As submitted to the Securities and Exchange Commission confidentially on January 27, 2015 as Amendment No. 1 to the confidential submission , 2015

As filed with the Securities and Exchange Commission on

Registration No. 333-

### **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1 REGISTRATION STATEMENT **UNDER** THE SECURITIES ACT OF 1933

### Seres Health, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

(Primary Standard Industrial Classification Code Number) 161 First Street

Cambridge, MA 02142 (617) 945-9626

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Roger J. Pomerantz, M.D. President and Chief Executive Officer Seres Health, Inc. 161 First Street Cambridge, Massachusetts 02142 (617) 945-9626

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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27-4326290

(I.R.S. Employer Identification No.)

following box.
If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.
If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.
If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer." "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the

Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

Large accelerated filer Non-accelerated filer

(DO	not cn	еск іт а	smailer	reporting	company)

Accelerated filer Smaller reporting company CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities	Proposed Maximum Aggregate Offering	Amount of
To Be Registered	Price <sup>(1)</sup>	Registration Fee <sup>(2)</sup>
Common Stock, \$0.001 par value per share	\$	\$

- Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the offering price of additional shares that the underwriters have the option to purchase.

  Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price. (1)
- (2)

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

### SUBJECT TO COMPLETION DATED JANUARY 27, 2015 PRELIMINARY PROSPECTUS



Shares		
Seres Health, Inc.		
Common Stock		
This is the initial public offering of shares of common stock of Seres Health, Inc. All of the sha by us.	ares of common stock a	re being sold
Prior to this offering, there has been no public market for the common stock. It is currently estimated t share will be between \$ and \$ . Application will be made for the quotation of the common stock "MCRB."	•	ering price per the symbol
We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups A elected to take advantage of certain reduced reporting requirements in this prospectus and may elect to company reporting requirements in future filings.		
Investing in our common stock involves risks. See " <u>Risk Factors</u> " beginning on page 12 to read about buying shares of the common stock.	factors you should cor	nsider before
Neither the Securities and Exchange Commission nor any other regulatory body has approved or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a		Total  \$ \$ \$
(1) See "Underwriting" beginning on page 158 for additional information regarding underwriting compensation	ation.	•
To the extent that the underwriters sell more than shares of common stock, the underwriters hadditional shares from Seres Health, Inc. at the initial public offering price less the underwriting disco		nase up to an
The underwriters expect to deliver the shares against payment in New York, New York on	, 2015.	
Goldman, Sachs & Co.	BofA Merri	II Lynch
Leerink Partners	Canacco	rd Genuity
Prospectus dated , 2015		

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Through and including , 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 Health" refer to Seres Health, Inc. and Seres Therapeutics Securities Corporation, 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 1/2 clinical study of SER-109 in recurrent CDI patients, 97% of patients achieved a clinical cure, which we define as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing. Based on these data and ongoing discussions with the FDA, we plan to begin enrollment for a Phase 3 clinical trial of SER-109 for recurrent CDI in the first half of 2015.

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, such as gastrointestinal infection and inflammatory and metabolic diseases.

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

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

Our approach to discovery and design is based on an iterative bedside-to-bench-to-bedside approach 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 impute 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 bacterial spores 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 health care 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, or 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, or CDC, has identified CDI as one of the top three most urgent antibiotic-resistant bacterial threats in the United States. It is a leading cause of hospital acquired infection in the United States and has overtaken methicillin-resistant *Staphylococcus aureus*, or MRSA, in prevalence. CDI is responsible for the death of approximately 14,000 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 approximately 783,000 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 approximately 103,000 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 an approximately 50 strain bacterial spore ecology 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 1/2 clinical study, 29 of 30 patients, or 97% of patients, achieved a clinical cure, which we define as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing. Additionally, 26 of 30 patients, or 87% of patients, achieved the primary efficacy endpoint of experiencing no recurrence of CDI associated diarrhea during the eight weeks post-treatment. The study demonstrated a favorable safety profile with no serious adverse events considered by the investigators to be attributable to SER-109 treatment. We also performed an analysis of the microbiome using sequencing technology and microbiological analysis to demonstrate a reestablishment of keystone organisms and a rapid increase in bacterial diversity, which enable the restoration of the microbiome to a healthy state. Based on these results, we are in the process of manufacturing SER-109 for use in clinical trials and plan to initiate a Phase 3 clinical trial for SER-109 for recurrent CDI in the first half of 2015. We plan to conduct manufacturing process validation studies for SER-109 in the second half of 2015 to support a biologics license application and commercial launch.

We believe the results of our open label Phase 1/2 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 15 strains 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 commence clinical studies of SER-262 in the second half of 2015.

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 Ecobiotic microbiome therapeutics that treat other enteric pathogens such as drug-resistant bacteria. We are also researching Ecobiotic microbiome therapeutics for the treatment of metabolic diseases, such as early-stage, non-insulin dependent diabetes, inflammatory diseases, such as Crohn's disease, and infections related to antibiotic use, cancer chemotherapy and immune suppression.

The following chart summarizes our current product pipeline:

Program	Discovery	Pre-Clinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones
SER-109 Recurrent CDI						Begin enrollment of Phase 3 clinical trial in the first half of 2015
SER-262 Primary CDI <sup>(1)</sup>						Commence clinical studies in the second half of 2015
SER-155 Drug-resistant bacteria & post-antibiotic restoration		-				Continue pre-clinical screening efforts to identify indication. Commence clinical studies in first half of 2016
SER-301 Crohn's diseases & Diabetes		-				Commence clinical studies in first half of 2016

<sup>(1)</sup> 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 28 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, or CMC, public company management and finance. Dr. Pomerantz, an infectious disease physician-scientist, has extensive experience in infectious disease drug development and commercialization, licensing and acquisitions over a 10-year career in senior executive positions at Merck & Co, Johnson & Johnson and Tibotec Pharmaceuticals. Dr. Pomerantz led the development and commercialization of eight FDA-approved infectious disease drugs in his career. In addition to Dr. Pomerantz, our management team includes Mr. Eric Shaff, Dr. David Cook, Dr. John Aunins, Dr. Michele Trucksis and Dr. Matthew Henn. Collectively, our management team has successfully developed 18 approved pharmaceutical drugs in infectious disease and other indications. Our management team has extensive experience in microbial ecology, microbiology and live biologicals, with a collective 23 years studying the microbiome and over 60 published papers on the science of the microbiome. Additionally, our team has extensive experience in building out commercial capabilities in specialty diseases and has a track record for success in launching vaccine products, which have analogous manufacturing processes to that of Ecobiotic microbiome therapeutics. In November 2014 and December 2014, we completed two preferred stock financings, which included as investors several prominent mutual funds and healthcare dedicated funds, as well as a multinational health sciences company.

### **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:

- Y rapidly advancing the development of our lead product candidate, SER-109, for the prevention of recurrent CDI;
- Ÿ advancing the clinical development of SER-262 to be used following antibiotic treatment of primary CDI to prevent an initial recurrence of CDI:
- Ÿ developing SER-155 for the treatment of antibiotic-resistant bacteria and SER-301 for the treatment of Crohn's disease and early-stage, non-insulin dependent diabetes;
- Ÿ 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;
- Ÿ commercializing our Ecobiotic microbiome therapeutics, including SER-109, directly in the United States and with collaborators outside the United States; and
- Ÿ 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:

- Ÿ 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;
- Ÿ 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;
- Ÿ 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;
- Ÿ 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;
- Ÿ 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
- Ÿ we may not be able to retain key executives or to attract, retain and motivate qualified personnel.

### **Our Corporate Information**

We were incorporated in the State of Delaware in 2010 under the name Newco LS21, Inc. In October 2011, we changed our name to Seres Health, Inc. Our principal executive offices are located at 161 First Street, Cambridge, Massachusetts 02142 and our telephone number is (617) 945-9626. Our website address is *www.sereshealth.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 defined in the Jumpstart Our Business Startups Act, 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:

- Ÿ 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;
- $\ddot{Y}$  not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended:
- Ÿ reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- Ÿ exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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

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

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

### THE OFFERING

Common stock offered by us shares

Common stock to be outstanding after this offering shares (or 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 additional shares of

our common stock.

Use of proceeds We intend to use the net proceeds from this offering, together with our existing cash and

cash equivalents, (1) to advance the clinical development and commercialization of SER-109, (2) to advance the development of our other product candidates, including SER-262, SER-155 and SER-301 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 54.

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.

Proposed symbol "MCRB"

The number of shares of our common stock to be outstanding after this offering is based on 6,890,250 shares of our common stock outstanding as of December 31, 2014 and excludes:

Ÿ 3,579,342 shares of common stock issuable upon exercise of stock options outstanding as of December 31, 2014, at a weighted average exercise price of \$1.38 per share;

Ÿ 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, upon the closing of this offering;

Ÿ additional shares of our common that will become available for future issuance under our 2015 Incentive Award Plan, which will become effective upon the closing of this offering, as well as shares of our common stock that become available pursuant to provisions in our 2015 Incentive Award Plan that automatically increase the share reserve under the 2015 Incentive Award Plan on January 1 of each calendar year as described in "Executive and Director Compensation—Incentive Plans—2015 Incentive Award Plan"; and

Ÿ additional shares of our common stock that will become available for future issuance under our 2015 Employee Stock Purchase Plan, which will become effective upon the closing of this offering.

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

- Ÿ the sale by us of 3,946,328 shares of Series C preferred stock in November 2014 for gross proceeds of \$48.0 million;
- Ÿ the sale by us of 2,222,222 shares of Series D preferred stock and 1,388,889 shares of Series D-1 preferred stock in December 2014 for aggregate gross proceeds of \$65.0 million;
- Ÿ the automatic conversion of all shares of our preferred stock outstanding as of December 31, 2014 into an aggregate of 22,866,987 shares of our common stock upon the closing of this offering;
- Y the automatic cashless exercise of an outstanding warrant to purchase 454,545 shares of common stock, or the funding warrant, which, based on an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would result in the issuance of shares of our common stock upon the closing of this offering and which is described in the section of this prospectus titled "Capitalization—Mayo Warrants":
- Ÿ the outstanding warrant to purchase our Series A-2 preferred stock becoming a warrant to purchase our common stock upon the closing of this offering;
- Ÿ no exercise of outstanding options or warrants after December 31, 2014, except for the automatic cashless exercise of the funding warrant;
- Ÿ 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
- $\dot{Y}$  no exercise by the underwriters of their option to purchase additional shares of our common stock.

### **SUMMARY FINANCIAL DATA**

You should read the following summary financial data together with our financial statements and the related notes appearing at the end of this prospectus and the "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus. We have derived the statement of operations data for the years ended December 31, 2012 and 2013 from our audited financial statements appearing at the end of this prospectus. The statement of operations data for the nine months ended September 30, 2013 and 2014 and the balance sheet data as of September 30, 2014 have been derived from our unaudited financial statements appearing at the end of this prospectus and have been prepared on the same basis as the audited 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 nine months ended September 30, 2014 are not necessarily indicative of the results to be expected for the full year ending December 31, 2014.

	Year I Decem		Nine Mon Septen	
	2012	2013	2013	2014
	(ir	thousands, exce	ept per share da	ta)
Statement of Operations Data:	_	_	_	•
Revenue	<u>\$</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>
Operating expenses:				
Research and development	2,077	4,805	3,288	5,658
General and administrative	956	1,247	859	2,211
Total operating expenses	3,033	6,052	4,147	7,869
Loss from operations	(3,033)	(6,052)	(4,147)	(7,869)
Other income (expense):				
Interest income (expense), net	(93)	(42)	(6)	(154)
Revaluation of preferred stock warrant liability		<u>(8)</u>		(504)
Total other income (expense), net	(93)	(50)	(6)	(658)
Net loss	(3,126)	(6,102)	(4,153)	(8,527)
Accretion of redeemable convertible preferred stock to redemption value	(276)	(875)	(654)	(1,019)
Net loss attributable to common stockholders	\$(3,402)	<u>\$ (6,977)</u>	\$(4,807)	\$ (9,546)
Net loss per share attributable to common stockholders, basic and diluted(1)	\$ (0.59)	\$ (1.09)	\$ (0.76)	\$ (1.42)
Weighted average common shares outstanding, basic and diluted(1)	5,725	6,395	6,331	6,732
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) <sup>(2)</sup>		\$ (0.36)		\$ (0.41)
Pro forma weighted average common shares outstanding, basic and diluted (unaudited)		16,873		19,536

<sup>(1)</sup> See Note 10 to our 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.

<sup>(2)</sup> See Note 11 to our financial statements appearing at the end of this prospectus for further details on the calculation of basic and diluted pro forma net loss per share attributable to common stockholders.

		As of September 30, 2014		
	Actual	Pro Forma <sup>(2)</sup>	Pro Forma As Adjusted <sup>(3)</sup>	
		(in thousands)		
Balance Sheet Data:				
Cash and cash equivalents	\$ 7,120	\$ 120,120	\$	
Working capital <sup>(1)</sup>	4,632	117,632		
Total assets	8,553	121,553		
Preferred stock warrant liability	668	_		
Long-term debt, net of discount, including current portion	2,788	2,788		
Redeemable convertible preferred stock	23,160	_		
Total stockholders' equity (deficit)	(19,640)	117,188		

- (1) We define working capital as current assets less current liabilities.
- (2) The pro forma balance sheet data give effect to:
  - $\dot{Y}$  the sale by us of 3,946,328 shares of Series C preferred stock in November 2014 for gross proceeds of \$48.0 million;
  - Ÿ the sale by us of 2,222,222 shares of Series D preferred stock and 1,388,889 shares of Series D-1 preferred stock in December 2014 for aggregate gross proceeds of \$65.0 million:
  - Ÿ the automatic conversion of all shares of our preferred stock outstanding as of December 31, 2014 into an aggregate of 22,866,987 shares of our common stock upon the closing of this offering;
  - Y the automatic cashless exercise of an outstanding warrant to purchase 454,545 shares of common stock, which, based on an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, will result in the issuance of shares of our common stock upon the closing of this offering and which is described in the section of this prospectus titled "Capitalization—Mayo Warrants"; and
  - Ÿ the outstanding warrant to purchase our Series A-2 preferred stock becoming a warrant to purchase our common stock upon closing of this offering.
- (3) The pro forma as adjusted balance sheet data give further effect to the sale by us of shares of our common stock in this offering at an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions. An increase or decrease of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease each of cash and cash equivalents, working capital, total assets and total stockholders' equity on a pro forma as adjusted basis by approximately \$ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions.

#### **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 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, 2013 and \$8.5 million for the nine months ended September 30, 2014. As of September 30, 2014, we had an accumulated deficit of \$19.7 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 a 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:

- Ÿ conduct our Phase 3 clinical trial of SER-109, our lead product candidate;
- Ϋ́ continue the research and development of our other product candidates, including commencing clinical studies and trials for SER-262, SER-155 and SER-301;
- Ÿ seek to enhance our microbiome therapeutics platform and discover and develop additional product candidates;
- Ÿ seek regulatory approvals for any product candidates that successfully complete clinical trials;
- Ÿ potentially establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- Ÿ maintain, expand and protect our intellectual property portfolio;
- Ÿ 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
- Ÿ experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing pre-clinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product

candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product and biological development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the U.S. Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA, or other regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase and revenue could be further delayed.

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

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

We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our Phase 3 clinical trial of SER-109, and continue to research, develop and initiate clinical trials of SER-262, SER-155 and SER-301 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 and cash equivalents of \$ million as of December 31, 2014, together with anticipated net proceeds from this offering, will enable us to fund our operating expenses and capital expenditures requirements through at least , which we expect will enable us to complete our Phase 3 clinical trial of SER-109. 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:

- $\ddot{Y}$  the commencement, progress and results of our Phase 3 clinical trial of SER-109;
- Ÿ the cost of manufacturing clinical supplies of our product candidates;
- Ÿ the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for our other product candidates, including SER-262;
- Y the costs, timing and outcome of regulatory review of our product candidates;
- Ÿ 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;
- Ÿ the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;

- Ÿ 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;
- Ÿ the effect of competing technological and market developments; and
- Ÿ 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 1/2 clinical study of SER-109, our lead product candidate, and plan to initiate a Phase 3 clinical trial for this product candidate in the first half of 2015, 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 3 or other pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

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

We are using our microbiome therapeutics platform to develop Ecobiotic microbiome therapeutics, with an initial focus on developing SER-109 for the prevention of further recurrences of CDI in patients suffering from recurrent CDI. While we believe our pre-clinical and Phase 1/2 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-*C. 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:

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

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

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

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

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

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

We currently plan to begin patient enrollment in a Phase 3 clinical trial of our lead product, SER-109, in the first half of 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 3 clinical trial for SER-109, we have refined the formulation of the inner capsule and changed the manufacturing process that we expect to use for commercial production. The Phase 3 clinical trial will represent the first clinical trial using this formulation and we cannot assure that the results of this new formulation will be consistent with those experienced in the Phase 1/2 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, the FDA generally requires that safety and efficacy be demonstrated in two adequate and well-controlled clinical trials. In some situations, evidence from a single trial can be sufficient for FDA approval, such as in cases where a single multicenter study provides highly reliable and statistically strong evidence of an important clinical benefit, and in which confirmation of the result in a second trial could be considered unethical. In the course of our

discussions with the FDA, we have provided our rationale for why we believe that our planned Phase 3 clinical trial for SER-109 will provide sufficient evidence for approval, but the FDA has indicated that, depending on the results of our planned Phase 3 clinical trial, the FDA may require more than one Phase 3 clinical trial of SER-109 in order to gain approval. If the FDA requires us to conduct additional clinical trials of SER-109 in order to gain approval, we will incur significant additional development costs, commercialization of SER-109 would be delayed or could be prevented and our business could be adversely affected.

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:

- Ÿ 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;
- Ÿ we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- Ÿ 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;
- Ÿ 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;
- Ÿ 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:
- Y 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;
- Ÿ 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:
- Y the cost of clinical trials of our product candidates may be greater than we anticipate;
- Ÿ 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;
- Y regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- Ÿ 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:

- Ÿ be delayed in obtaining marketing approval for our product candidates;
- $\dot{Y}$  lose the support of any future collaborators, requiring us to bear more of the burden of development of certain compounds;

- Ÿ not obtain marketing approval at all;
- Ÿ obtain marketing approval in some countries and not in others;
- Y obtain approval for indications or patient populations that are not as broad as we intend or desire:
- Ÿ obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- Ÿ be subject to additional post-marketing testing requirements; or
- Ÿ have the product removed from the market after obtaining marketing approval.

We recently completed our Phase 1/2 clinical study of SER-109 and plan to initiate a Phase 3 clinical trial for this product candidate in the first half of 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 1/2 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 1/2 clinical study of SER-109, it stated that continued clinical evaluation of SER-109 will require an IND. We intend to conduct all future clinical studies of SER-109, including our planned pivotal Phase 3 clinical trial, under an IND, which we filed in December 2014. The FDA may refuse to authorize our IND for SER-109 or there may be a delay in authorizing our IND if the FDA disagrees with the design of our proposed Phase 3 clinical trial of SER-109 or for other reasons. Since this is our most advanced product candidate, such regulatory actions could adversely affect future development plans, collaborations and our stock price. Unlike 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 approximately 103,000 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:

- Ÿ the severity of the disease under investigation;
- $\ddot{\mathrm{Y}}$  the patient eligibility criteria for the study in question;

- Ÿ the perceived risks and benefits of the product candidate under study;
- Ÿ the availability of other treatments for the disease under investigation;
- Ÿ the existence of competing clinical trials;
- Ÿ the efforts to facilitate timely enrollment in clinical trials;
- Ÿ our payments for conducting clinical trials;
- Ÿ the patient referral practices of physicians;
- Ÿ the ability to monitor patients adequately during and after treatment; and
- $\ddot{Y}$  the proximity and availability of clinical trial sites for prospective patients.

