specified performance targets was not deemed probable as of December 31, 2014, the Company did not record any expense for these stock options from date of issuance through December 31, 2014 and March 31, 2015.

As of December 31, 2013 and 2014 and March 31, 2015, there were outstanding unvested service-based stock options held by non-employees for the purchase of 135,961, 69,688 and 48,126 shares, respectively, of common stock.

Restricted Common Stock

The Company has granted restricted common stock with time-based vesting conditions. Unvested shares of restricted common stock may not be sold or transferred by the holder. These restrictions lapse according to the time-based vesting conditions of each award. The table below summarizes the Company's restricted stock activity since January 1, 2012:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted common stock as of January 1, 2012	400,000	$ 0.001
Issued	2,440,000	$ 0.001
Vested	(981,250)	$ 0.001
Forfeited and repurchased	(250,000)	$ 0.001
Unvested restricted common stock as of December 31, 2012	1,608,750	$ 0.001
Vested	(675,000)	$ 0.001
Forfeited and repurchased	(735,000)	$ 0.001
Unvested restricted common stock as of December 31, 2013	198,750	$ 0.001
Vested	(146,250)	$ 0.001
Unvested restricted common stock as of December 31, 2014	52,500	$ 0.001
Vested	(25,625)	$ 0.001
Unvested restricted common stock as of March 31, 2015 (unaudited)	26,875	$ 0.001

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During the years ended December 31, 2012 and 2013, the Company reacquired, at their original issuance price, 250,000 shares and 735,000 shares, respectively, of restricted common stock that were forfeited by former employees.

The aggregate intrinsic value of restricted stock awards that vested during the years ended December 31, 2012, 2013 and 2014 and March 31, 2015 was $33, $185, $684 and $404, respectively.

Stock-based Compensation

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:

	Year Ended December 31,			Three Months Ended March 31,	
	2012	2013	2014	2014	2015
				(unaudited)	
Research and development expenses	$ 26	$ 177	$1,068	$ 32	$ 623
General and administrative expenses	2	32	1,000	13	704
	$ 28	$ 209	$2,068	$ 45	$ 1,327

As of December 31, 2014, the Company had an aggregate of $10,309 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 3.2 years. As of March 31, 2015, the Company had an aggregate of $15,573 of unrecognized compensation cost, which is expected to be recognized over a weighted average period of 3.3 years.

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11. Net Loss per Share

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

	Year Ended December 31,			Three Months Ended March 31,	
	2012	2013	2014	2014	2015
				(unaudited)	
Numerator:					
Net loss	$ (3,126)	$ (6,102)	$ (16,709)	$ (1,689)	$ (7,971)
Accretion of convertible preferred stock to redemption value	(276)	(875)	(1,291)	(233)	—
Net loss attributable to common stockholders	$ (3,402)	$ (6,977)	$ (18,000)	$ (1,922)	$ (7,971)
Denominator:					
Weighted average common shares outstanding, basic and diluted	5,725,120	6,394,916	6,748,037	6,686,389	6,912,725
Net loss per share attributable to common stockholders, basic and diluted	$ (0.59)	$ (1.09)	$ (2.67)	$ (0.29)	$ (1.15)

The Company's potential dilutive securities, which include stock options, unvested restricted common stock, convertible preferred stock and warrants to purchase convertible preferred stock or common stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. 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:

	Year Ended December 31,			Three Months Ended March 31,	
	2012	2013	2014	2014	2015
				(unaudited)	
Stock options to purchase common stock	317,836	1,261,836	3,579,342	1,261,836	3,989,246
Unvested restricted common stock	1,608,750	198,750	52,500	129,375	26,875
Warrants for the purchase of convertible preferred stock	—	92,127	92,127	92,127	92,127
Warrants for the purchase of common stock	—	—	738,635	—	738,635
Convertible preferred stock (as converted to common stock)	10,478,189	10,478,189	21,478,098	10,478,189	22,866,987
	12,404,775	12,030,902	25,940,702	11,961,527	27,713,870

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12. Unaudited Pro Forma Net Loss per Share

The unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2014 and the three months ended March 31, 2015 gives effect to adjustments arising upon the closing of a qualified initial public offering. The unaudited pro forma net loss attributable to common stockholders used in the calculation of unaudited basic and diluted pro forma net loss per share attributable to common stockholders does not include the effects of the accretion of convertible preferred stock to redemption value or loss from revaluation of preferred stock warrant liability because the calculation assumes that the conversion of convertible preferred stock into common stock had occurred on the later of January 1, 2014 or the issuance date of the convertible preferred stock.

