Seres Therapeutics, Inc.
Form 424B4
June 26, 2015
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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.

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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

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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

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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

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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.

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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

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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.

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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.

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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

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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.

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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.

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	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.

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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

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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;

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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.

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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.

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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

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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;

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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;

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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.

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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.

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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.

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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.

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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.

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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

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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

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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;

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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.

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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.

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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.

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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

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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;

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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

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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;

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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.

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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.

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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

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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.

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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

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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

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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.

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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

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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

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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

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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

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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

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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.

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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 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.

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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.

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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.

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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.

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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	7	30	38

and outstanding, pro forma; 200,000,000 shares authorized, 37,834,057 shares issued and outstanding, pro forma as adjusted			
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

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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.

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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

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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

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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.

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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.

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	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.

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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;

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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;

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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.

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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.

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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,

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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
	2012	2013	2014	March 31, 2015
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.

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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

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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

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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

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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.

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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.

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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.

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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.

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General and Administrative Expenses

	Year Ended December 31,		Increase (Decrease)
	2012	2013	
	(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.

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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.

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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;

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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.

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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.

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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.

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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