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

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

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

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years. The scope and amount of clinical data required to obtain marketing approvals can vary substantially from jurisdiction to jurisdiction, and it may be difficult to predict whether a particular regulatory body will require additional or different studies than those conducted by a sponsor, especially for novel product candidates such as our Ecobiotic microbiome therapeutics. The FDA or foreign regulatory authorities may delay, limit, or deny approval to market our product candidates for many reasons, including: our inability to demonstrate that the clinical benefits of our product candidates outweigh any safety or other perceived risks; the regulatory authority's disagreement with the interpretation of data from nonclinical or clinical studies; the regulatory agency's requirement that we conduct additional pre-clinical studies and clinical trials; changes in marketing approval policies during the development period; changes in or the enactment of additional statutes or regulations, or changes in regulatory review process for each submitted product application; or the regulatory authority's failure to approve the manufacturing processes or third-party manufacturers with

which we contract. Regulatory authorities have substantial discretion in the approval process and may refuse to accept a marketing application as deficient. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Of the large number of drugs in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized.

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

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

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

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

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

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

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

We may seek a breakthrough therapy designation for some of our 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. 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 accelerated approval.

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, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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

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

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

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

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

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

We expect to continue to rely on third parties, such as contract research organizations, or CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct and manage our clinical trials, including our planned Phase 3 clinical trial 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, or GCPs, 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. The contract manufacturers we rely on to produce SER-109 plan to produce four batches of SER-109 over the next few months in order to provide an adequate supply of SER-109 for our planned Phase 3 clinical trial. If there are delays in the production of SER-109 we may have to delay the start of our Phase 3 clinical trial or we may be delayed in completing the trial.

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:

- $\ddot{Y}$  failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- Ÿ breach of manufacturing agreements by the third-party manufacturers;
- Ÿ failure to manufacture our product according to our specifications;
- Y failure to manufacture our product according to our schedule or at all;
- Ÿ misappropriation or disclosure of our proprietary information, including our trade secrets and know-how; and
- Ÿ 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 current good manufacturing processes, or cGMP. We do not have any manufacturing facilities that meet the FDA's cGMP requirements for the production of any product candidates used in humans.

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

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

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

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

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current CDI treatment involves the use of antibiotics that are well established in the medical community or the use of fecal microbiota transplantation, 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:

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

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

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

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

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

- Y our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- Y the inability of sales personnel to obtain access to or educate physicians on the benefits of our products;
- Ÿ 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;
- $\ddot{Y}$  unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- Y inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies.

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

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

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

worldwide. We are aware of a number of large pharmaceutical and biotechnology companies, including Merck, Shire, Sanofi, Pfizer, Novartis and Cubist, 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 health care insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for

particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. We may also be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

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

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

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

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

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  m Y}$  regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- $\ddot{Y}$  decreased demand for any product candidates or products that we may develop;
- Ÿ injury to our reputation and significant negative media attention;

- Ÿ withdrawal of clinical trial participants;
- Ÿ significant costs to defend the related litigation;
- Ÿ substantial monetary awards to trial participants or patients:
- Ÿ loss of revenue:
- Ÿ reduced resources of our management to pursue our business strategy; and
- Ÿ 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 his proposed budget for fiscal year 2014, President Obama 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, but to date, no biosimilar or interchangeable product has been approved. Although it is unclear what final implementation of the BCPIA will entail, such FDA implementation could have a material adverse effect on the future commercial prospects for our product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

- Y 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:
- Ÿ 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;
- Ÿ 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;
- Y 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;
- Ÿ 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; and
- Y 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
- Ÿ State and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain a robust systems to comply with multiple jurisdictions with different compliance and/or 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:

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

- Y an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- Ÿ 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;
- Ÿ a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- Ÿ extension of manufacturers' Medicaid rebate liability;
- Ÿ expansion of eligibility criteria for Medicaid programs;
- $\dot{Y}$  expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- $\dot{Y}$  new requirements to report financial arrangements with physicians and teaching hospitals;
- Ÿ a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- Ÿ 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 PPACA 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 up to 2% per fiscal year, which went into effect on April 1, 2013 and 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 the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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

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

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

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

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

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

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

#### Risks Related to Our Intellectual Property

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

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

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

or in all jurisdictions. Prosecution of our patent portfolio is at a very early stage, and we have not yet reached the statutory deadlines in any of our application families 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 one issued U.S. patent. 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 patent 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 own 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 our 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 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 patents 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:

- Ÿ 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;
- $\ddot{Y}$  any of our pending patent applications will issue as patents at all;
- Ÿ we will be able to successfully commercialize our product candidates, if approved, before our relevant patents expire;
- $\ddot{Y}$  we were the first to make the inventions covered by each of our patents and pending patent applications;
- Ÿ we were the first to file patent applications for these inventions;
- Ÿ others will not develop similar or alternative technologies that do not infringe or design around our patents;
- Ÿ others will not use pre-existing technology to effectively compete against us;
- $\ddot{Y}\,$  any of our patents, if issued, will be found to ultimately be valid and enforceable;
- Y third parties will not compete with us in jurisdictions where we do not pursue and obtain patent protection;
- $\ddot{Y}$  we will be able to obtain and/or maintain necessary or useful licenses on reasonable terms or at all;

- Ÿ 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;
- Ÿ we will develop additional proprietary technologies or product candidates that are separately patentable; or
- Ÿ 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 partners, 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-Lahey-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 the U.S. 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. It is also possible that we 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. 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. Moreover, we are aware of several pending patent applications containing one or more claims that could be construed to cover our product candidates or technology, should those claims issue in their original form or in the form presently being pursued. We may also fail to identify such patent applications or incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. For these reasons, the issuance, scope, validity, enforceability and commercial value of our patents are subject to a level of uncertainty.

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.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. If we are found to infringe a third party's intellectual property rights, we could be required 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 required 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:

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

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

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

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

found invalid or unenforceable, the claims of our patents could be construed narrowly or in a manner that does not cover the allegedly infringing technology in question. Such a loss of patent protection would have a material adverse impact on our business.

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

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

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

It is our policy to enter into confidentiality and intellectual property assignment agreements with our employees, consultants, contractors and advisors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. For example, even if we have a consulting agreement in place with an academic advisor pursuant to which such academic advisor is required to assign any inventions developed in connection with providing services to us, such academic advisor may not have the right to assign such inventions to us, as it may conflict with his or her obligations to assign all such intellectual property to his or her employing institution.

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

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

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may also engage advisors and consultants who are concurrently employed at universities or other organizations or who perform services for other entities. Although we try to ensure that our employees, advisors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, advisors or consultants have used or disclosed

intellectual property, including trade secrets or other proprietary information, of any such party's former or current employer or in violation of an agreement with another party. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims.

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

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

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

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

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

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than in the United States, assuming that rights are obtained in the United States and assuming that rights are pursued outside the United States. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications. For all of the patent families in our portfolio, including the families that may provide coverage for our lead product candidates, the relevant statutory deadlines have not yet expired. Therefore, for each of the patent families that we believe

provide coverage for our lead product candidates, we will need to decide whether and where to pursue protection outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, even if we do elect to pursue patent rights outside the United States, we may not be able to obtain relevant claims and/or we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

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

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

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

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

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

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

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other

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

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

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

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

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

- $\ddot{Y}$  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;
- $\ddot{
  m Y}$  failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- Ÿ additional potentially relevant third-party patent rights;
- Ÿ complexities and difficulties in obtaining protection and enforcing our intellectual property;
- $\ddot{Y}$  difficulties in staffing and managing foreign operations;
- Y complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- Ÿ limits in our ability to penetrate international markets;

- Ÿ 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;
- Ÿ natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- Y certain expenses including, among others, expenses for travel, translation and insurance; and
- Ÿ regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions, or its anti-bribery provisions.

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

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

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

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

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

- $\dot{Y}$  disruption in our relationships with future customers or with current or future distributors or suppliers as a result of such a transaction;
- Ÿ unanticipated liabilities related to acquired companies;
- $\ddot{Y}$  difficulties integrating acquired personnel, technologies and operations into our existing business;
- Ÿ diversion of management time and focus from operating our business to acquisition integration challenges;
- $\dot{Y}$  increases in our expenses and reductions in our cash available for operations and other uses;
- $\ddot{\mathrm{Y}}$  possible write-offs or impairment charges relating to acquired businesses; and
- Ÿ 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 we intend to apply to list our common stock on the and active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult for you to sell shares you purchase in this offering without depressing the market price for the shares or at all.

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

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

- Ÿ the success of competitive products or technologies;
- Ÿ actual or anticipated changes in our growth rate relative to our competitors;
- Ÿ results of clinical trials of our product candidates or those of our competitors;
- Ÿ developments related to any future collaborations;
- Ÿ regulatory or legal developments in the United States and other countries;
- Ÿ development of new product candidates that may address our markets and may make our product candidates less attractive;
- Y changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;
- Ÿ announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- Ÿ developments or disputes concerning patent applications, issued patents or other proprietary rights;
- $\ddot{\mathrm{Y}}$  the recruitment or departure of key personnel;
- Y the level of expenses related to any of our product candidates or clinical development programs;
- $\ddot{Y}$  failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;

- $\ddot{Y}$  the results of our efforts to discover, develop, acquire or in-license additional product candidates or products:
- Ÿ actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- Ÿ variations in our financial results or those of companies that are perceived to be similar to us;
- Ÿ changes in the structure of healthcare payment systems;
- Ÿ market conditions in the pharmaceutical and biotechnology sectors;
- Ÿ general economic, industry and market conditions; and
- Ÿ 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 December 31, 2014, 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 % of our outstanding voting stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

- Ÿ delay, defer or prevent a change in control;
- Ÿ entrench our management and the board of directors; or
- $\ddot{Y}$  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 an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of \$ per share, 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 % of the aggregate price paid by all purchasers of our stock but will own only approximately % 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 and cash equivalents, to advance the clinical development and commercialization 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, including SER-262, SER-155 and SER-301; 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 shares of common stock based on the number of shares outstanding as of December 31, 2014. 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 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 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. 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 defined 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:

Ÿ 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;

- Y not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- Ÿ 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:
- Ÿ reduced disclosure obligations regarding executive compensation; and
- Ÿ 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 provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To

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

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

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our target animal studies and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

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

- Ÿ 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;
- $\ddot{Y}$  no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- Y 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;
- Ÿ 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;

- Y the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- Y 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;
- Ÿ a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders:
- Y 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
- Ÿ advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Furthermore, our restated certificate of incorporation that will become effective upon the closing of this offering specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders. We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in such action.

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the loan and security agreement 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 pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this prospectus. These forward-looking statements are subject to numerous risks, including, without limitation, the following:

- Y our status as a development-stage company and our expectation to incur losses in the future;
- Ÿ our future capital needs and our need to raise additional funds;
- Y our ability to build a pipeline of product candidates and develop and commercialize drugs;
- Ÿ our unproven approach to therapeutic intervention;
- Y our ability to enroll patients in clinical trials, timely and successfully complete those trials and receive necessary regulatory approvals;
- Y our ability to establish our own manufacturing facilities and to receive or manufacture sufficient quantities of our product candidates;
- Ÿ our ability to protect and enforce our intellectual property rights;
- $\dot{Y}$  federal, state, and foreign regulatory requirements, including FDA regulation of our product candidates;
- Ÿ our ability to obtain and retain key executives and attract and retain qualified personnel; and
- $\ddot{\mathrm{Y}}~$  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 gualify all of our forward-looking statements by these cautionary statements.

#### **INDUSTRY AND OTHER DATA**

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

# TRADEMARKS, SERVICE MARKS AND TRADENAMES

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

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

#### **USE OF PROCEEDS**

We estimate that our net proceeds from the sale of shares of our common stock in this offering will be approximately \$million, or \$million if the underwriters exercise in full their option to purchase additional shares, assuming an initial public offering price of \$per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease our net proceeds from this offering by approximately \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions. An increase or decrease of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease our net proceeds from this offering by approximately \$ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions.

We currently estimate that we will use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- Ÿ approximately \$ million to \$ million to advance the clinical development and commercialization 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 clinical development and commence initial commercialization;
- Ÿ approximately \$ million to \$ million to advance the development of our other product candidates, including SER-262, SER-155 and SER-301; and
- Ÿ 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 and our existing cash and cash equivalents as of December 31, 2014 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-155, SER-301 and any other product candidates we identify. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from pre-clinical studies and any ongoing clinical trials or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

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

# **DIVIDEND POLICY**

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

#### **CAPITALIZATION**

The following table sets forth our cash and cash equivalents and our capitalization as of September 30, 2014:

- Ÿ on an actual basis;
- Ÿ on a pro forma basis, after giving effect to:
  - Y the sale by us of 3,946,328 shares of Series C preferred stock in November 2014 for gross proceeds of \$48.0 million;
  - Ÿ the sale by us of 2,222,222 shares of Series D preferred stock and 1,388,889 shares of Series D-1 preferred stock in December 2014 for aggregate gross proceeds of \$65.0 million;
  - Ÿ the automatic conversion of all shares of our preferred stock outstanding at December 31, 2014 into an aggregate of 22,866,987 shares of our common stock upon the closing of this offering;
  - Ý the automatic cashless exercise of a warrant to purchase 454,545 shares of common stock, which, based on an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, will result in the issuance of shares of our common stock upon closing of this offering and which is described in "—Mayo Warrants" below;
  - Ÿ the outstanding warrant to purchase our Series A-2 preferred stock becoming a warrant to purchase our common stock upon the closing of this offering; and
  - $\ddot{Y}$  the filing and effectiveness of our restated certificate of incorporation; and
- Y 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 shares of our common stock in this offering at an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with our financial statements and related notes appearing at the end of this prospectus and the sections of this prospectus titled "Selected Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Description of Capital Stock."

	As of September 30, 2014			
	Actual	Pro Forma	Pro Forma As Adjusted <sup>(1)</sup>	
		(in thousands, except share data)		
Cash and cash equivalents	<u>\$ 7,120</u>	<u>\$ 120,120</u>	\$	
Preferred stock warrant liability	\$ 668	\$ —	\$	
Long-term debt, net of discount, including current portion	2,788	2,788		
Redeemable convertible preferred stock (Series A, A-2 and B), \$0.001 par value; 15,401,675 shares authorized, 15,309,548 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	23,160	_		
Stockholders' equity (deficit):				
Preferred stock, \$0.001 par value; no shares authorized, issued or outstanding, actual; shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	_	_		
Common stock, \$0.001 par value; 28,000,000 shares authorized, 6,884,187 shares issued and outstanding, actual; shares authorized, shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	7			
Additional paid-in capital	3			
Accumulated deficit	(19,650)	(19,650)		
Total stockholders' equity (deficit)	(19,640)	117,188		
Total capitalization	\$ 6,976	\$ 119,976	\$	

<sup>(1)</sup> A \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by approximately \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions. An increase or decrease of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by approximately \$ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions.

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

- Ÿ 3,056,805 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2014 at a weighted average exercise price of \$0.59 per share;
- Ÿ 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, upon the closing of this offering;

- Ÿ 475,844 shares of common stock available for future issuance under our 2012 Stock Incentive Plan as of September 30, 2014;
- Y additional shares of our common that will become available for future issuance under our 2015 Incentive Award Plan, which will become effective upon the closing of this offering, as well as shares of our common stock that become available pursuant to provisions in our 2015 Incentive Award Plan that automatically increase the share reserve under the 2015 Incentive Award Plan on January 1 of each calendar year as described in "Executive and Director Compensation—Incentive Plans—2015 Incentive Award Plan"; and
- Ÿ additional shares of our common stock that will become available for future issuance under our 2015 Employee Stock Purchase Plan, which will become effective upon the closing of this offering.

# **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, provides the Mayo Foundation a right to purchase 454,545 shares of our common stock at a purchase price of \$0.01 per share. The warrant provides that, unless earlier exercised, it will be automatically cashless exercised on the date prior to its termination, which will be the date prior to the closing of this offering. Investors can determine the number of shares issuable upon the automatic cashless exercise of this warrant by (i) subtracting \$0.01 from the public offering price, (ii) dividing the remainder by the public offering price and (iii) multiplying the quotient by 454,545. Based on an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus, this warrant would be cashless exercised for shares of common stock prior to the closing of this offering.

A \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would, in the case of an increase, increase the number of shares of common stock issuable by shares and, in the case of a decrease, decrease the number of shares of common stock issuable by shares, upon the automatic cashless exercise of the funding warrant.

The second warrant is an incentive warrant tied to certain milestones that, as of December 31, 2014, had not been accomplished. The incentive warrant will terminate upon the closing of this offering.

#### DILUTION

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

Our historical net tangible book value (deficit) as of September 30, 2014 was \$(19.8) million, or \$(2.87) 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 September 30, 2014.

Our pro forma net tangible book value as of September 30, 2014 was \$117.0 million, or \$ 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 sale by us of 3,946,328 shares of Series C preferred stock in November 2014 for gross proceeds of \$48.0 million, (2) the sale by us of 2,222,222 shares of Series D preferred stock and 1,388,889 shares of Series D-1 preferred stock in December 2014 for aggregate gross proceeds of \$65.0 million, (3) the automatic conversion of all shares of our preferred stock outstanding as of December 31, 2014 into an aggregate of 22,866,987 shares of our common stock upon the closing of this offering, (4) the automatic cashless exercise of a warrant to purchase 454,545 shares of common stock, which, based on an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, will result in the issuance of shares of our common stock upon the closing of this offering and which is described in the section of this prospectus titled "Capitalization—Mayo Warrants" and (5) the outstanding warrant to purchase our Series A-2 preferred stock becoming a warrant to purchase our common stock upon the closing of 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 September 30, 2014, after giving effect to the pro forma adjustments described in (3) and (4) above.

After giving effect to our sale of shares of common stock in this offering at an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2014 would have been approximately \$ million, or \$ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$ per share to existing stockholders and an immediate dilution of \$ 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:

Assumed initial public offering price per share	\$
Historical net tangible book value (deficit) per share as of September 30, 2014 \$(2.87)	
Increase per share attributable to the conversion of all shares of preferred stock outstanding, the automatic cashless exercise of a warrant to purchase common stock and a warrant to purchase preferred stock becoming a warrant to purchase common stock upon the closing of this offering	
Pro forma net tangible book value per share as of September 30, 2014	
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing shares in this offering	
Pro forma as adjusted net tangible book value per share after this offering	
Dilution per share to new investors purchasing shares in this offering	\$

A \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease our pro forma as adjusted net tangible book value by \$ million, our pro forma as adjusted net tangible book value per share after this offering by approximately \$ and dilution per share to new investors purchasing shares in this offering by approximately \$ , assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions. An increase of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase the pro forma as adjusted net tangible book value per share after this and decrease the dilution per share to new investors participating in this offering by approximately \$ offering by approximately \$ assuming no change in the assumed initial public offering price and after deducting estimated underwriting discounts and commissions. A decrease of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value per share after this offering by approximately \$ and increase the dilution per share to new investors participating in this offering by approximately \$ , assuming no change in the assumed initial public offering price and after deducting estimated underwriting discounts and commissions.