The unaudited pro forma basic and diluted weighted average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2014 and the three months ended March 31, 2015 give effect to the automatic conversion upon a qualified initial public offering of all outstanding shares of convertible preferred stock as of December 31, 2014 and March 31, 2015 into 22,866,987 shares of common stock as if the conversion had occurred on the later of January 1, 2014 or the issuance date of the convertible preferred stock.

Unaudited pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Year Ended December 31, 2014	Three Months Ended March 31, 2015
		(unaudited)
Numerator:		
Net loss attributable to common stockholders	$ (18,000)	$ (7,971)
Accretion of convertible preferred stock to redemption value	1,291	—
(Gain) loss from revaluation of preferred stock warrant liability	1,418	(213)
Pro forma net loss attributable to common stockholders	$ (15,291)	$ (8,184)
Denominator:		
Weighted average common shares outstanding, basic and diluted	6,748,037	6,912,725
Pro forma adjustment for assumed automatic conversion of all outstanding shares of convertible preferred stock upon the closing of the proposed initial public offering	13,935,474	22,866,987
Pro forma weighted average common shares outstanding, basic and diluted	20,683,511	29,779,712
Pro forma net loss per share attributable to common stockholders, basic and diluted	$ (0.74)	$ (0.27)

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13. Commitments and Contingencies

Leases

The Company leases office and laboratory space under an operating lease agreement. The lease expires in January 2018 with no extension periods. The Company does have a right of expansion over the term as additional space becomes available but not an obligation. During the years ended December 31, 2012, 2013 and 2014 and the three months ended March 31, 2014 and 2015, the Company recognized $99, $152, $543, $42 and $186, respectively, of rental expense related to office and laboratory space.

Future minimum lease payments for this operating lease as of December 31, 2014 were as follows:

Year Ending December 31,	
2015	$ 681
2016	695
2017	709
2018	60
Total	$2,145

On February 13, 2015, the Company entered into a sublease for office space with a term expiring in February 2016. On April 1, 2015, the Company entered into a lease for additional office and laboratory space with a term expiring in April 2020. Minimum lease payments due under these new leases are $594 during the year ending December 31, 2015, $481 year ending December 31, 2016, $427 during each of the years ending December 31, 2017, 2018 and 2019, and $107 thereafter.

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 December 31, 2013 or 2014 or March 31, 2015.

14. Income Taxes

During the years ended December 31, 2012, 2013 and 2014 and the three months ended March 31, 2014 and 2015, the Company recorded no income tax benefits for the net operating losses incurred in each year or interim period, due to its uncertainty of realizing a benefit from those items.

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A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,		
	2012	2013	2014
Federal statutory income tax rate	(34.0)%	(34.0)%	(34.0)%
Research and development tax credits	(1.1)	(6.1)	(3.8)
State taxes, net of federal benefit	(5.3)	(5.3)	(5.3)
Stock-based compensation	0.5	1.2	2.3
Revaluation of preferred stock warrant liability	—	—	3.3
Nondeductible interest expense	1.2	—	—
Other	0.2	—	0.2
Change in deferred tax asset valuation allowance	38.5	44.2	37.3
Effective income tax rate	—%	—%	—%

Net deferred tax assets as of December 31, 2013 and 2014 consisted of the following:

	December 31,	
	2013	2014
Deferred tax assets:		
Net operating loss carryforwards	$ 3,076	$ 7,946
Research and development tax credit carryforwards	419	1,055
Capitalized organization costs	615	571
Stock-based compensation expense	16	436
Accrued expenses	46	447
Capitalized research and development expenses	147	136
Total deferred tax assets	4,319	10,591
Deferred tax liabilities:		
Depreciation and amortization	(25)	(69)
Total deferred tax liabilities	(25)	(69)
Valuation allowance	(4,294)	(10,522)
Net deferred tax assets	$ —	$ —