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 \$ per share, representing an immediate increase in pro forma as adjusted net tangible book value per share of \$ to existing stockholders and immediate dilution of \$ in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering, assuming an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus.

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 an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price	
	Number	Percent	Amount	Percent	Per Share	
Existing stockholders		<del></del> %	\$	<del></del> %	\$	
New investors					\$	
Total		100.0%	\$	100.0%		

A \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the total consideration paid by new investors by approximately \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase or decrease of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease the total consideration paid by new investors by approximately \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming no change in the assumed initial public offering price.

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 % 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 % of the total number of shares of our common stock outstanding after this offering.

The above discussion and tables exclude:

- Ÿ 3,056,805 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2014 at a weighted average exercise price of \$0.59 per share;
- Ÿ 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, upon the closing of this offering;
- Ÿ 475,844 shares of common stock available for future issuance under our 2012 Stock Incentive Plan as of September 30, 2014;
- Y additional shares of our common that will become available for future issuance under our 2015 Incentive Award Plan, which will become effective upon the closing of this offering, as well as shares of our common stock that become available pursuant to provisions in our 2015 Incentive Award Plan that automatically increase the share reserve under the 2015 Incentive Award Plan on January 1 of each calendar year as described in "Executive and Director Compensation—Incentive Plans—2015 Incentive Award Plan"; and
- Ÿ additional shares of our common stock that will become available for future issuance under our 2015 Employee Stock Purchase Plan, which will become effective upon the closing of this offering.

To the extent that outstanding options are exercised, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

#### **SELECTED FINANCIAL DATA**

You should read the following selected financial data together with our 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 statement of operations data for the years ended December 31, 2012 and 2013 and the balance sheet data as of December 31, 2012 and 2013 from our audited financial statements appearing at the end of this prospectus. The statement of operations data for the nine months ended September 30, 2013 and 2014 and the balance sheet data as of September 30, 2014 have been derived from our unaudited financial statements appearing at the end of this prospectus and have been prepared on the same basis as the audited 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 nine months ended September 30, 2014 are not necessarily indicative of the results to be expected for the full year ending December 31, 2014.

		Ended nber 31,	Nine Months Ended September 30,		
	2012	2013	2013	2014	
Ctatement of Operations Date:		(in thousands, exc			
Statement of Operations Data:	ф	ф	Φ.	Φ.	
Revenue	<u> </u>	<u> </u>	<u> </u>	<u> </u>	
Operating expenses:					
Research and development	2,077	4,805	3,288	5,658	
General and administrative	956	1,247	859	2,211	
Total operating expenses	3,033	6,052	4,147	7,869	
Loss from operations	(3,033)	(6,052)	(4,147)	(7,869)	
Other income (expense):					
Interest income (expense), net	(93)	(42)	(6)	(154)	
Revaluation of preferred stock warrant liability	<u></u>	(8)		(504)	
Total other income (expense), net	(93)	(50)	(6)	(658)	
Net loss	(3,126)	(6,102)	(4,153)	(8,527)	
Accretion of redeemable convertible preferred stock to redemption value	(276)	(875)	(654)	(1,019)	
Net loss attributable to common stockholders	\$ (3,402)	\$ (6,977)	\$ (4,807)	\$ (9,546)	
Net loss per share attributable to common stockholders, basic and diluted(1)	\$ (0.59)	\$ (1.09)	\$ (0.76)	\$ (1.42)	
Weighted average common shares outstanding, basic and diluted(1)	5,725	6,395	6,331	6,732	
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) <sup>(2)</sup>		\$ (0.36)		\$ (0.41)	
Pro forma weighted average common shares outstanding, basic and diluted (unaudited) <sup>(2)</sup>		16,873		19,536	

<sup>(1)</sup> See Note 10 to our 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.

<sup>(2)</sup> See Note 11 to our financial statements appearing at the end of this prospectus for further details on the calculation of basic and diluted pro forma net loss per share attributable to common stockholders.

	As of December 31,			As of September 30,	
	2012	2013		2014	
		(in thousands)			
Balance Sheet Data:					
Cash and cash equivalents	\$ 6,215	\$ 1,654	\$	7,120	
Working capital <sup>(1)</sup>	6,067	649		4,632	
Total assets	6,538	2,125		8,553	
Preferred stock warrant liability	_	164		668	
Long-term debt, net of discount, including current portion	_	838		2,788	
Redeemable convertible preferred stock	10,708	11,583		23,160	
Total stockholders' deficit	(4,348)	(11,116)		(19,640)	

<sup>(1)</sup> We define working capital as current assets less current liabilities.

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

You should read the following discussion and analysis of financial condition and results of operations together with the section titled "Selected Financial Data" and our 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 and other product candidates to treat enteric pathogens such as drug-resistant bacteria and metabolic diseases, such as early-stage, non-insulin dependent diabetes and 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, 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 September 30, 2014, we have financed our operations through private placements of our redeemable 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 September 30, 2014, we had received gross proceeds of \$24.0 million from such transactions and we had repaid \$0.1 million of the total \$3.0 million borrowed under the loan and security agreement. Subsequent to September 30, 2014, we received gross proceeds of \$48.0 million from the sale of 3,946,328 shares of our Series C convertible preferred stock in November 2014 and we received aggregate gross proceeds of \$65.0 million from the sale of 2,222,222 shares of our Series D convertible preferred stock in December 2014.

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 and \$8.5 million for the nine months ended September 30, 2014. As of September 30, 2014, we had an accumulated deficit of \$19.7 million.

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

- Ÿ advance the clinical development of SER-109 for the prevention of further recurrences of CDI in patients suffering from recurrent CDI, through a Phase 3 clinical trial;
- Ÿ initiate Phase 1 clinical development of SER-262 to be used following antibiotic treatment of primary CDI to prevent an initial recurrence of CDI:

- Ÿ conduct research and initiate pre-clinical and clinical development of additional Ecobiotic microbiome therapeutics in non-*C. difficile* infection and metabolic and inflammatory diseases, including SER-301 and SER-155;
- Ÿ make strategic investments in manufacturing capabilities, including potentially planning and building a small-scale commercial manufacturing facility;
- Ÿ maintain our current intellectual property portfolio and opportunistically acquire complimentary intellectual property; and
- Ÿ 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 and cash equivalents as of December 31, 2014, together with anticipated net proceeds from this offering, will enable us to fund our operating expenses and capital expenditures requirements through at least . 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:

- Y expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct research, preclinical 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;
- Ÿ salaries, benefits and other related costs, including stock-based compensation expense, for personnel in our research and development functions;
- Ÿ costs of outside consultants, including their fees, stock-based compensation and related travel expenses;

- Ÿ the cost of laboratory supplies and acquiring, developing and manufacturing pre-clinical study and clinical trial materials;
- Ÿ costs related to compliance with regulatory requirements; and
- Ÿ 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,		Nine Months Ended September 30,	
	2012	2013	2013	2014	
		(in thousands)			
Microbiome therapeutics platform	\$2,077	\$3,424	\$2,408	\$4,477	
SER-109	_	729	425	1,169	
SER-262		652	455	12	
Total research and development expenses	<u>\$2,077</u>	\$4,805	\$3,288	\$5,658	

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, continue to discover and develop additional product candidates, including SER-155 and SER-301, and pursue later stages of clinical development of our product candidates.

#### General and Administrative Expenses

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

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support the expected growth in our research and development activities and the potential commercialization of our product candidates. We also expect to incur increased expenses associated with being a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs and investor and public relations costs.

#### Other Income (Expense), Net

Interest Income (Expense), Net. Interest income (expense), net consists of interest earned on our cash and cash equivalents and interest expense incurred on our debt. In 2013 and 2014, 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 redeemable 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 redeemable 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. Upon the closing of this offering, the underlying redeemable 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, 2013, we had federal and state net operating loss carryforwards of \$7.9 million and \$7.7 million, respectively, both of which begin to expire in 2031. As of December 31, 2013, we also had federal and state research and development tax credit carryforwards of \$0.3 million and \$0.2 million, respectively, which begin to expire in 2031 and 2026, respectively.

# Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States of America. The preparation of our financial statements and related disclosures requires us to make estimates 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 financial statements and, therefore, consider these to be our critical accounting policies. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.

#### Accrued Research and Development Expenses

As part of the process of preparing our 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 predetermined 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:

- Ÿ CROs in connection with performing research services on our behalf and clinical trials;
- Ÿ investigative sites or other providers in connection with clinical trials;
- Ÿ vendors in connection with pre-clinical and clinical development activities; and
- Ÿ 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 nonemployees 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 nonemployees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option-pricing model.

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

the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. Because we are currently a private company and lack company-specific historical and implied volatility information, we estimate our expected volatility based on the historical volatility of a group of publicly traded peer companies. We expect to continue to do so until such time as we have adequate historical data regarding the volatility of our traded stock price. We use the simplified method prescribed by Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term of options granted to employees and directors. We base the expected term of options granted to consultants and nonemployees 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 En Decembe		Nine Months Ended September 30,	
	2012	2013	2013	2014
Risk-free interest rate	0.92%	1.27%	1.08%	1.84%
Expected term (in years)	6.0	6.0	6.0	6.0
Expected volatility	109.4%	85.9%	86.5%	84.1%
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 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 statements of operations:

		Ended nber 31,		Nine Months Ended September 30,	
	2012	2013	2013	2014	
		(in t	housands)		
Research and development	\$26	\$177	\$ 137	\$ 344	
General and administrative	2	32	23	356	
	\$28	\$209	\$ 160	\$ 700	

#### Determination of the Fair Value of Common Stock

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

In the absence of a public trading market for our common stock, our determination of the fair value of our common stock was performed using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants' *Audit and Accounting Practice Aid Series: 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 and \$7.79 per share as of November 17, 2014. 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:

- Ÿ 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;
- Ÿ the progress of our research and development programs, including the status of pre-clinical studies and clinical trials for our product candidates;
- Ÿ our stage of development and commercialization and our business strategy;
- Ÿ external market conditions affecting the biotechnology industry;
- Ÿ trends within the biotechnology industry;
- Y our financial position, including cash on hand and our historical and forecasted performance and operating results;
- Ÿ the lack of an active public market for our common stock and our preferred stock;
- Ÿ 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
- $\ddot{Y}$  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

#### Valuation Methodologies

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

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

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

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

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

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

#### Option Grants

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

Grant Date	Number of Shares Subject to Options Granted	Exerc	Share ise Price otions <sup>(1)</sup>	Comm per S Date	Value of non Stock Share on of Option Grant	Estim Va	Share lated Fair llue of ons <sup>(2)(3)</sup>
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 1, 2014	206,500	\$	3.14	\$	6.70(5)	\$	5.42
December 9, 2014	320,192	\$	7.79	\$	7.79	\$	5.56

<sup>(1)</sup> 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.

<sup>(2)</sup> 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 nonemployees, 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 nonemployees reflect only the grant-date fair value of options granted to nonemployees 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 1, 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 1, 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 initial public offering 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 Redeemable Convertible Preferred Stock

We classify a warrant to purchase shares of our Series A-2 redeemable 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 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 redeemable 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 redeemable convertible preferred stock, results obtained from third-party valuations and additional factors that we deem relevant. We have historically been a private company and lack company-specific historical and implied volatility information of our stock. Therefore, we estimate expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrant. The risk-free interest rate is determined

by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrant. We have estimated a 0% dividend yield based on the expected dividend yield and the fact that we have never paid or declared dividends.

Upon the closing of this offering, the underlying redeemable 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 Nine Months Ended September 30, 2013 and 2014

The following table summarizes our results of operations for the nine months ended September 30, 2013 and 2014:

		Nine Months Ended September 30,		
	2013 2014		(Decrease)	
		(in thousands)		
Revenue	<u>\$ — </u>	<u>\$ — </u>	<u>\$</u>	
Operating expenses:				
Research and development	3,288	5,658	2,370	
General and administrative	859	2,211	1,352	
Total operating expenses	4,147	7,869	3,722	
Loss from operations	(4,147)	(7,869)	(3,722)	
Other income (expense):				
Interest income (expense), net	(6)	(154)	(148)	
Revaluation of preferred stock warrant liability		(504)	(504)	
Total other income (expense), net	(6)	(658)	(652)	
Net loss	\$(4,153)	\$(8,527)	\$ (4,374)	

# Research and Development Expenses

	Nine Mor	Nine Months Ended		
	Septe	mber 30,	Increase	
	2013	2014	(Decrease)	
		(in thousands)		
Microbiome therapeutics platform	\$2,408	\$4,477	\$ 2,069	
SER-109	425	1,169	744	
SER-262	<u>455</u>	12	(443)	
Total research and development expenses	<u>\$3,288</u>	\$5,658	\$ 2,370	

Research and development expenses were \$3.3 million for the nine months ended September 30, 2013, compared to \$5.7 million for the nine months ended September 30, 2014. The increase of \$2.4 million was due primarily to the following:

- Ÿ an increase of \$2.1 million in research expenses related to our microbiome therapeutics platform, due primarily to higher payroll and consultant costs of \$0.9 million and, to a lesser extent, higher lab supplies costs, facility-related costs and licensing costs;
- Ÿ an increase of \$0.7 million in expenses related to our SER-109 program, due primarily to higher clinical trial costs, partially offset by lower animal studies costs; and
- Ÿ a decrease of \$0.4 million in expenses of our SER-262 program due to our shifted focus to SER-109 and our microbiome therapeutics platform research. Beginning in 2015, we expect to increase our expenses in connection with our current pre-clinical and planned clinical development activities related to SER-262

We expect that our research and development expenses will continue to increase in the foreseeable future as we initiate clinical trials for certain product candidates, including SER-262, continue to discover and develop additional product candidates, including SER-301 and SER-155, and pursue later stages of clinical development of our product candidates.

# General and Administrative Expenses

		ths Ended nber 30,	Increase
	2013	2014	(Decrease)
	· <u> </u>	(in thousands)	
Personnel related (including stock-based compensation)	\$ 364	\$ 861	\$ 497
Professional fees	399	1,036	637
Facility-related and other	96	314	218
Total general and administrative expenses	\$ 859	\$ 2,211	\$ 1,352

General and administrative expenses were \$0.9 million for the nine months ended September 30, 2013, compared to \$2.2 million for the nine months ended September 30, 2014. The increase of \$1.4 million was primarily due to an increase in professional fees of \$0.6 million, an increase in personnel related costs of \$0.5 million (including an increase of \$0.3 million in stock-based compensation) and an increase in facility-related and other costs of \$0.2 million. Personnel related costs increased primarily due to the hiring of eight new employees to support corporate operations and business development activities, including the hiring of our Chief Executive Officer in June 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 an amendment of our lease to increase the rentable square footage.

#### Other Income (Expense), Net

Other income (expense), net for the nine months ended September 30, 2013 was an expense of \$6,000, compared to an expense of \$0.7 million for the nine months ended September 30, 2014. During the nine months ended September 30, 2014, there was an increase of \$0.1 million in interest expense incurred on borrowings under our loan and security agreement, as compared to the nine months ended September 30, 2013. In addition, loss from revaluation of preferred stock warrant liability for the nine months ended September 30, 2014 included a \$0.5 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 redeemable 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. There was no such expense recorded during the nine months ended September 30, 2013.

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

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

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

General and Administrative Expenses

	Year Ended		
	Dece	mber 31,	Increase
	2012	2013	(Decrease)
		(in thousands)	
Personnel related (including stock-based compensation)	\$633	\$ 419	(214)
Professional fees	233	691	458
Facility-related and other	90	<u>137</u>	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 redeemable convertible preferred stock, the issuance of convertible promissory notes and borrowings under our loan and security agreement. From our inception through September 30, 2014, we had received gross proceeds of \$24.0 million from such transactions and we had repaid \$0.1 million of the total \$3.0 million borrowed under the loan and security agreement. As of September 30, 2014, we had cash and cash equivalents totaling \$7.1 million and an accumulated deficit of \$19.7 million. Subsequent to September 30, 2014, we received gross proceeds of \$48.0 million from the sale of 3,946,328 shares of our Series C convertible preferred stock in November 2014 and we received aggregate gross proceeds of \$65.0 million from the sale of 2,222,222 shares of our Series D convertible preferred stock and 1,388,889 shares of our Series D-1 convertible preferred stock in December 2014. In conjunction with the closing of the Series C convertible preferred stock financing, the redemption rights of our Series A, Series A-2 and Series B preferred stock were removed.

On September 9, 2013, we entered into the loan and security agreement, which provided for total borrowings of up to \$3.0 million. Through September 30, 2014, we had borrowed the full \$3.0 million available under the loan and security agreement and had made \$0.1 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% (which equated to 6.25% at September 30, 2014). In addition, a final payment of \$60,000 is due upon the earlier of the maturity date, acceleration of the term loans or prepayment of all or part of the term loans. Borrowings under the loan and security agreement are secured by substantially all of our assets, except for our intellectual property, which is subject to a negative pledge.

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

In connection with entering into the loan and security agreement, in September 2013, we issued the lender a warrant to purchase 92,127 shares of our Series A-2 redeemable 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		Nine Months Ended September 30,	
	Decem	per 31,	Septem	per 30,	
	2012	2013	2013	2014	
		(in thou	ısands)		
Cash used in operating activities	\$(2,925)	\$(5,321)	\$(3,687)	\$ (6,243)	
Cash used in investing activities	(319)	(184)	(150)	(729)	
Cash provided by financing activities	9,435	944	944	12,438	
Net increase (decrease) in cash and cash equivalents	\$ 6,191	\$(4,561)	\$(2,893)	\$ 5,466	

Operating Activities. During the nine months ended September 30, 2013, operating activities used \$3.7 million of cash, primarily resulting from our net loss of \$4.2 million, partially offset by non-cash charges of \$0.2 million and by cash provided by changes in our operating assets and liabilities of \$0.2 million. Our non-cash charges during the nine months ended September 30, 2013 consisted of stock-based compensation expense of \$0.2 million and depreciation and amortization expense of \$0.1 million. Net cash provided by changes in our operating assets and liabilities during the nine months ended September 30, 2013 consisted primarily of a \$0.2 million increase in accounts payable and a \$0.1 million increase in accounts payable was due to the timing of vendor invoicing and payments. The increase in our accrued expenses and other current liabilities was primarily due to an increase in our accruals for consultant fees.

During the nine months ended September 30, 2014, operating activities used \$6.2 million of cash, primarily resulting from our net loss of \$8.5 million, partially offset by non-cash charges of \$1.7 million and by cash provided by changes in our operating assets and liabilities of \$0.6 million. Our net non-cash charges during the nine months ended September 30, 2014 consisted of stock-based compensation expense of \$0.7 million, expenses from the revaluation of our preferred stock warrant of \$0.5 million, license fees paid by issuance of a common stock warrant of \$0.3 million, non-cash interest expense of \$0.1 million and depreciation and amortization expense of \$0.1 million. Net cash provided by changes in our operating assets and liabilities during the nine months ended September 30, 2014 consisted primarily of a \$0.5 million increase in accounts payable and a \$0.3 million increase in accrued expenses and other current liabilities, both partially offset by a \$0.2 million increase in prepaid expenses and other current assets. The increases in our accounts payable and prepaid expenses and other current assets were due to the timing of vendor invoicing and payments. The increase in our accrued expenses and other current liabilities was primarily due to an increase in our accruals for rent and facility-related costs.

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.

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. Our net non-cash charges in the year consisted primarily of stock-based compensation expense of \$0.2 million and depreciation and amortization expense of \$0.1 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 our accrued expenses and other current liabilities was primarily due to an increase in our accruals for consultant fees.

*Investing Activities.* During the nine months ended September 30, 2013, we used \$0.2 million of cash in investing activities, primarily consisting of purchases of property and equipment.

During the nine months ended September 30, 2014, we used \$0.7 million of cash in investing activities, consisting of purchases of property and equipment of \$0.6 million and an increase in restricted cash of \$0.1 million related to our facility lease, which we expect to be returned at the completion of the lease.

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 nine months ended September 30, 2013, net cash provided by financing activities was \$0.9 million as a result of net proceeds of \$0.9 million received from borrowings under our loan and security agreement.

During the nine months ended September 30, 2014, net cash provided by financing activities was \$12.4 million as a result of net proceeds of \$10.6 million received from our sale of Series B redeemable convertible preferred stock and \$2.0 million from borrowings under our loan and security agreement, partially offset by principal repayments of \$0.1 million of 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 redeemable convertible preferred stock and proceeds of \$0.5 million from our issuance of convertible promissory notes, which were converted to Series A redeemable convertible preferred stock.

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.

# **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:

- Ÿ conduct our Phase 3 clinical trial of SER-109, our lead product candidate;
- Ÿ continue the research and development of our other product candidates, including commencing clinical trials for SER-262;

- Ÿ seek to enhance our microbiome therapeutics platform and discover and develop additional product candidates, including SER-301 and SER-155:
- Ÿ seek regulatory approvals for any product candidates that successfully complete clinical trials;
- Ÿ potentially establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- Ÿ maintain, expand and protect our intellectual property portfolio;
- Ÿ 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
- Ÿ 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 and cash equivalents as of December 31, 2014, together with anticipated net proceeds from this offering, will enable us to fund our operating expenses and capital expenditures requirements through at least . 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:

- $\ddot{\mathrm{Y}}$  the commencement, progress and results of our Phase 3 clinical trial of SER-109;
- Ÿ the cost of manufacturing clinical supplies of our product candidates;
- Ÿ the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for our other product candidates, including SER-262;
- Ÿ the costs, timing and outcome of regulatory review of our product candidates;
- Ÿ 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;
- $\dot{Y}$  the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- Ÿ 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;
- Ÿ the effect of competing technological and market developments; and
- Ÿ 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 September 30, 2014 and the effect such obligations are expected to have on our liquidity and cash flow in future periods:

Payments Due by Period					
	Less Than			More Than	
Total	1 Year	1 - 3 Years	4 - 5 Years	5 Years	
		(in thousands)			
\$2,314	\$ 678	\$ 1,397	\$ 239	\$ —	
3,175	1,343	1,832			
\$5,489	\$ 2,021	\$ 3,229	\$ 239	<u> </u>	
	\$2,314 3,175	Total         Less Than 1 Year           \$2,314         \$ 678           3,175         1,343           \$5,489         \$ 2,021	Less Than 1 Year         1 - 3 Years           (in thousands)         \$2,314         \$ 678         \$ 1,397           3,175         1,343         1,832           \$5,489         \$ 2,021         \$ 3,229	Less Than 1 Year         1 - 3 Years         4 - 5 Years           (in thousands)         \$2,314         \$ 678         \$ 1,397         \$ 239           3,175         1,343         1,832         —           \$5,489         \$ 2,021         \$ 3,229         \$ 239	

1) We lease laboratory and office space in Cambridge, Massachusetts under an operating lease agreement that expires on January 31, 2018.

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

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

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

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

# **Recently Issued Accounting Pronouncements**

In June 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-10, Development Stage Entities. The amendments in this update removed all incremental financial reporting requirements, including inception-to-date information and certain other disclosures currently required under GAAP, in the financial statements of development stage

companies. The amendments are effective for annual reporting periods beginning after December 15, 2014 and interim reporting periods beginning after December 15, 2015. Early adoption is permitted. We elected to early adopt this guidance and, therefore, have not presented inception-to-date and other related disclosures in our financial statements.

In July 2013, the FASB issued changes to the presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. These changes require an entity to present an unrecognized tax benefit as a liability in the financial statements if (i) a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the applicable jurisdiction to settle any additional income taxes that would result from the disallowance of a tax position, or (ii) the tax law of the applicable jurisdiction does not require the entity to use, and the entity does not intend to use, the deferred tax asset to settle any additional income taxes that would result from the disallowance of a tax position. Otherwise, an unrecognized tax benefit is required to be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward. These changes became effective for us as of January 1, 2014, and the adoption of this guidance did not have a significant impact on our 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.

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 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. Our cash and cash equivalents consist of cash and money market accounts. 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 be expected to have a material impact on the fair market value of our investment portfolio or on our financial condition or results of operations.

#### **BUSINESS**

#### Overview

We are a microbiome therapeutics platform company developing a novel class of biological drugs, which we refer to as Ecobiotic microbiome therapeutics. The human microbiome is an ecology of microorganisms, including bacteria, fungi and viruses, that, when unhealthy, or dysbiotic, can leave the body more susceptible to infections, metabolic disorders, allergies, autoimmune disease, inflammation and other conditions. Our drugs are designed to restore health by repairing the function of a dysbiotic microbiome. We are initially focused on implementing our microbiome therapeutics platform to develop Ecobiotic microbiome therapeutics that treat dysbiosis in the colonic microbiome, one of the most diverse microbiomes in the human body. SER-109, our lead product candidate and, if approved by the FDA, could be a first-in-field drug, is designed to prevent further recurrences of *Clostridium difficile* infection, or CDI, a debilitating infection of the colon. In our Phase 1/2 clinical study of SER-109 in recurrent CDI patients, 97% of patients achieved a clinical cure, which we define as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing. Based on these data and ongoing discussions with the United States Food and Drug Administration, or FDA, we plan to begin enrollment for a Phase 3 clinical trial of SER-109 for recurrent CDI in the first half of 2015.

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, such as gastrointestinal infection and inflammatory and metabolic diseases.

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

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

Our approach to discovery and design is based on an iterative bedside-to-bench-to-bedside approach 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 set we have generated through our SER-109 clinical trial. We believe we can impute 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 bacterial spores 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 a leading 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 14,000 Americans each year. We estimate the incidence of primary CDI in the United States is about 783,000 patients per year. While the epidemiological data are varied outside the United States, we believe that, due to the widespread use of antibiotics, CDI is a growing global disease. The standard of care for CDI is to treat with antibiotics. In many cases, antibiotic treatments may resolve the acute infection caused by C. difficile. However, these antibiotic treatments kill bacteria indiscriminately, inducing a dysbiosis of the microbiome and potentially making patients more susceptible to a recurrence of CDI. For those patients who experience a recurrence of their CDI, we believe it is this dysbiosis of the microbiome, not the presence of C. difficile, which is the proximal cause of disease. Research suggests that the risk of recurrence is approximately 25% after the primary occurrence of CDI, 40% after a first recurrence and greater than 60% for those experiencing two or more recurrences. In addition, a recent randomized trial comparing two antibiotics for the treatment of primary CDI indicated that 8% of patients receiving fidaxomicin and 9% of patients receiving vancomycin did not respond to these antibiotics two days after completing their antibiotic regimen. Based on this information, we estimate that the addressable population of patients in the United States with recurrent CDI, defined as patients who have experienced at least three occurrences of CDI in the past nine months, is approximately 103,000 patients per year.

SER-109 is an approximately 50 strain bacterial spore ecology created 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 1/2 clinical study, 29 of 30 patients, or 97%, achieved a clinical cure, which we define as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing. The study demonstrated that SER-109 is well-tolerated and has a favorable safety profile with no serious adverse

events considered by the investigators to be attributable to SER-109 treatment. We also performed an analysis of the microbiome using next-generation sequencing technology and microbiological analysis. These studies demonstrated a re-establishment of keystone organisms and a rapid increase in bacterial diversity, which enable the restoration of the microbiome to a healthy state. Based on these results, we are in the process of manufacturing SER-109 for use in clinical trials and plan to initiate a Phase 3 clinical trial for SER-109 for recurrent CDI in the first half of 2015. We plan to conduct manufacturing process validation studies for SER-109 in the second half of 2015 to support a biologics license application and commercial launch.

We believe the results of our open label Phase 1/2 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 15 strains of bacteria that are a subset of the bacterial ecology comprising SER-109. Unlike SER-109, SER-262 strains are clonally isolated and produced in fermenters and do not require donations from human sources. Pre-clinical studies of SER-262 have demonstrated efficacy in preventing the initial recurrence of CDI in mouse and hamster models. We intend to commence clinical studies of SER-262 in the second half of 2015.

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

The following chart summarizes our current product pipeline:

Program	Discovery	Pre-Clinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones
SER-109 Recurrent CDI						Begin enrollment of Phase 3 clinical trial in the first half of 2015
SER-262 Primary CDI <sup>(1)</sup>		-				Commence clinical studies in the second half of 2015
SER-155 Drug-resistant bacteria & post-antibiotic restoration						Continue pre-clinical screening efforts to identify indication. Commence clinical studies in first half of 2016
SER-301 Crohn's diseases & Diabetes		-				Commence clinical studies in first half of 2016

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

We have assembled a world class group of scientists, clinicians, directors and investors, who have established our leadership in the field of microbiome therapeutics. We were co-founded by Drs. Noubar Afeyan, David Berry and Geoffrey von Maltzahn of Flagship VentureLabs, the innovation foundry of Flagship Ventures, which has founded 28 life sciences companies. Through Flagship VentureLabs' contribution of foundational scientific concepts and intellectual property, assembly of our management team and critical early-stage support, we launched as the first company focused on the ecological nature of the microbiome. Led by Dr. Roger Pomerantz, our Chairman, President and Chief Executive Officer, our experienced management team possesses core capabilities in microbiome therapeutics, infectious disease, drug development, commercialization, chemistry, manufacturing and controls, or CMC, public company management and finance. Dr. Pomerantz, an infectious disease physician-scientist, has extensive experience in infectious disease drug development and commercialization, licensing and acquisitions over a 10-year career in senior executive positions at Merck & Co, Johnson & Johnson and Tibotec Pharmaceuticals. Dr. Pomerantz led the development and commercialization of eight FDA-approved infectious disease drugs in his career. In addition to Dr. Pomerantz, our management team includes Mr. Eric Shaff, Dr. David Cook, Dr. John Aunins, Dr. Michele Trucksis and Dr. Matthew Henn. Collectively, our management team has successfully developed 18 approved pharmaceutical drugs in infectious disease and other indications. Our management team has extensive experience in microbial ecology, microbiology and live biologicals, with a collective 23 years studying the microbiome and over 60 published papers on the science of the microbiome. Additionally, our team has extensive experience in building out commercial capabilities in specialty diseases and has a track record for success in launching vaccine products, which have analogous manufacturing processes to that of Ecobiotic microbiome therapeutics. In November 2014 and December 2014, we completed two preferred stock financings, which included as investors several prominent mutual funds and healthcare dedicated funds, as well as a multinational health-science company.

# **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:

- Ÿ Rapidly advancing the development of our lead product candidate, SER-109, for the prevention of further recurrences of CDI in patients with recurrent CDI. Based on the results from our recently completed Phase 1/2 clinical study of SER-109, we plan to conduct a Phase 3 clinical trial in patients with three or more occurrences of CDI within the previous nine months. We have submitted an investigational new drug application, or IND, to the FDA and are currently in discussions with the FDA to finalize the trial design. We expect to enroll 135 patients in a double-blinded and placebo controlled clinical trial, with patients randomized in a ratio of 2:1 into a SER-109 arm or placebo arm. We expect the primary endpoint of the trial will be the absence of CDI recurrence requiring antibiotic treatment during the eight-week follow-up period after dosing. We also plan to follow patients for an additional four weeks to document the safety profile of SER-109 compared to a placebo. We expect secondary endpoints to include the time to CDI recurrence and the proportion of patients experiencing CDI recurrence at four weeks and 12 weeks. We also plan to compare changes in the composition of the colonic microbiome from baseline to week eight post-treatment using genomic analysis. In addition, subjects that recur in either arm of the study will have the option to enroll in a parallel open label safety study in which patients will receive SER-109. We plan to initiate a Phase 3 clinical trial for SER-109 for recurrent CDI in the first half of 2015.
- Ÿ Advancing the clinical development of SER-262 to be used following antibiotic treatment of primary CDI to prevent an initial recurrence of CDI. We are developing SER-262 as a therapeutic to be used following antibiotic treatment of primary CDI to prevent an initial

recurrence of CDI. SER-262 contains a subset of the bacterial ecology comprising SER-109, however, SER-262 is not derived from human stool and is made in bacterial fermenters in a rational *in vitro* design. Pre-clinical studies of SER-262 have demonstrated efficacy similar to SER-109 in mouse and hamster models of CDI. We intend to commence clinical studies of SER-262 in the second half of 2015.

- Ż Developing SER-155 for the treatment of antibiotic resistant bacteria and SER-301 for the treatment of Crohn's disease and early-stage, non-insulin dependent diabetes. We are currently designing and developing SER-155, a 9 strain Ecobiotic microbiome therapeutic that is expected to have activity against enteric bacterial pathogens. We expect SER-155 to be used for the treatment of antibiotic-resistant bacteria to eliminate colonization and prevent infection. We anticipate filing an IND to initiate exploratory clinical trials with SER-155 in the first half of 2016. We also have an active pre-clinical program to develop SER-301 for the treatment of Crohn's disease and early-stage, non-insulin dependent diabetes, which, based on current research and our experience with SER-109, we believe can be treated by restoring the underlying dysbiotic microbiome. We anticipate filing an IND to initiate exploratory clinical trials with SER-301 in the first half of 2016.
- Y Leveraging our leading microbiome therapeutics platform to develop additional innovative and novel Ecobiotic microbiome therapeutics across a range of medical conditions with high unmet need. We believe that the combination of experience, proprietary data and proprietary know-how related to the microbiome and of the production of microbial strains provides us a competitive advantage in the design and development of microbiome therapeutics. Our platform enables us to build upon our existing and growing clinical experience to rationally approach the treatment of acute and complex chronic diseases. We intend to leverage this advantage to develop additional innovative Ecobiotic microbiome therapeutics.
- Y Commercializing our Ecobiotic microbiome therapeutics, including SER-109, directly in the United States and with collaborators outside the United States. We have retained the worldwide rights to SER-109 and SER-262 and expect to initially maintain similar rights with respect to other Ecobiotic microbiome therapeutics we develop. We believe the market for recurrent CDI is sufficiently concentrated to permit us to effectively commercialize SER-109 in the United States with a direct sales force of less than 100 individuals. We intend to leverage the experience gained by commercializing SER-109 in the United States to further build our direct sales force to address the larger patient population to be addressed by SER-262. Outside the United States and for chronic diseases in larger populations, we expect to rely on collaborators to commercialize our Ecobiotic microbiome therapeutics.
- Y Developing manufacturing capabilities sufficient to support commercialization of any approved Ecobiotic microbiome therapeutic candidates. If approved by the FDA, we believe SER-109 could be a first-in-field drug, which will require manufacturing capabilities that are distinct from other biologic drugs. We intend to make strategic investments in manufacturing capabilities to help ensure that we maintain control of our know-how and also because we believe these capabilities will be necessary and highly advantageous for the development of future Ecobiotic microbiome therapeutics such as SER-262. Our bioprocess and manufacturing personnel are focused on creating a platform of manufacturing expertise that will set the stage for further advances in the emerging field of microbiome therapeutics.

#### **Understanding the Microbiome and Its Impact on Disease**

The human microbiome is one of the richest and most diverse ecosystems on earth with a population of more than 100 trillion microorganisms that live in our intestines, mouth, skin and elsewhere in the body. These microbiomes have numerous beneficial functions necessary to

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

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

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

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

- Ÿ The results of a study published in *PLOS Pathogens* in 2012 suggested that a mixture of six different bacteria found naturally in the gastrointestinal system of mice, when isolated from stool and reintroduced into the infected mice, was effective at suppressing CDI. Researchers in the study found that a single treatment of the bacteria was sufficient and that the suppression lasted for months.
- Ÿ An article published in the *Annals of the New York Academy of Sciences* in 2011 reviewed data from various animal and human studies linking alterations in the colonic microbiome with type 1 diabetes. The article concluded, among other things, that the microbiota in the gastrointestinal tract, through their impact on the development of the immune system and the structure of the intestine, are vital to the pathogenesis of type 1 diabetes, though the mechanisms by which this occurred were still unclear.
- Y A study published in *Nature* in 2006 suggested that the microbiome of obese mice demonstrated an increased capacity to harvest energy from the diet. Additionally, the study suggested this trait was transmissible, and the colonization of germ-free mice with the microbiota from obese mice resulted in significantly greater total body fat than colonization with microbiota from a lean mouse. These results suggest the microbiome of the gastrointestinal tract is a contributing factor to the pathophysiology of obesity.

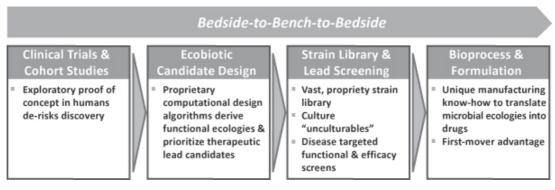
Ÿ An article published in *Science* in 2011 suggested that a bacterium found in the gastrointestinal tract of humans appeared to keep mice safe from food allergies. The study noted that mice given antibiotics early in life were far more susceptible to peanut sensitization, a model of human peanut allergy. When these mice were given a solution containing Clostridia, a common class of bacteria found in the gastrointestinal tract, the animals' peanut sensitization disappeared. The same reaction was not obtained when another common type of bacteria, bacteroides, was introduced to similarly situated mice. Researchers concluded that the Clostridia were operating in the gastrointestinal tract to keep peanut proteins that caused allergic reactions out of the blood stream.

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

# **Our Microbiome Therapeutics Platform**

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

Our microbiome therapeutics platform integrates genomic and related data sets, proprietary algorithms and computational analysis, sequencing and screening and clinical insights. This allow us to design microbiology algorithms that enable the rational design, testing, optimization, formulation and manufacturing of Ecobiotic microbiome therapeutics. Our microbiome therapeutics platform provides a framework that we believe can significantly reduce the time typically required to advance therapeutics to the clinic. The following diagram depicts the steps in our fully end-to-end microbiome therapeutics platform:

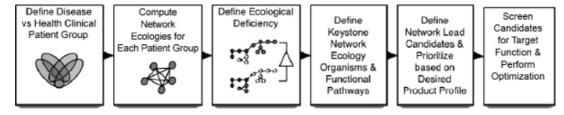


#### Clinical Trials and Cohort Studies

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

#### **Ecobiotic Candidate Design**

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



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

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

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

#### Strain Library and Lead Screening

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

# **Bioprocess and Formulation**

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

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

#### Pre-clinical and Clinical Testing

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

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

# **Our Management Team**

We were co-founded by Drs. Noubar Afeyan, David Berry and Geoffrey von Maltzahn of Flagship VentureLabs, the innovation foundry of Flagship Ventures, which has founded 28 life sciences companies. Through Flagship VentureLabs' contribution of foundational scientific concepts and intellectual property, assembly of our management team and critical early–stage support, we launched as a company focused on the ecological nature of the microbiome. We are led by a team of experienced pharmaceutical industry executives and recognized experts in infectious diseases, microbiome therapeutics and biological manufacturing.