As of December 31, 2014, the Company had net operating loss carryforwards for federal and state income tax purposes of $20,288 and $19,852, respectively, which begin to expire in 2031 and 2031, respectively. As of December 31, 2014, the Company also had available research and development tax credit carryforwards for federal and state income tax purposes of $796 and $393, respectively, which begin to expire in 2031 and 2026, respectively. During the three months ended March 31, 2015, gross deferred tax assets increased by approximately $3,160 due to the operating loss incurred by the Company during that period. Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of

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carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2013 and 2014 and March 31, 2015. Management reevaluates the positive and negative evidence at each reporting period.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2012, 2013 and 2014 related primarily to the increases in net operating loss carryforwards and research and development tax credit carryforwards and were as follows:

	Year Ended December 31,		
	2012	2013	2014
Valuation allowance at beginning of year	$ (394)	$(1,599)	$ (4,294)
Decreases recorded as benefit to income tax provision	—	—	—
Increases recorded to income tax provision	(1,205)	(2,695)	(6,228)
Valuation allowance as of end of year	$(1,599)	$(4,294)	$(10,522)

15. 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 $528, $391 and $454 during the years ended December 31, 2012, 2013 and 2014, respectively, and of $146 and $118 during the three months ended March 31, 2014 and 2015, respectively. There were no amounts due to Flagship Ventures Management, Inc. related to the services agreement as of December 31, 2013 and 2014. As of March 31, 2015, the amount due to Flagship Ventures Management, Inc. related to the services agreement was less than $1.

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16. 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. Company contributions to the plan may be made at the discretion of the Company's board of directors. The Company has not made any contributions to date under the 401(k) Savings Plan.

17. Subsequent Events

For its consolidated financial statements as of December 31, 2014 and for the year then ended, the Company evaluated subsequent events through April 8, 2015, the date on which those financial statements were issued.

18. Subsequent Events (unaudited)

For its consolidated financial statements as of March 31, 2015 and for the three months then ended, the Company evaluated subsequent events through May 13, 2015, the date on which those financial statements were issued.

Exercise of Common Stock Warrant

On April 29, 2015, a holder of a warrant to purchase 454,545 shares of the Company's common stock at an exercise price of $0.01 per share exercised the warrant in full for a payment of $5 (see Note 10).

Change of Company Name

On May 20, 2015, the Company changed its name from Seres Health, Inc. to Seres Therapeutics, Inc. through the filing of an amendment to its amended and restated certificate of incorporation.

Increase in Number of Authorized Shares of Common Stock

On June 16, 2015, the Company effected an increase in the number of authorized shares of its common stock from 38,000,000 shares to 65,000,000 shares.

2015 Incentive Award Plan

On June 16, 2015, the Company's stockholders approved the 2015 Incentive Award Plan (the "2015 Plan"), which will become effective one day prior to the first day of trading on a securities exchange of shares of the Company's common stock. The 2015 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares initially reserved for issuance under the 2015 Plan is the sum of (i) 2,200,000 shares of common stock and (ii) the number of shares subject to awards outstanding under the 2012 Plan, as of the effective date of the 2015 Plan,

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that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company. In addition, the number of shares of common stock that may be issued under the 2015 Plan is subject to increase on the first day of each calendar year, beginning with the year ending December 31, 2016 and continuing for each calendar year until, and including, the year ending December 31, 2025, equal to the lesser of (i) 4% of the number of shares of the Company's common stock outstanding on the last day of the preceding applicable calendar year and (ii) an amount determined by the Company's board of directors.

2015 Employee Stock Purchase Plan

On June 16, 2015, the Company's stockholders approved the 2015 Employee Stock Purchase Plan. A total of 365,000 shares of common stock were reserved for issuance under this plan. The 2015 Employee Stock Purchase Plan will become effective one day prior to the first day of trading on a securities exchange of shares of the Company's common stock. In addition, the number of shares of common stock that may be issued under the plan will automatically increase on the first day of each calendar year, commencing on January 1, 2016 and ending on December 31, 2025, by an amount equal to the least of (i) 400,000 shares, (ii) 1% of the number of shares of the Company's common stock outstanding on the last day of the applicable preceding calendar year and (iii) an amount determined by the Company's board of directors.

7,430,555 Shares

Common Stock

Goldman, Sachs & Co.

BofA Merrill Lynch

Leerink Partners

Canaccord Genuity

Through and including July 20, 2015 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

June 25, 2015