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

#### **Our Product Pipeline**

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

The following chart summarizes our current product pipeline:



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

#### **Our CDI Product Candidates**

We are developing SER-109 as an Ecobiotic microbiome therapeutic designed to prevent further recurrences of CDI in patients suffering from recurrent CDI, defined as at least three occurrences of CDI in a nine-month period, by restoring the dysbiotic microbiome to a healthy state. In our recently completed Phase 1/2 clinical study, 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. Additionally, 29 of 30 patients, or 97% of patients, achieved a clinical cure, which we define as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing. The results of the trial suggest a favorable safety profile with no serious adverse events considered by the investigators to be attributable to SER-109. We also performed an analysis of the microbiome using next-generation sequencing technology and microbiological analysis. These studies demonstrated a re-establishment of keystone organisms and a rapid increase in bacterial diversity, which enable the restoration of the microbiome towards a healthy state. Based on these results, we are in the process of manufacturing SER-109 for use in clinical trials and plan to initiate a Phase 3 clinical trial for SER-109 for recurrent CDI in the first half of 2015. We plan to conduct manufacturing process validation studies for SER-109 in the second half of 2015 to support a biologics license application and commercial launch.

We are also developing SER-262 to be used following antibiotic treatment of primary CDI to prevent an initial recurrence of CDI. Pre-clinical studies of SER-262 have demonstrated efficacy similar to SER-109 in mouse and hamster models of CDI. We intend to commence clinical studies of SER-262 in the second half of 2015.

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

#### Clostridium difficile Infection, or CDI

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

CDI is generally not present in healthy adults, although approximately 1% to 5% of adults may carry low levels of *C. difficile* without clinical symptoms. CDI is most often associated with the prior use of antibiotics, although age and poor immune status are important risk factors as well. Antibiotics are thought to decrease resistance to CDI by causing dysbiosis in the microbiome. Since *C. difficile* spores are able to survive for long periods of time outside the body, and because health care 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, or drugs that inhibit or prevent the function of cells, and they may be heavily treated with antibiotics to treat infections. More recently, the rise of community-acquired CDI has been recognized as a growing problem.

The U.S. Centers for Disease Control, or CDC, has identified C. difficile as one of the top three most urgent antibiotic-resistant bacterial threats in the United States. It is the leading cause of hospital acquired infection in the United States, having overtaken MRSA. CDI is responsible for the deaths of approximately 14,000 Americans each year. CDI is also very costly to the healthcare system. According to a study published in Clinical Infectious Diseases, the economic burden of CDI in 2008 in U.S. acute care facilities alone was estimated to be as much as \$4.8 billion. In addition, a summary of studies published in 2009 in The Journal of Hospital Infection, calculated that the treatment cost per episode of primary CDI was as much as \$5,000 and as much as \$18,000 per recurrence of CDI. The CDC estimates the incidence of primary CDI by focusing on 10 catchment areas covering 11 million residents. Based on this analysis, it is estimated that there are approximately 483,000 new cases of primary CDI per year. Further, according to a 2014 article in the American Journal of Infection Control, from 2001 to 2010, incidence of CDI per 1,000 patients discharged increased from 4.5 to 8.2 with an average hospital stay of eight days. However, we believe the CDC method underestimates incidence based on several factors. First, residents who are diagnosed outside of their catchment area are not included in estimates. Second, many of the CDC diagnostic labs use a lower sensitivity test, which results in about 17% lower detection rates than the current most sensitive method. In addition, the CDC approach misses community cases, which are estimated to account for 30% to 40% of total cases. As a result, we estimate the incidence of primary CDI in the United States is about 783,000 patients per year. Additional research suggests that the risk of recurrence is approximately 25% after primary CDI, 40% after a first recurrence and greater than 60% for those experiencing two or more recurrences. In addition, in a recent randomized trial comparing two antibiotics for primary CDI, 8% of patients receiving fidaxomicin and 9% of patients receiving vancomycin did not respond two days after completing their antibiotic regimen. Based on this information, we estimate that the addressable population of patients in the United States with recurrent CDI, defined as patients who have experienced at least three occurrences of CDI in the past nine months, is approximately 103,000 patients per year.

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

# Current treatment alternatives and their limitations

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

#### **Antibiotics**

The current standard of care for CDI is to treat with antibiotics, such as metronidazole and vancomycin. Metronidazole has been found to be ineffective in approximately 29% of cases and is not recommended beyond initial infection. Vancomycin is more expensive, but has a lower relapse rate of 25%. In addition, fidaxomicin, a recently approved antibiotic for CDI, may have higher initial efficacy compared to metronidazole, but it does not have a label claim to reduce or prevent CDI recurrence. No antibiotic therapeutics are currently approved for treatment of recurrence of CDI.

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

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

#### Fecal microbiota transplantation

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

# Probiotic therapies

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

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

#### SER-109

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

SER-109 is formulated as oral capsules for single-dose administration after completion of antibiotics. A single dose of SER-109 comprises 100 million spores that we anticipate delivering in four small oral capsules. The spores in SER-109 are intended to germinate in the gastrointestinal tract and immediately compete for the same nutrients required by *C. difficile*. The spore forming organisms from SER-109 are also intended to shift the balance of bile acids toward secondary acids that are less efficient for promoting germination of *C. difficile* spores. The following picture is a commercial prototype of a single dose of SER-109 (and is not necessarily a single dose of SER-109 for Phase 3 clinical trials):



# Study design

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

Part 1 of the study evaluated a single dose of SER-109 administered orally in 30 capsules over two days, with the dose derived from approximately 75 grams of stool. Part 2 of the study evaluated a

single dose of SER-109 administered orally in a range of one to 12 capsules over one day. The dose in Part 2 was based on spore count, as opposed to fecal mass, which is expected to allow for a more precise dosing regimen. The target dose in Part 2 was 1x108 spores per dose, which was approximately 15-fold lower than the mean dose in Part 1. The SER-109 doses were derived from seven different healthy human donors. Prior to receiving treatment with SER-109, patients were on antibiotic therapy consisting of either fidaxomicin, vancomycin or metronidazole to control their CDI symptoms. At least 24 hours prior to starting treatment with SER-109, antibiotic therapy was discontinued.

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

<u>Cohort</u>	Mean Dose (spore units)	Male/Female	Age Median (Range)	Number of CDI Recurrences in Prior 12 months Median (Range)
1	1.5x10 <sup>9</sup>	5 / 10	71 years (22 – 88)	3 (2 – 6)
2	1.0x10 <sup>8</sup>	5 / 10	58 years (39 – 83)	3(2-5)

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

#### Study results

Efficacy. Twenty-six of 30 patients, or 87% of patients, in the Phase 1/2 clinical study achieved the primary efficacy endpoint of experiencing no recurrence of CDI during the eight weeks post-treatment. These 26 patients consisted of 13 patients in each of Part 1 and Part 2 of the study, all of whom also tested negative for *C. difficile* at Week 8. Among the 26 patients was one patient who experienced an initial recurrence on Day 26 and was re-treated, per protocol, with a dose from the same donor. Following re-treatment, this patient also achieved the primary efficacy endpoint and tested negative for *C. difficile* carriage at Week 8 after re-treatment. Efficacy results were not dependent upon the initial human donor or the dose over the range of 3.4x10<sup>7</sup> to 2.3x10<sup>10</sup> spores.

One patient had a recurrence of CDI on Day 5 and did not receive a second treatment with SER-109. The three other patients who failed the protocol-defined primary efficacy endpoint were determined by their attending investigator to be recovering from their diarrheal episode by the time they submitted their stool sample for CDI testing. In each case, the investigator advised the patient to refrain from antibiotic use and the patients' condition resolved without antibiotic therapy. All three patients

were determined to be clinically CDI free at eight weeks and had no detectable *C. difficile* on Week 8. As a result, the clinical cure rate for the study, which we define as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing, was 97%, or 29 of 30 patients.

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

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

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

Based on the results from our Phase 1/2 clinical study, we plan to initiate a Phase 3 clinical trial of SER-109 in the first half of 2015 and are in ongoing conversations with the FDA regarding trial design and CMC requirements. We are currently planning and conducting validation studies of our manufacturing process for SER-109, and we expect to obtain sufficient data from these studies to commence our Phase 3 clinical trial as planned.

#### Clinical development plan

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

- Ÿ due to microbiota interactions being species-specific, animal data would not be more representative than our human clinical data;
- $\ddot{\mathrm{Y}}$  the favorable safety profile of SER-109 in patients demonstrated in the Phase 1/2 clinical study;
- $\ddot{\mathrm{Y}}$  that Ecobiotic microbiome therapeutics are not absorbed outside of the gastrointestinal tract;
- $\ddot{Y}$  the engraftment of spores is not dependent on dose; and

Ÿ that SER-109 comprises spores from microbes found in a healthy human gastrointestinal tract. We believe these parameters allow for rapid and inexpensive development relative to typical drug design and development.

#### Phase 3 clinical trial design

We are in discussions with the FDA regarding trial design for our Phase 3 clinical trial. We expect our Phase 3 clinical trial to be a randomized, double-blinded, placebo-controlled, parallel group study with two treatment arms enrolling a total of 135 patients. Eligible patients will be selected from 30 sites across North America and randomized 2:1 to receive either an oral dose of SER-109 in four capsules or a matching placebo in four capsules. We expect the single dose of SER-109 to contain 1x108 spore units. In preparation for the Phase 3 clinical trial, we have refined the formulation of the inner capsule and changed the manufacturing process that we expect to use for commercial production. The changes have resulted in a more pure form of SER-109 that is highly comparable and consistent with the formulation used in the Phase 1/2 clinical study; however, the Phase 3 clinical trial will be the first clinical trial to evaluate the current formulation.

The trial is designed to enroll patients 18 years or older, with documented history of three or more occurrences of CDI in the previous nine months (as compared to 12 months in the Phase 1/2 clinical study). Additionally, enrolled patients must have been clinically responsive to 10 to 21 days of standard care antibiotics, with no evidence of diarrhea for three or more consecutive days prior to randomization. In contrast, enrolled patients in the Phase 1/2 clinical study were permitted to be on long-term antibiotic therapy. Exclusion criteria for the Phase 3 clinical trial are generally similar to the Phase 1/2 clinical study but exclude patients using a broader range of disease states and a broader range of prior treatment regimens.

We expect the primary efficacy objective to be to demonstrate the superiority of SER-109 versus placebo in these adult patients based on the proportion of patients experiencing CDI recurrence up through eight weeks after treatment. In this trial, recurrent CDI will be defined as three or more unformed stools per day over two days (as compared to more than three unformed stools over one day in the Phase 1/2 clinical study) with a positive *C. difficile* stool test and requiring antibiotic treatment. We believe the decision to treat with antibiotics will be based on physician assessment according to guidelines specified in the clinical protocol. The primary safety objective is to evaluate the safety of SER-109 in these patients up to 12 weeks after treatment as determined by clinical and laboratory safety assessments. The safety follow-up period was 24 weeks in the Phase 1/2 clinical study. During the follow-up period, all patients will be contacted by phone weekly and asked about adverse events and diarrheal symptoms. If diarrheal symptoms meeting the definition of recurrent CDI return during the follow-up period, patients will be asked to return to the clinic for a *C. difficile* test. In addition, all patients will return to the clinic at 12 weeks for safety evaluations, and those who were CDI free at the eight-week visit will be assessed for clinical CDI episodes up to 12 weeks after treatment.

We also plan to evaluate secondary objectives including comparing the time to CDI recurrence in patients who receive SER-109 or placebo, and comparing the proportion of patients experiencing clinical CDI recurrence up to four weeks and up to 12 weeks post-treatment. We also expect to compare changes in the composition of the colonic microbiome from baseline to Week 8 post-treatment using genomic analysis. Upon enrollment of 75 patients, we plan to conduct an interim evaluation for safety, efficacy and futility.

The following table summarizes the expected dose, route and schedule of administration for the proposed Phase 3 clinical trial:

Study Arm		Daily Dose			Capsules Day 1		Number of Doses of	
	Treatment	(spore units)	Patients	Duration (Days)	Active	Placebo	SER-109	Route
1	SER-109	1 x 10 <sup>8</sup>	90	1	4	0	1	Oral
2	Placebo	0	45	1	0	4	0	Oral

# Sample size and power considerations

Assuming a 20% CDI recurrence rate in the SER-109 group and a 60% CDI recurrence rate in the placebo comparator group in the modified intention-to-treat population, a minimum sample size of 72 patients with a 2:1 randomization will have 90% power to demonstrate the superiority of SER-109 to the placebo with respect to episodes of CDI, at a 2-sided significance level of 0.05. We plan to enroll 135 patients in total, randomized 2:1 to receive SER-109 or placebo. We expect an independent Data and Safety Monitoring Committee, or DSMC, will review blinded safety data on an ongoing basis and will conduct a formal review of safety and efficacy data when at least 50% of patients have been enrolled and followed for eight weeks. With 135 patients, the interim analysis should have a power of 81% and the final analysis more than 90%. If our assumptions regarding CDI recurrence rates are found to be incorrect, the power of the trial could be adversely affected.

#### Open label extension study

Patients in either arm of the proposed Phase 3 clinical trial who relapse and experience a clinical CDI recurrence within one week of treatment will be permitted to enroll in an open label extension study in which they will receive a dose of SER-109. Participation in the open label extension will be conditioned upon the patient's continued satisfaction of the inclusion and exclusion criteria for the Phase 3 clinical trial. We believe that providing the open label extension will assist in facilitating enrollment in the Phase 3 clinical trial by providing participants the opportunity to ultimately receive SER-109. In addition, we believe the open label study will provide additional safety data and may provide us with greater understanding of the impact of a second dose of SER-109. We currently intend to begin patient enrollment in the Phase 3 clinical trial in the first half of 2015.

# Manufacturing

SER-109 is a purified ecology of spores produced through a process of extraction from the natural human stool source, obtained from qualified, highly tested donors. The donor raw material is collected in a controlled setting, under a protocol that stringently ensures that donors meet qualification criteria. Donors are required to be in good health, and to possess a medical history and a lifestyle that minimizes the risk of infectious disease transmission. Donors are tested for infectious agents and screened for gastrointestinal and other health factors. After initial qualification, the donor is eligible to donate for a defined period of time, and donors are monitored periodically for health status changes during the donation period. In the middle, and at the end of the donation period, the qualification assessment is repeated to help ensure the donor has maintained their health status. After successful completion of an exit screening the donations are released from quarantine for use in manufacturing.

We initially process the donor material and then transfer a production intermediate to a contract manufacturing organization, or CMO, to isolate the spores and to concentrate them for conversion to the oral capsule dosage form. The purified, concentrated drug substance is tested for identity, potency and purity, and subsequently formulated and filled into capsules at a controlled potency. The final drug product dosage form is four hard capsules for oral administration. Steps are specifically built into the

process to remove and kill non-spore microbes. We are currently planning and conducting validation studies demonstrating the ability of the process to inactivate and clear the potential pathogens of concern, and we expect to obtain sufficient data from these studies to commence our Phase 3 clinical trial in the first half of 2015.

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

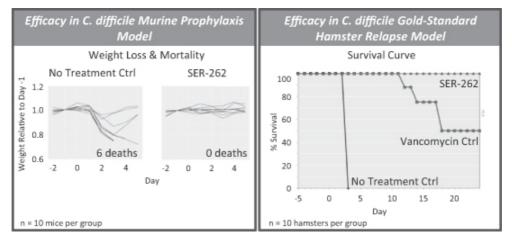
Once ingested, SER-109 spores administered to a patient multiply rapidly within the gastrointestinal tract. Therefore, the dosage required to treat a patient is modest. Moreover, based on the size of the recurrent CDI market, we expect the number of SER-109 doses necessary to meet expected market demand to also be modest. As a result, we believe we can address market demand with a relatively small-scale manufacturing process. Additionally, the need for donors to address anticipated market supply are also modest. We believe that donations from 14 or fewer donors collected over a period of three months will be required to supply the entire U.S. recurrent CDI market during the first year of commercialization. The contract manufacturer we rely on to produce SER-109 bulk drug substance plans to produce four batches in order to provide an adequate supply of SER-109 for our Phase 3 clinical trial.

# SER-262

We are developing SER-262, which is a 15 strain Ecobiotic microbiome therapeutic intended to be used following antibiotic treatment of primary CDI to prevent an initial recurrence of CDI. We are designing SER-262 to increase and improve diversity in the colonic microbiome using an ecology of defined strains. The results of our Phase 1/2 clinical study of SER-109 provided multiple insights that we are employing in the spore ecology used in SER-262, which consists of a subset of bacteria found in SER-109. Pre-clinical studies of SER-262 have demonstrated efficacy in mouse and hamster models of CDI.

As part of our pre-clinical development of SER-262 we have screened SER-262 for efficacy, compositional optimization and pre-clinical safety in animal models. SER-262 provided significant protection against CDI with reduced mortality, minimum weight loss and clinical score measures of efficacy all performing comparably to SER-109. Protection was observed across a 100-fold dose range with the magnitude of the efficacy signal decreasing at lower doses. Through additional screening of various derivative compositions of SER-262, we believe we have confirmed the composition of SER-262 as optimal. Treatment with SER-262 was non-toxic in mice across the dose range tested. We plan to conduct additional mouse and hamster studies as well as conduct further *in vitro* characterization of individual strains, including whole genome sequencing, sporulation efficiency and metabolic requirements in preparation for filing an IND.

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



We intend to commence clinical studies of SER-262 in the second half of 2015. Each of the strains in SER-262 used in our pre-clinical studies were purified from a single qualified donor who participated in the SER-109 Phase 1/2 clinical study. We believe that the prior clinical use of these strains may ease concerns over their safety in humans and may also limit pre-clinical toxicological requirements that might otherwise be required. Additionally, given our ability to grow the spores in bacterial fermenters we will not require any additional donations from human donors for purposes of manufacturing SER-262.

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

#### Manufacturing

To manufacture SER-262, bacterial components for formulation will be fermented and purified as single strains. The bacterial components will originate from cGMP master cell banks that will be manufactured and released starting from proprietary research cell banks. Research cell banks have been made for each strain by clonal isolation and multiple rounds of purification, followed by banking. We expect these banks will be ready for transfer to cGMP manufacturing for master cell banking following testing for identity and microbiological purity. The strains have been cultured in controlled fermentations with above-target yields on average for the projected Phase 1/2 clinical needs. Optimization is on-going to define cultivation conditions that promote spore formation. We expect that subsequent purification processing, and formulation chemistries and processes, will enable both spore-only and spore/vegetative bacteria-containing final drug products.

# Other Product Candidates and Products in Discovery

SER-155

We have an active pre-clinical program to develop Ecobiotic microbiome therapeutics for other infectious diseases. The Phase 1/2 clinical study of SER-109 provided initial evidence suggesting that

Ecobiotic microbiome therapeutics have the potential to eliminate colonization by microbial pathogens, such as VRE and gram negative *Enterobacteriacea*. *Enterobacteriacea*, such as *Klebsiella*, *Pseudomonas* and *Proteus*, normally are present at low levels in the healthy colon, but like *C. difficile*, they can overgrow after antibiotic use. *Enterobacteriaceae* include several multidrug resistant organisms, or MDROs, that represent significant public health concerns. For example, carbapenem resistant *Enterobacteriacea*, or CRE, is a significant problem in the United States. VRE, CRE and other MDROs colonize the gastrointestinal tract after antibiotic use and can spread through contact with patients and healthcare workers both in institutional and in community settings.

We are currently designing and developing SER-155, a 9 strain Ecobiotic microbiome therapeutic that is expected to have activity against gram-positive and gram-negative enteric bacterial pathogens. We expect SER-155 to be used for the treatment of antibiotic-resistant bacteria to eliminate colonization and prevent infection. We have initiated *in vitro* and *in vivo* screening efforts of SER-155 and ecological variations of SER-155 in multiple disease models. The selection of indication will be based on these pre-clinical screening efforts, and the assessment of clinical development plan, regulatory path and market opportunities. We plan to conduct additional mouse and hamster studies as well as conduct further *in vitro* characterization of individual strains, including whole genome sequencing, sporulation efficiency and metabolic requirements in preparation for filing an IND. We anticipate filing an IND to initiate exploratory clinical trials with SER-155 in the first half of 2016.

# SER-301

We have an active pre-clinical program to develop an Ecobiotic microbiome therapeutic for chronic conditions including early-stage, non-insulin-dependent diabetes and Crohn's disease. Consistent with our approach to rational drug design, we based this program on clinical observations and hypotheses about the role of a dysbiotic microbiome as the proximal cause of disease.

#### Early-stage non-insulin-dependent diabetes

Published studies indicate that a dysbiosis of the colonic microbiome may underlie diabetes by stimulating low-level inflammation that induces cytokine production leading to insulin resistance. Recently published research shows that FMT derived from lean donors led to a significant increase in insulin sensitivity in obese men with metabolic syndrome while autologous FMT did not. We believe that this shows that repopulating a dysbiotic colonic microbiome with certain keystone organisms and functional pathways could eliminate insulin sensitivity. Further supporting our hypothesis is that the beneficial clinical results of the lean donor FMT procedures correlated with the transfer of *E. hallii* and *R. intestinalis*. In addition, the reversal of early-stage non-insulin-dependent diabetes following gastric bypass surgery in humans is rapid and animal research conducted by a third party indicates that these changes likely reflect underlying changes in the microbiome.

#### Crohn's disease

Recent published third-party research show dramatic changes in the microbiome in new-onset Crohn's disease compared to healthy individuals. The changes in new-onset Crohn's disease include higher levels of *Enterobacteriaceae* and *Fusobacteriaceae* and lower levels of *Clostridiales*, all of which present in spore ecologies and show engraphment after treatment. In addition, the changes also include lower levels of Bacteroides, which are shown to be augmented by treatment with spore ecologies. The changes in these organisms induces dysbiosis and we believe that if we can repopulate these keystone organisms and functional pathways we could restore the colonic microbiome thereby treating new-onset Crohn's disease.

Based on this research and our experience with SER-109, we believe that we can use a complex spore ecology to restore the underlying dysbiosis. To derive SER-301, we refine SER-109 by proprietary methods and may formulate the drug as a solid in oral capsules with a dose in the range of 10<sup>5</sup> to 10<sup>8</sup> spores per capsule to enable daily dosing. We believe we may need more than one dose to treat for chronic diseases. Dried solid capsule formulations generally allow for longer storage and shelf life to accommodate repeat, long-term dosing. SER-301 is distinct from SER-109 based on manufacturing methods, thus enabling it to be clinically tested and ultimately marketed as a distinct product. We are currently researching SER-301 and anticipate filing an IND to initiate exploratory clinical trials with SER-301 in the first half of 2016.

# Sales and Marketing

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

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

# Manufacturing

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

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

Ÿ Fermentation. We believe that microscale screening is possible for optimization of the bacterial cultures of interest in our current and foreseeable candidates. These screens will focus a given strain on the fermentation platform that is best-suited for optimization and scale-up. Small-scale fermentation systems (0.1 L to 20 L) enable the optimization of a wide variety of culture conditions and have been demonstrated to be scalable to commercial fermentation processes and enable technology transfer to clinical and final manufacturing scales. We employ platform fermentation processes as starting conditions for cGMP production schemes, and when required, will develop strain specific process parameters. To develop master cell banks and bulk drug substance for commercial product, we plan to use bacterial strains originating from the research cell bank so we expect the research cell banks and final drug product will be genetically and physiologically similar.

- Ÿ *Purification*. Similar to fermentation, we believe small-scale purification, formulation, filling and dosage preparation operations are available to complete bench-scale manufacturing and/or spores, which quickly assess the final process yield, quality and robustness.
- Ÿ Formulation. Our Ecobiotic microbiome therapeutics are combinations of live bacteria and can be administered by a number of methods and by different routes. The primary goal in developing formulation is to deliver the bacteria to the intended location in a condition where they are able to replicate and correct dysbiosis. Formulation development will generally use approved excipients and preservatives, and will include screening of both liquid and solid formulations to maximize the opportunity for extended stability with minimal cold-chain requirements.
- Ŷ Analytical. We intend to address quality control requirements for our Ecobiotic microbiome therapeutics using proprietary microbiological and sequence-based testing schemes. We have available and are further developing quality control and in-process analytical tools that can quantitatively measure the composition of spore, vegetative microbe and spore/vegetative combinations, which we believe enable a wide variety of drug substances to be manufactured. Throughout the bioprocess and formulation development platform we plan to use high-throughput quantitative analytics to assess the identity, potency and purity of the final product.

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

# **Intellectual Property**

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

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

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

issue, will cover our product candidates, or whether the claims of any issued patents will provide sufficient protection from competitors or otherwise provide any competitive advantage.

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

Our patent portfolio includes patent applications in the early stages of prosecution, and one issued patent. The time periods for electing to pursue foreign patent protection for the inventions disclosed in our patent applications by filing national stage applications in individual jurisdictions have not yet expired. We anticipate determining, in advance of the applicable deadlines, whether to pursue these applications and if so will pursue them in the United States and selected ex-United States jurisdictions. Substantive patent prosecution before the USPTO was begun in four applications from two patent families. One of these has issued as a patent and a Notice of Allowance was received from the USPTO for two of those patent applications. We believe the issued and allowed claims will provide protection for SER-109, SER-262 and SER-155 Ecobiotic microbiome therapeutics product candidates.

Our patent estate leverages both offensive and defensive strategies. As of January 27, 2015, we owned a total of nine patent application families that include Patent Cooperation Treaty, or PCT, applications and/or U.S. patent applications, and some of these families are described briefly below. We also own three additional patent application families that include only U.S. provisional applications that will not themselves be examined and for which the deadline to file PCT applications and/or U.S. non-provisional applications has not yet expired. The pending patent applications in six of the patent application families in our portfolio are described briefly below.

- Ý A family related to binary combinations of microbes that includes the following issued and pending applications: (i) the issued United States patent described above which claims therapeutic compositions that include selected binary combinations of microbes; (ii) an additional United States application which was recently allowed, as noted above, and claims methods of using such compositions to treat or prevent CDI; and (iii) a PCT application claiming similar methods and compositions. The time period for electing to pursue foreign patent protection by filing national stage applications in individual jurisdictions based on this PCT application has not yet expired, and we will need to decide whether and where to pursue ex-U.S. protection before expiration of the applicable deadlines. Patents issuing from or based on these applications, if any, are expected to expire in 2033, assuming all required maintenance fees are paid and absent any applicable patent term extension or patent term adjustment. We expect this patent application family to provide patent protection for SER-109, SER-262 and SER-155.
- Y A family related to combinations of bacterial spores that includes the following pending applications: (i) two United States applications, one of which was recently allowed, that claim certain methods of treatment of gastrointestinal diseases, including Crohn's disease, using combinations of bacterial spores and (ii) a PCT application claiming similar methods, as well as related compositions. The time period for electing to pursue foreign patent protection by filing national stage applications in individual jurisdictions based on this PCT application has not yet expired, and we will need to decide whether and where to pursue ex-U.S. protection before expiration of the applicable deadlines. Patents issuing from or based on these applications, if any, are expected to expire in 2034, assuming all required maintenance fees are paid and absent any applicable patent term extension or patent term adjustment. We expect this patent application family to provide patent protection for SER-109, SER-262 and SER-155.

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

### Patent term

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

The term of a U.S. patent may be eligible for patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act, to account for at least some of the time the drug is under development and regulatory review after the patent is granted. With regard to a drug for which FDA approval is the first permitted marketing of the active ingredient, the Hatch-Waxman Act allows for extension of the term of one U.S. patent that includes at least one claim covering the composition of matter of such an FDA-approved drug, an FDA-approved method of treatment using the drug and/or a method of manufacturing the FDA-approved drug. The extended patent term cannot exceed the shorter of five years beyond the non-extended expiration of the patent or fourteen years from the date of the FDA approval of the drug, and a patent

cannot be extended more than once or for more than a single product. During the period of extension, if granted, the scope of exclusivity is limited to the approved product for approved uses. Some foreign jurisdictions, including Europe and Japan, have analogous patent term extension provisions, which allow for extension of the term of a patent that covers a drug approved by the applicable foreign regulatory agency. In the future, if and when our pharmaceutical product candidates receive FDA approval, we expect to apply, if appropriate, for patent term extension on patents covering those product candidates, their methods of use and/or methods of manufacture.

#### Trade secrets

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

# Competition

The development and commercialization of new drug and biologic products is highly competitive and is characterized by rapid and substantial technological development and product innovations. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. We are aware of a number of large pharmaceutical and biotechnology companies, including Merck, Shire, Sanofi, Pfizer, Novartis and Cubist, 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, fecal microbiota transplantation, or FMT, is a procedure that has resulted in high cure rates for recurrent CDI and our competitors and physicians may continue to seek to standardize and implement this procedure. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

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

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

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

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

## **Government Regulation**

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs and biologics such as those we are developing. We, along with our contract manufacturers, will be required to navigate the various pre-clinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval for our product candidates. The process of obtaining regulatory approvals and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

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

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

- Ÿ completion of pre-clinical laboratory tests and animal studies performed in accordance with the FDA's good laboratory practice, or GLP, regulations;
- Ÿ submission to the FDA of an investigational new drug, or IND, application which must become effective before clinical trials in the United States may begin;
- Ÿ performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication, conducted in accordance with the FDA's good clinical practice, or GCP, regulations;

- Ÿ submission to the FDA of a BLA:
- Ÿ satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP regulations; and
- $\ddot{Y}$  FDA review and approval of the BLA prior to any commercial marketing, sale or shipment of the product.

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

### Pre-clinical and Clinical Trials

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

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

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

- Ÿ Phase 1 Phase 1 clinical trials involve initial introduction of the investigational product into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2 Phase 2 clinical trials involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.

Y Phase 3 — Phase 3 clinical trials involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

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

Although most clinical research performed in the United States in support of BLA must be authorized in advance by the FDA under the IND regulations and procedures described above, there are certain circumstances under which clinical trials can be conducted without submission of an IND application. For example, a sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. Similarly, the FDA may exercise enforcement discretion to permit sponsors to conduct certain types of clinical investigations without an IND. Pursuant to the FDA guidance document "Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies" (July 2013), the FDA currently exercises enforcement discretion regarding the IND requirements for the use of FMT to treat *C. difficile* infection not responding to standard therapies, provided that the treating physician obtains adequate informed consent from the patient or his or her legally authorized representative for the use of FMT products. The FDA provided confirmation that it intends to exercise enforcement discretion with respect to our Phase 1/2 clinical study of SER-109, a modified FMT product, and accordingly, we did not conduct this trial under an IND. However, the guidance document states that the FDA will continue to work with any sponsors who wish to submit IND applications for this use of FMT, and we intend to conduct all future clinical studies of SER-109, including our planned pivotal Phase 3 program, under an IND.

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

## **BLA Submission and FDA Review**

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

Once a BLA has been accepted for filing, by law the FDA has 180 days to review the application and respond to the applicant. However, the review process is often significantly extended by FDA requests for additional information or clarification. Under the Prescription Drug User Fee Act, the FDA

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

The FDA may deny approval of a BLA if the applicable statutory and regulatory criteria are not satisfied, or it may require additional preclinical or clinical data. Even if such data are submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than sponsors. Once the FDA approves a BLA, such approval may limit the indicated uses for which the biologic may be marketed. The FDA may also require implementation of a Risk Evaluation and Mitigation Strategy, or REMS, which can include a medication guide, communication plan, or elements to assure safe use, such as restricted distribution methods, physician training, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling claims or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the market. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing based on the results of these post-marketing studies.

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

## **Expedited Development and Review Programs**

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

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

Any product submitted to the FDA for approval, including a product with fast track or breakthrough therapy designation, may also be eligible for additional FDA programs intended to expedite the review process, including priority review designation and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. The FDA aims to review applications for new products designated for priority review within six months, compared to ten months under standard review. Additionally, products intended to treat serious or life-threatening diseases or conditions may receive accelerated approval. Products are eligible for accelerated approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Accelerated approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. In addition, the FDA currently requires, as a condition for accelerated approval, pre-approval of all promotional materials intended for dissemination or publication within 120 days following marketing approval, which could adversely impact the timing of commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review designation and accelerated approval do not change the standards for approval but may expedite the development or approval process. We may apply for one or more of the FDA's expedited programs for our product candidates, but the FDA may disagree that our product candidates satisfy the criteria for such programs, or such programs may fail to ultimately result in expedited development or approval timelines.

### Post-Approval Requirements

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

Any biologics manufactured or distributed by us or our contract manufactures pursuant to FDA approvals would be subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences associated with the product. Manufacturers and their

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

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

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

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

#### **Biosimilars**

We believe that any of our product candidates approved under a BLA should qualify for a twelve-year period of exclusivity against biosimilar competition currently permitted by the Biologics Price Competition and Innovation Act, or BPCIA. Specifically, as part of the Patient Protection and Affordable Care Act enacted in 2010, the BPCIA established an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The new abbreviated regulatory pathway provides legal authority for the FDA to review and approve biosimilar biologics based on their similarity to an existing brand product, referred to as a reference product, including the possible designation of a biosimilar as interchangeable with a brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until twelve years after the original brand product was approved under a BLA. There is a risk that, as proposed by President Obama, the U.S. Congress could amend the BPCIA to

significantly shorten this exclusivity period or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological drug products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. The BPCIA is complex and is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning is subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes that operate to limit the scope or length of exclusivity afforded by the BPCIA could have a material adverse effect on the future commercial prospects for our biological products. In addition, the period of exclusivity provided by the BPCIA only operates against third parties seeking approval via the abbreviated pathway, but would not prevent third parties from pursuing approval via the traditional approval pathway. In addition, foreign regulatory authorities may also provide for exclusivity periods for approved biological products. For example, biological products in the European Union may be eligible for at least a ten-year period of exclusivity.

# **Orphan Drug Designation**

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

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

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

### Other Healthcare Laws

Although we currently do not have any products on the market, if our product candidates are approved and we begin commercialization, we will be subject to healthcare regulation and enforcement

by the federal government and the states in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations.

The federal anti-kickback statute prohibits the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts and free or reduced price items and services. The government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham research or consulting and other financial arrangements with physicians. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act (discussed below). Many states have similar laws that apply to their state health care programs as well as private payors.

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

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

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The federal Health Insurance Portability and

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

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

## Coverage and Reimbursement

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

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

Outside the United States, ensuring adequate coverage and payment for our products will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly approved health care products. Recent budgetary pressures in many countries are also causing governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates. If budget pressures continue, governments may implement additional cost-containment measures. Cost-control initiatives could decrease the price we might establish for products that we may develop or sell, which would result in lower product revenues or royalties payable to us. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products.

## Healthcare Reform

In the United States, there have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biological products, government control and other changes to the healthcare system. It is uncertain what legislative proposals will be adopted or what actions federal, state or private payors for medical goods and services may take in response to any healthcare reform proposals or legislation. We cannot predict the effect medical or healthcare reforms may have on our business, and no assurance can be given that any such reforms will not have a material adverse effect.

By way of example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, was signed into law, which, among other things, includes changes to the coverage and payment for drug products under government health care programs. Among other things, the Affordable Care Act:

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

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect

through 2024 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals. Adoption of other new legislation at the federal or state level could further limit reimbursement for pharmaceuticals, including our product candidates if approved.

### **Employees**

As of December 31, 2014, we had 25 full-time permanent employees. Five employees work in administration and operations and 20 work in research and development.

### **Facilities**

### Research and Offices

We currently lease 13,568 square feet in Cambridge, Massachusetts for our offices and laboratories pursuant to a lease that expires in January 2018.

## Manufacturing

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

In preparation for commercial production of SER-109, we intend to bring raw material donor qualification and management and donation processing into a new facility operated by us that will meet commercial requirements. The location of this facility is yet to be determined. We estimate that capital costs for setting up such a facility will be approximately \$2 million, and that it will be operated by our staff.

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

### **Legal Proceedings**

We are not party to any material legal proceedings.

#### **MANAGEMENT**

### **Executive Officers, Key Employees and Directors**

The following table sets forth the name, age and position of each of our executive officers, key employees and directors as of December 31, 2014

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<u>Name</u>	<u>Age</u>	Position
Executive Officers		
Roger J. Pomerantz, M.D.	57	President and Chief Executive Officer and Director
John Aunins, Ph.D.	53	Chief Technology Officer and Executive Vice President of Bioprocess Development
David N. Cook, Ph.D.	56	Chief Scientific Officer and Executive Vice President of Research & Development
Eric D. Shaff.	39	Chief Financial Officer and Executive Vice President
Michele Trucksis, M.D., Ph.D.	61	Chief Medical Officer and Executive Vice President
Other Key Employees		
Matthew Henn, Ph.D.	39	Head of Drug Discovery & Bioinformatics and Senior Vice President
Directors		
Noubar B. Afeyan, Ph.D.	52	Director
Grégory Behar	45	Director
David A. Berry, M.D., Ph.D.	36	Director
Werner Cautreels, Ph.D.	62	Director
Peter Barton Hutt	80	Director
Richard N. Kender	58	Director
Lorence H. Kim, M.D.	40	Director

- Member of the audit committee.

  Member of the compensation committee.
- Member of the nominating and corporate governance committee.

## **Executive Officers and Other Key Employees**

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

John Aunins, Ph.D., has served as our Chief Technology Officer and Executive Vice President of Bioprocess Development since December 2012. Prior to joining our company, Dr. Aunins served on

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

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

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

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

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

### **Directors**

Noubar B. Afeyan, Ph.D., has served as a member of our board of directors since October 2010. Since 1999, Dr. Afeyan has served as the Managing Partner and Chief Executive Officer of Flagship Ventures, an early-stage venture capital firm that he co-founded. Dr. Afeyan has served on the board of directors of BG Medicine, Inc., a medical diagnostic device company, since April 2000 and on the board of directors of Eleven Biotherapeutics, a biopharmaceutical company, since September 2008.

Dr. Afeyan received a B.S. from McGill University and a Ph.D. in Biochemical Engineering from the Massachusetts Institute of Technology. We believe Dr. Afeyan is qualified to serve on our board of directors because of his extensive investment experience and his knowledge of the biotechnology industry.

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

David A. Berry, M.D., Ph.D., has served as a member of our board of directors since March 2012. Since 2005, Dr. Berry has been with Flagship Ventures, an early-stage venture capital firm, where he has served as a Partner since 2008. From March 2013 to May 2014, Dr. Berry served as our Interim President and Chief Executive Officer. Dr. Berry has served on the board of directors of Eleven Biotherapeutics, a biopharmaceutical company, since September 2009. Dr. Berry received a B.S. from the Massachusetts Institute of Technology, a M.D. from Harvard Medical School and a Ph.D. from the Massachusetts Institute of Technology. We believe Dr. Berry is qualified to serve on our board of directors because of his investment experience, his scientific and clinical qualifications and his knowledge of the biotechnology industry.

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

Peter Barton Hutt has served as a member of our board of directors since May 2013. Mr. Hutt is senior counsel at Covington & Burling LLP, specializing in food and drug law. Mr. Hutt has served as a member of the board of directors of Momenta Pharmaceuticals, Inc. since 2001, Q Therapeutics, Inc. since 2002, Xoma Corporation since 2005, Concert Pharmaceuticals since 2007, BIND Therapeutics, Inc. since 2008 and DBV Technologies since 2009, each a biotechnology company. Mr. Hutt received a B.A. from Yale University, an LL.B. from Harvard Law School and an LL.M. from the New York University School of Law. We believe that Mr. Hutt is qualified to serve on our board of directors because of his experience serving as a director of biotechnology companies and his legal and regulatory knowledge.

Richard N. Kender has served as a member of our board of directors since October 2014. From October 1978 to September 2013, Mr. Kender held positions in a variety of corporate areas at Merck & Co., Inc., a pharmaceutical company, most recently serving as Senior Vice President of Business Development and Corporate Licensing. Mr. Kender received a B.S. from Villanova University and an MBA from Fairleigh Dickinson University. We believe Mr. Kender is qualified to serve on our board of directors because of his extensive business experience and his knowledge of the pharmaceutical industry.

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

# **Board Composition and Election of Directors**

### **Director Independence**

Our board of directors currently consists of seven members. Our board of directors has determined that of our seven directors, Drs. Afeyan, Berry, Cautreels and Kim and Messrs. Hutt and Kender do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of . There are no family relationships among any of our directors or executive officers.

## **Classified Board of Directors**

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

- Ÿ the Class I directors will be , and , and their terms will expire at our first annual meeting of stockholders following this offering;
- $\dot{Y}$  the Class II directors will be , and , and their terms will expire at our second annual meeting of stockholders following this offering; and
- $\dot{Y}$  the Class III directors will be , and , and their terms will expire at the third annual meeting of stockholders following this offering.

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

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

### **Board Leadership Structure**

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

### Role of the Board in Risk Oversight

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

#### **Board Committees**

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

### **Audit Committee**

The audit committee's responsibilities include:

- $\ddot{Y}$  appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- Y overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;
- Ÿ reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;
- Ÿ monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;

- Y discussing our risk management policies;
- Ÿ establishing policies regarding hiring employees from the registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- $\dot{Y}$  meeting independently with our internal auditing staff, if any, registered public accounting firm and management;
- Ÿ reviewing and approving or ratifying any related person transactions; and
- Ÿ preparing the audit committee report required by SEC rules.

The members of our audit committee are . serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and . Our board has determined that and are independent under the applicable rules and regulations. Our board of directors has determined that is an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable rules and regulations.

#### **Compensation Committee**

The compensation committee's responsibilities include:

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

The members of our compensation committee are and . serves as the chairperson of the committee. Our board has determined that each of and is independent under the applicable rules and regulations, is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act and is an "outside director" as that term is defined in Section 162(m) of the Internal Revenue Code of 1986, as amended.

## Nominating and Corporate Governance Committee

The nominating and corporate governance committee's responsibilities include:

- Ÿ identifying individuals qualified to become board members;
- $\ddot{Y}$  recommending to our board the persons to be nominated for election as directors and to each of the board's committees;
- Y reviewing and making recommendations to the board with respect to management succession planning;
- $\ddot{Y}\,$  developing and recommending to the board corporate governance principles; and
- Ÿ overseeing an annual evaluation of the board.

The members of our nominating and corporate governance committee are
Our board has determined that and are independent under the applicable and regulations.

serves as the chairperson of the committee.

### Compensation Committee Interlocks and Insider Participation

No member of our compensation committee is or has been our current or former officer or employee. None of our executive officers served as a director or a member of a compensation committee (or other committee serving an equivalent function) of any other entity, one of whose executive officers served as a director or member of our compensation committee during the fiscal year ended December 31, 2013.

## **Code of Ethics and Code of Conduct**

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

### **EXECUTIVE AND DIRECTOR COMPENSATION**

### **Executive Compensation**

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

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

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

We are an "emerging growth company," within the meaning of the JOBS Act, and have elected to comply with the reduced compensation disclosure requirements available to emerging growth companies under the JOBS Act.

## 2014 Summary Compensation Table

Name and Principal Position Roger J. Pomerantz, M.D. <sup>(1)</sup> President and Chief Executive Officer	<u>Year</u> 2014	Salary (\$) 247,917	Bonus _(\$) <sup>(4)</sup> 	Option Awards (\$) <sup>(5)</sup> 6,567,603	All Other Compensation (\$) 69,393 <sup>(6)</sup>	Total (\$) 6,884,913
David A. Berry, M.D., Ph.D. <sup>(2)</sup> Former Interim President and Chief Executive Officer	2014 2013	136,500 125,667	_	_	_	136,500 125,667
Eric D. Shaff <sup>(3)</sup> Executive Vice President and Chief Financial Officer	2014	35,192	_	1,413,756	_	1,448,948
David N. Cook, Ph.D.  Executive Vice President of Research & Development and Chief Scientific Officer	2014 2013	300,000 300,000	_	 113,119	 21,201	300,000 434,320

- We hired Dr. Pomerantz as our President and Chief Executive Officer effective June 1, 2014. Dr. Pomerantz's 2014 annual base salary was \$425,000. Dr. Pomerantz also serves as Chairman of our board of directors but receives no additional compensation for this service
- Dr. Berry served as our Interim President and Chief Executive Officer from March 29, 2013 through May 30, 2014. Dr. Berry is a Partner of Flagship Ventures and also serves as a Dr. Berry services as our interim Festient and chief Executive Officer for as a member of our board of directors. Dr. Berry received no compensation from us for his service as our Interim Chief Executive Officer or as a member of our board of directors during 2014. However, we paid Flagship Ventures Management, Inc., an affiliate of Flagship Ventures, a total of \$136,500 for services provided to us by Dr. Berry during 2014. For a further discussion of the services agreement, refer to "Certain Relationships and Related Person Transactions—Services Agreement" below.

  We hired Mr. Shaff as our Chief Financial Officer and Executive Vice President effective November 19, 2014. Mr. Shaff's 2014 annual base salary was \$300,000.

  As of the date of this prospectus, the amount of any bonus payments to be made to our NEOs for services performed in 2014 has not yet been determined by our board of directors. We
- expect that the amount of any such bonus awards will be determined by our board of directors in the first quarter of 2015
- Represents the aggregate grant date fair value of the option awards computed in accordance with FASB ASC Topic 718. For a description of the assumptions used in valuing these awards, see Note 9 to our audited financial statements included elsewhere in this prospectus.
- Represents reimbursement of travel and lodging costs associated with working in the Cambridge, Massachusetts area.

### **Narrative Disclosure to Summary Compensation Table**

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

### Base Salary

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

### **Annual Cash Bonuses**

Our NEOs have the opportunity to earn annual performance bonuses based on the achievement of short-term performance goals. Dr. Pomerantz's and Mr. Shaff's employment offer letters entitle them to receive an annual bonus with a target amount equal to 50% and 30% of their annual base salary, respectively. Mr. Shaff's employment offer letter provides that his 2014 annual bonus will be prorated to reflect his partial year of service.

We expect 2014 annual bonuses for our NEOs will be based on our achievement of business development and financing milestones, completion of capital raising transactions and successful executive recruitment and hiring during 2014 and the individual NEO's contributions to these successes. As of the date of this prospectus, the amount of any bonus payments to be made to our NEOs for services performed in 2014 has not yet been determined by our board of directors. We expect that bonus determinations will be made in the first guarter of 2015.

# **Equity-Based Compensation**

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

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

In connection with Dr. Pomerantz's hire as our President and Chief Executive Officer, in August 2014, we granted him an option to purchase 1,675,751 shares of our common stock for an exercise price per share of \$0.71, which our board of directors determined to be the fair market value of our common stock on the date of grant. The option is subject to our standard vesting terms described above. In connection with Mr. Shaff's hire as our Chief Financial Officer and Executive Vice President, in December 2014, we granted him an option to purchase 262,692 shares of our common stock for an exercise price per share of \$7.79, which our board of directors determined to be the fair market value of our common stock on the date of grant. The option is subject to our standard vesting terms described above. Dr. Cook did not receive an equity award grant during 2014.

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

## Retirement, Health, Welfare and Additional Benefits

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

## **Outstanding Equity Awards at 2014 Fiscal Year-End**

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

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

### **Employment Agreements**

We have entered into employment offer letters with Dr. Pomerantz, Mr. Shaff and Dr. Cook. Certain key terms of these agreements are described below.

### Roger J. Pomerantz, M.D.

Dr. Pomerantz's employment offer letter entitles him to an initial annual base salary of \$425,000, which will increase to \$475,000 upon the closing of a partnership valued at over \$100,000,000 with a pharmaceutical company, and an annual bonus with a target amount equal to 50% of his annual base salary based on our board of directors' assessment of Dr. Pomerantz's individual performance and our company's performance against established goals. The employment offer letter further entitles Dr. Pomerantz, during his first year of employment with us, to reimbursement for his reasonable travel and lodging costs associated with his working in the Cambridge, Massachusetts area.

If we terminate Dr. Pomerantz's employment without cause or if he resigns for good reason within the six months following a sale of our company, subject to his executing a release of claims, he is entitled to receive six months of base salary continuation, up to six months of company-paid healthcare premiums if he elects continuation coverage pursuant to COBRA and accelerated vesting of the option we granted to him in connection with his commencing employment with us.

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

For purposes of Dr. Pomerantz's offer letter:

- Ÿ "cause" means (i) fraudulent, unlawful or grossly negligent conduct in connection with his performance of duties for us, (ii) a material breach of material responsibilities to the company or willful failure to comply with company policies or a lawful directive of our board of directors, (iii) a breach of the provisions of his offer letter or employee non-competition, non-solicitation, confidentiality and assignment agreement with us or (iv) material misconduct that seriously discredits or damages us or our affiliates;
- Ÿ "good reason" means, subject to Dr. Pomerantz providing timely notice and our right to cure, (i) a material reduction in responsibility, authority and function, (ii) a reduction in base salary or (iii) a change in his principal work location to more than 50 miles outside the greater Boston area; and
- Y "sale of the company" means (i) our dissolution or liquidation, (ii) the sale of all or substantially all of our assets, (iii) a merger, reorganization or consolidation after which our shares of voting stock immediately prior to the transaction represent less than 50% of the voting securities of the surviving or successor entity, (iv) the acquisition in a single transaction or series of related transactions by an individual, entity or group of a majority of our voting stock or (v) any other acquisition of our business, as determined by our board of directors; provided that a public offering or other capital raising event will not constitute a sale of the company.

# Eric D. Shaff

Mr. Shaff's employment offer letter entitles him to an initial annual base salary of \$300,000, and an annual bonus with a target amount equal to 30% of his annual base salary based on our board of directors' assessment of Mr. Shaff's individual performance and our company's performance against established goals. If we terminate Mr. Shaff's employment without cause or if he resigns for good reason within the six months following a sale event, subject to his executing a release of claims, he is

entitled to receive six months of base salary continuation, up to six months of company-paid healthcare premiums if he elects continuation coverage pursuant to COBRA and accelerated vesting of the option we granted to him in connection with his commencing employment with us.

Mr. Shaff has agreed to refrain from disclosing our confidential information during or at any time following his employment with us and from competing with us or soliciting our employees or consultants for 18 months following termination of his employment.

For purposes of Mr. Shaff's offer letter, "cause," "good reason" and "sale event" have substantially the same meanings as in Dr. Pomerantz's employment offer letter.

### David N. Cook, Ph.D.

Dr. Cook's offer letter entitles him to an initial annual base salary of \$300,000, and an annual bonus in an amount determined by our board of directors based on the overall performance of the company and Dr. Cook individually. If Dr. Cook's employment is terminated by us without cause or if he resigns for good reason, subject to his executing a release of claims, he is entitled to receive four months of base salary continuation and up to four months of company-paid healthcare premiums if he elects continuation coverage pursuant to COBRA. In addition, if Dr. Cook's termination by us without cause or resignation by him for good cause occurs within the nine months following a change in control, the stock option we granted to Dr. Cook pursuant to his employment offer letter will vest in full.

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

For purposes of Dr. Cook's offer letter:

- Ÿ "cause" means (i) a determination by our board of directors of the NEO's repeated and willful failure, after receipt of notice, to perform the duties of the NEO or engagement in dishonesty, gross negligence or willful misconduct, (ii) the NEO's conviction for any crime involving moral turpitude or any felony or (iii) the NEO's breach of any material provision of an invention and nondisclosure agreement or non-competition and non-solicitation agreement with the company that remains uncured for 30 days after the NEO's receipt of written notice:
- Ÿ "good reason" means, subject to the NEO providing timely notice and our right to cure, (i) a material reduction in base salary without the NEO's consent, unless, as a result of our financial hardship, similarly situated company executives are also subject to a reduction in base salary by approximately the same percentage; (ii) a material reduction in authority or responsibilities or (iii) a change in the principal work location of at least 50 miles; and
- Y "change in control" means (i) the acquisition, other than directly from us, by an individual, entity or group not affiliated with us or our principal stockholders of at least 50% of our outstanding shares of common stock or the combined voting power of our voting securities or (ii) the consummation of a merger, reorganization, recapitalization or share exchange involving the company or a sale or other disposition of all or substantially all of our assets unless, after such transaction, (x) our stockholders continue to hold, in the substantially same proportions as before such transaction, more than 50% of the common stock and combined voting power of the surviving or successor entity and (y) no individual, entity or group holds 50% or more of the common stock and combined voting power of the surviving or successor entity.

## Potential Payments upon a Change in Control

As described above, under the terms of their offer letters, our NEOs may become entitled to certain payments and benefits upon a change in control or if their employment terminates under certain circumstances following a change in control or sale of our company.

#### Incentive Plans

### 2015 Incentive Award Plan

In connection with this offering, we intend to adopt and have our stockholders approve a 2015 Incentive Award Plan, or the 2015 Plan, under which we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which we compete. The material terms of the 2015 Plan, as it is currently contemplated, are summarized below. Our board of directors is still in the process of developing, approving and implementing the 2015 Plan and, accordingly, this summary is subject to change.

### Eligibility and Administration

Our employees, consultants and directors, and employees, consultants and directors of our subsidiaries, will be eligible to receive awards under the 2015 Plan. Following our initial public offering, the 2015 Plan will be administered by our board of directors with respect to awards to non-employee directors and by our compensation committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to certain limitations that may be imposed under Section 16 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and/or stock exchange rules, as applicable. The plan administrator will have the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2015 Plan, subject to its express terms and conditions. The plan administrator will also set the terms and conditions of all awards under the 2015 Plan, including any vesting and vesting acceleration conditions.

## Limitation on Awards and Shares Available

An aggregate of shares of our common stock will initially be available for issuance under awards granted pursuant to the 2015 Plan. The number of shares initially available for issuance will be increased by (i) the number of shares represented by awards outstanding under our 2012 Plan (defined below) that are forfeited, lapse unexercised or are settled in cash and which following the effective date of the 2015 Plan are not issued under the 2012 Plan and (ii) an annual increase on January 1 of each calendar year beginning in 2016 and ending in 2024, equal to the lesser of (A) shares, (B) percent of the shares of common stock outstanding (on an as converted basis) on the final day of the immediately preceding calendar year and (C) such smaller number of shares as determined by our board of directors. No more than shares of common stock may be issued upon the exercise of incentive stock options. Shares issued under the 2015 Plan may be authorized but unissued shares, or shares purchased in the open market.

If an award under the 2015 Plan is forfeited, expires or is settled for cash, any shares subject to such award may, to the extent of such forfeiture, expiration or cash settlement, be used again for new grants under the 2015 Plan. Awards granted under the 2015 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by an entity with which we enter into a merger or similar corporate transaction will not reduce the shares available for grant under the 2015 Plan. The maximum number of shares of our common stock that may be subject to one or more awards granted to any non-employee director for services as a director pursuant to the 2015 Plan during any calendar year will be

# Awards

The 2015 Plan provides for the grant of stock options, including incentive stock options, or ISOs, and nonqualified stock options, or NSOs, restricted stock, dividend equivalents, stock payments, restricted stock units, or RSUs, performance shares, other incentive awards, stock appreciation rights,

or SARs and cash awards. No determination has been made as to the types or amounts of awards that will be granted to specific individuals pursuant to the 2015 Plan. Certain awards under the 2015 Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Internal Revenue Code, which may impose additional requirements on the terms and conditions of such awards. All awards under the 2015 Plan will be set forth in award agreements, which will detail the terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. Awards other than cash awards generally will be settled in shares of our common stock, but the plan administrator may provide for cash settlement of any award. A brief description of each award type follows.

- Ÿ Stock Options. Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Internal Revenue Code are satisfied. The exercise price of a stock option generally will not be less than 100% of the fair market value of the underlying share on the date of grant (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders). Vesting conditions determined by the plan administrator may apply to stock options and may include continued service, performance and/or other conditions.
- Ÿ SARs. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a SAR will generally not be less than 100% of the fair market value of the underlying share on the date of grant (except with respect to certain substitute SARs granted in connection with a corporate transaction), and the term of a SAR may not be longer than ten years. Vesting conditions determined by the plan administrator may apply to SARs and may include continued service, performance and/or other conditions.
- Ÿ Restricted Stock, RSUs and Performance Shares. Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met, and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met. Delivery of the shares underlying RSUs may be deferred under the terms of the award or at the election of the participant, if the plan administrator permits such a deferral. Performance shares are contractual rights to receive a range of shares of our common stock in the future based on the attainment of specified performance goals, in addition to other conditions which may apply to these awards. Conditions applicable to restricted stock, RSUs and performance shares may be based on continuing service, the attainment of performance goals and/or such other conditions as the plan administrator may determine.
- Ÿ Stock Payments, Other Incentive Awards and Cash Awards. Stock payments are awards of fully vested shares of our common stock that may, but need not, be made in lieu of base salary, bonus, fees or other cash compensation otherwise payable to any individual who is eligible to receive awards. Other incentive awards are awards other than those enumerated in this summary that are denominated in, linked to or derived from shares of our common stock or value metrics related to our shares, and may remain forfeitable unless and until specified conditions are met. Cash awards are cash incentive bonuses subject to performance goals.
- Ÿ Dividend Equivalents. Dividend equivalents represent the right to receive the equivalent value of dividends paid on shares of our common stock and may be granted alone or in tandem with awards. Dividend equivalents are credited as of dividend record dates during the period between the date an award is granted and the date such award vests, is exercised, is distributed or expires, as determined by the plan administrator.

#### Performance Awards

Performance awards include any of the foregoing awards that are granted subject to vesting and/or payment based on the attainment of specified performance goals or other criteria the plan administrator may determine, which may or may not be objectively determinable. Performance criteria upon which performance goals are established by the plan administrator may include but are not limited to: (i) net earnings (either before or after one or more of (A) interest, (B) taxes, (C) depreciation and (D) amortization); (ii) gross or net sales or revenue; (iii) net income (either before or after taxes); (iv) adjusted net income; (v) operating earnings or profit; (vi) cash flow (including, but not limited to, operating cash flow and free cash flow); (vii) return on assets; (viii) return on capital; (ix) return on stockholders' equity; (x) total stockholder return; (xi) return on sales; (xii) gross or net profit or operating margin; (xiii) costs; (xiv) expenses; (xv) working capital; (xvi) earnings per share; (xvii) adjusted earnings per share; (xviii) price per share; (xix) regulatory body approval for commercialization of a product; (xx) implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; (xxi) market share; (xxii) economic value; (xxiii) revenue and (xxiv) revenue growth.

#### Certain Transactions

The plan administrator has broad discretion to take action under the 2015 Plan, as well as make adjustments to the terms and conditions of existing and future awards, to prevent the dilution or enlargement of intended benefits and facilitate necessary or desirable changes in the event of certain transactions and events affecting our common stock, such as stock dividends, stock splits, mergers, acquisitions, consolidations and other corporate transactions. In addition, in the event of certain non-reciprocal transactions with our stockholders known as "equity restructurings," the plan administrator will make equitable adjustments to the 2015 Plan and outstanding awards. In the event of a change in control of our company (as defined in the 2015 Plan), to the extent that the surviving entity declines to continue, convert, assume or replace outstanding awards, then all such awards may become fully vested and exercisable in connection with the transaction. Upon or in anticipation of a change of control, the plan administrator may cause any outstanding awards to terminate at a specified time in the future and give the participant the right to exercise such awards during a period of time determined by the plan administrator in its sole discretion. Individual award agreements may provide for additional accelerated vesting and payment provisions.

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

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

### Plan Amendment and Termination

Our board of directors may amend or terminate the 2015 Plan at any time; however, except in connection with certain changes in our capital structure, stockholder approval will be required for any amendment that increases the number of shares available under the 2015 Plan. The plan administrator will have the authority, without the approval of our stockholders, to amend any outstanding stock option

or SAR to reduce its price per share. No award may be granted pursuant to the 2015 Plan after the tenth anniversary of the date on which our board of directors adopts the 2015 Plan.

### Employee Stock Purchase Plan

In connection with this offering, we may adopt and ask our stockholders to approve an Employee Stock Purchase Plan, or the ESPP. The material terms of the ESPP, as it is currently contemplated, are summarized below. Our board of directors is still in the process of considering the ESPP and, accordingly, this summary is subject to change.

#### Shares Available: Administration

A total of shares of our common stock are initially reserved for issuance under our ESPP. In addition, the number of shares available for issuance under the ESPP will be annually increased on the January 1 of each year during the term of the ESPP, beginning on January 1, 2016, by an amount equal to the least of: (a) shares, (b) % of the shares outstanding (on an as-converted basis) on the final day of the immediately preceding calendar year and (c) such smaller number of shares as is determined by our board of directors, provided that no more than shares may be issued under the ESPP.

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

## Eligibility

Our employees are eligible to participate in the ESPP if they are customarily employed by us or a participating subsidiary for at least 20 hours per week and more than five months in any calendar year. However, an employee may not be granted rights to purchase stock under our ESPP if such employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our common or other class of stock.

#### Awards

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

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

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

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

### Certain Transactions

In the event of certain non-reciprocal transactions with our stockholders known as "equity restructurings," the plan administrator will make equitable adjustments to the ESPP and outstanding awards. In the event of certain significant transactions or a change in control, the plan administrator may provide for (1) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (2) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, if any, (3) the adjustment in the number and type of shares of stock subject to outstanding rights, (4) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods or (5) the termination of all outstanding rights.

### Plan Amendment

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

#### 2012 Stock Incentive Plan

Our board of directors and stockholders have approved the 2012 Stock Incentive Plan, or the 2012 Plan, under which we may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards to employees, directors and consultants of our company. We have reserved a total of 3,608,029 shares of our common stock for issuance under the 2012 Plan.

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

#### Administration

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

## Types of Awards; Eligibility

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

#### Certain Transactions

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

### Amendment and Termination

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

## **Director Compensation**

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

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

### 2014 Director Compensation Table

	Option Awards	
<u>Name</u>	(\$) <sup>(1)</sup>	Total (\$)
Noubar B. Afeyan, Ph.D.		
Werner Cautreels, Ph.D.	_	_
Peter Barton Hutt	_	_
Lorence H. Kim, M.D.	407,302	407,302
Richard N. Kender	407,302	407,302

(1) Represents the aggregate grant date fair value of the option awards granted during 2014 computed in accordance with FASB ASC Topic 718. For a description of the assumptions used in valuing these awards, see Note 9 to our audited financial statements included elsewhere in this prospectus. The following table shows the number of option awards and unvested stock awards held as of December 31, 2014 by each of our directors who are not NEOs:

<u>Name</u>	Stock Options (#)	Restricted Shares (#)
Noubar B. Afeyan, Ph.D.		
Werner Cautreels, Ph.D.	100,000	
Peter Barton Hutt	50,000	6,250
Lorence H. Kim, M.D.	75,000	_
Richard N. Kender	75,000	<del>-</del>

Following this offering, we expect to implement a compensation program for our non-employee directors under which each non-employee director will receive the following amounts for their services on our board of directors:

- Ÿ an option to purchase shares of our common stock upon the director's initial election or appointment to our board of directors that occurs after our initial public offering;
- Ÿ if the director has served on our board of directors for at least six months as of the date of an annual meeting of stockholders, an option to purchase shares of our common stock on the date of the annual meeting;
- Ÿ an annual director fee of \$ , or if the director serves as chairman of our board of directors, an annual director fee of \$ ; and
- $\ddot{\mathrm{Y}}$  if the director serves on a committee of our board of directors, an additional annual fee as follows:
  - Ÿ chairman of the audit committee—\$;
  - Ÿ audit committee member other than the chairman—\$
  - Y chairman of the compensation committee—\$
  - $\ddot{ ext{Y}}$  compensation committee member other than the chairman—\$ ;
  - Ÿ chairman of the nominating and corporate governance committee—\$; and
  - $\ddot{Y}$  nominating and corporate governance committee member other than the chairman—\$

Stock options granted to our non-employee directors under the program will have an exercise price equal to the fair market value of our common stock on the date of grant and will expire ten years after the date of grant. The stock options granted upon a director's initial election or appointment will vest in annual installments over four years following the date of grant. The stock options granted annually to directors will vest in a single installment on the earlier of the day before the next annual meeting or the first anniversary of the date of grant. In addition, all unvested stock options will vest in full upon the occurrence of a change in control.

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

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

### CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following includes a summary of transactions since January 1, 2011 to which we have been a party in which the amount involved exceeded or will exceed \$120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and Director Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

### **Preferred Stock Financings**

Series A Preferred Stock Financing. In June 2012, we issued and sold to investors in private placements an aggregate of 6,329,114 shares of our Series A preferred stock at a purchase price of \$0.79 per share, for aggregate consideration of approximately \$5.0 million and issued 1,901,883 shares related to the cancellation of convertible debt.

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

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

The following table sets forth the aggregate number of these securities acquired by the listed holders of more than 5% of our capital stock. Each share of our preferred stock identified in the following table will convert into one share of common stock upon the closing of this offering.

Participant_	Series A	Series A-2	Series B
5% or Greater Stockholders <sup>(1)</sup>	·		
Entities affiliated with Flagship Ventures Funds <sup>(2)</sup>	8,230,997	1,123,596	2,272,727
Enso Ventures 2 Limited	_	1,123,596	681,818
Directors and Executive Officers			
Roger J. Pomerantz, M.D.	_	_	22,727
John Aunins, Ph.D.	_	_	34,090
David N. Cook, Ph.D.	_	_	45,454

1) Additional details regarding these stockholders and their equity holdings are provided under the caption "Principal Stockholders."

<sup>(2)</sup> Flagship Ventures Funds consists of Flagship VentureLabs IV LLC, Flagship Ventures Fund IV, L.P., Flagship Ventures Fund IV-Rx, L.P. and Flagship Ventures Fund 2007 L.P.

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

<u>Director</u>	Principal Stockholder
Noubar B. Afeyan, Ph.D.	Flagship Ventures Funds
David A. Berry, M.D., Ph.D.	Flagship Ventures Funds
Roger J. Pomerantz, M.D.	Flagship Ventures Funds

# **Services Agreement**

On October 19, 2010, we entered into a services agreement with Flagship Ventures Management, Inc., or Flagship Management, an affiliate of Flagship Ventures, under which Flagship Management provides us with personnel and advisory and administrative services on an asneeded basis. From October 19, 2010 to December 31, 2014, we paid Flagship Management an aggregate of \$1.7 million for services provided under the agreement, inclusive of the services provided by Dr. Berry, who served as our Interim President and Chief Executive Officer from March 29, 2013 through May 30, 2014.

## **Investors' Rights Agreement**

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

## **Voting Agreement**

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

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

# **Employment Agreements**

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

# **Indemnification Agreements**

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

# Stock Option Grants to Executive Officers and Directors

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

### Policies and Procedures for Related Person Transactions

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

### PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock, as of December 31, 2014, and as adjusted to reflect the sale of shares of common stock in this offering, by:

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

The number of shares beneficially owned by each stockholder is determined under rules issued by the Securities and Exchange Commission. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. Applicable percentage ownership is based on 29,757,237 shares of common stock outstanding as of December 31, 2014, assuming the conversion of all of our preferred stock into common stock upon the closing of this offering. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of December 31, 2014 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless noted otherwise, the address of all listed stockholders is 161 First Street, Cambridge, Massachusetts 02142. Each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Number of Share		Beneficially	entage of Shares neficially Owned	
Name of Beneficial Owner	Beneficially Owned Prior to Offering	Prior to Offering	After Offering	
5% or Greater Stockholders		<u> </u>	<u> </u>	
Entities affiliated with Flagship Ventures Funds(1)	16,627,320	55.9%		
Nestlé Health Science US Holdings, Inc. <sup>(2)</sup>	5,555,555	18.7%		
Entities affiliated with Fidelity Management & Research Company <sup>(3)</sup>	2,466,457	8.3%		
Enso Ventures 2 Limited	1,805,414	6.1%		
Named Executive Officers and Directors				
Roger J. Pomerantz, M.D. <sup>(4)</sup>	105,227	*		
Noubar B. Afeyan, Ph.D. <sup>(1)</sup>	16,627,320	55.9%		
Grégory Behar	_	_		
David A. Berry, M.D., Ph.D.(1)(5)	17,327,320	58.2%		
Werner Cautreels, Ph.D. <sup>(6)</sup>	50,000	*		
Peter Barton Hutt <sup>(7)</sup>	71,875	*		
Richard N. Kender	_	_		
Lorence H. Kim, M.D.	_	_		
John Aunins, Ph.D. <sup>(8)</sup>	196,590	*		
David N. Cook, Ph.D. <sup>(9)</sup>	229,674	*		
Eric D. Shaff	_	_		
All executive officers and directors as a group (12 persons) <sup>(10)</sup>	17,980,685	60.4%		

- \* Less than 1%
- (1) Consists of (a) 5,000,000 shares of common stock held by Flagship VentureLabs IV LLC ("Flagship VentureLabs"), (b) 1,944,444 shares of common stock held by Nestlé Health Science US Holdings, Inc. for which Flagship VentureLabs exercises voting control under certain circumstances, which voting control terminates upon the closing of the company's initial public offering, (c) 8,822,420 shares of common stock held by Flagship Ventures Fund IV, L.P. ("Flagship Fund IV"), (d) 2,205,603 shares of common stock held by Flagship Ventures Fund IV-Rx, L.P. ("Flagship Fund IV-Rx") and (e) 599,297 shares of common stock held by Flagship Ventures Fund 2007, L.P. ("Flagship Fund 2007" and together with Flagship VentureLabs, Flagship Fund IV and Flagship Fund IV-Rx, the "Flagship Funds"). Flagship Fund IV is a member of Flagship VentureLabs and also serves as its manager. The general partner of each of Flagship Fund IV and Flagship Fund IV-Rx is Flagship Ventures Fund IV General Partner LLC ("Flagship Fund IV GP"), and the general partner of Flagship Fund 2007 is Flagship Ventures 2007 General Partner LLC ("Flagship Fund IV GP"), and the general Partners"). Noubar Afeyan and David Berry are directors of Seres Health and members of the Flagship General Partners. In addition, Mr. Afeyan serves as a managing member of the Flagship General Partners and may be deemed to possess voting and investment control over the shares held by the Flagship Funds. Neither of the Flagship General Partners directly own any of the shares held by the Flagship Funds, and each of the Flagship Funds is one Memorial Drive, 7th Floor, Cambridge, MA 02142.
- address of the Flagship Funds is One Memorial Drive, 7th Floor, Cambridge, MA 02142.

  (2) Nestlé Health Science US Holdings, Inc. is a wholly owned, indirect subsidiary of Nestlé S.A., a publicly traded company. The address for Nestlé Health Science US Holdings, Inc. is c/o Nestlé USA, Inc. 383 Main Ave, 5th Floor, Norwalk, CT 06851.
- (3) Consists of (a) 1,292,035 shares of common stock held by Fidelity Select Portfolios: Biotechnology Fund, (b) 352,270 shares of common stock held by Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund, (c) 107,186 shares of common stock held by Fidelity Growth Company Comingled Pool, (d) 142,139 shares of common stock held by Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund and (e) 572,827 shares of common stock held by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund. These accounts are managed by direct or indirect subsidiaries of FMR LLC. Edward C. Johnson 3d is a Director and the Chairman of FMR LLC and Abigail P. Johnson is a Director, the Vice Chairman and the President of FMR LLC. Members of the family of Edward C. Johnson 3d, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B stockholders have entered into a stockholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Edward C. Johnson 3d nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act ("Fidelity Funds") advised by Fidelity Management & Research Company ("FMR Co"), a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees.
- (4) Includes 82,500 shares of common stock which Dr. Pomerantz has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of December 31, 2014.
- (5) Includes 16,627,320 shares of common stock held by entities affiliated with Flagship Ventures Funds (see footnote 1).
- (6) Consists of 50,000 shares of common stock which Dr. Cautreels has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of December 31, 2014.
- (7) Includes 21,875 shares of common stock which Mr. Hutt has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of December 31, 2014.
- (8) Includes 112,500 shares of common stock which Dr. Aunins has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of December 31, 2014.
- (9) Includes 184,220 shares of common stock which Dr. Cook has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of December 31, 2014.
- (10) Consists of (a) 17,529,591 shares of common stock and (b) 451,094 shares of common stock which the holders have the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of December 31, 2014.

### **DESCRIPTION OF CAPITAL STOCK**

### General

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

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

As of December 31, 2014, we had issued and outstanding:

- Ÿ 6,890,250 shares of our common stock held of record by 20 stockholders;
- Y 8.230,997 shares of our Series A preferred stock that are convertible into 8,230,997 shares of our common stock as of such date:
- Y 2,247,192 shares of our Series A-2 preferred stock that are convertible into 2,247,192 shares of our common stock as of such date;
- Ÿ 4,831,359 shares of our Series B preferred stock that are convertible into 4,831,359 shares of our common stock as of such date;
- Ÿ 3,946,328 shares of our Series C preferred stock that are convertible into 3,946,328 shares of our common stock as of such date;
- Ÿ 2,222,222 shares of our Series D preferred stock that are convertible into 2,222,222 shares of our common stock as of such date; and
   Ÿ 1,388,889 shares of our Series D-1 preferred stock that are convertible into 1,388,889 shares of our Series D preferred stock, that are then convertible into 1,388,889 shares of our common stock as of such date.

In connection with this offering, all of the outstanding shares of our preferred stock will automatically convert into an aggregate of 22.866.987 shares of our common stock.

### **Common Stock**

As of December 31, 2014, 29,757,237 shares of our common stock were held of record by stockholders, assuming the conversion of all of our outstanding shares of preferred stock into shares of our common stock.

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

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

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

#### **Preferred Stock**

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

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

#### **Options**

As of December 31, 2014, options to purchase 3,579,342 shares of our common stock were outstanding under our 2012 Stock Incentive Plan.

### Warrants

On June 6, 2014, we issued two warrants to the Mayo Foundation for Medical Education and Research, or the Mayo Foundation, in connection with our research and option agreement with the Mayo Foundation. In each case, the warrant, unless earlier exercised or terminated, will terminate upon the closing of this offering. The first warrant provides the Mayo Foundation a right to purchase 454,545 shares of our common stock at a purchase price of \$0.01 per share. Unless earlier exercised, the warrant will be automatically cashless exercised on the date prior to its termination, which will be the date prior to the closing of this offering. Investors can determine the number of shares issuable upon the automatic cashless exercise of this warrant by (i) subtracting \$0.01 from the public offering price, (ii) dividing the remainder by the public offering price and (iii) multiplying the quotient by 454,545. Based on an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus, this warrant would be cashless exercised for shares of

common stock prior to the closing of this offering. The second warrant is contingent upon the accomplishment of certain milestones. As of December 31, 2014, the Mayo Foundation had not accomplished any of the milestones, and, therefore, there were no shares of our common stock exercisable pursuant to this warrant.

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

### **Registration Rights**

Upon the closing of this offering, holders of shares of our common stock as of December 31, 2014, including shares issuable upon the exercise of a warrant for 97,127 common shares, or their transferees will be entitled to the following rights with respect to the registration of such shares for public resale under the Securities Act, pursuant to an amended and restated investors' rights agreement by and among us and certain of our stockholders, until such shares can otherwise be sold without restriction under Rule 144, or until the rights otherwise terminate pursuant to the terms of the investors' rights agreement. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

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

# Piggyback Registration Rights

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

# Form S-3 Registration Rights

If, at any time after we become entitled under the Securities Act to register our shares on a registration statement on Form S-3, the holders of the registrable securities request in writing that we effect a registration with respect to registrable securities at an aggregate price to the public in the offering of at least \$5,000,000, we will be required to effect such registration; provided, however, that we will not be required to effect such a registration if, within a given six-month period, we have already effected two registrations on Form S-3 for the holders of registrable securities.

# Expenses

Ordinarily, other than underwriting discounts and commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these

registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements of a counsel for the selling security holders and blue sky fees and expenses.

#### Termination of Registration Rights

The registration rights terminate upon the earlier of five years after the effective date of the registration statement of which this prospectus is a part, or, with respect to the registration rights of an individual holder, when the holder can sell all of such holder's registrable securities in a 90-day period without restriction under Rule 144 under the Securities Act.

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

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

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

### Undesignated Preferred Stock

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

# Stockholder Meetings

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

### Requirements for Advance Notification of Stockholder Nominations and Proposals

Our restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

# Elimination of Stockholder Action by Written Consent

Our restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

# Staggered Board

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see "Management—Board Composition and Election of Directors." This system of electing and removing directors may tend to discourage a third-party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

#### Removal of Directors

Our restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote in the election of directors.

# Stockholders Not Entitled to Cumulative Voting

Our restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

# Delaware Anti-Takeover Statute

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

### Choice of Forum

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine. Our restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

### Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, the provision prohibiting cumulative voting and the Delaware anti-takeover statute would require approval by holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote thereon.

The provisions of Delaware law, our restated certificate of incorporation and our restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests

# **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock will be

# **National Securities Exchange Listing**

We will apply to have our common stock listed on

under the symbol "MCRB."

### SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock.

Upon the closing of this offering, we will have outstanding an aggregate of shares of common stock, based on our shares outstanding as of December 31, 2014 and assuming the issuance of shares of common stock offered by us in this offering, the automatic conversion of all outstanding shares of our preferred stock into 22,866,987 shares of our common stock and the issuance of shares of common stock upon the cashless exercise of a warrant for common stock. Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below. Upon expiration of the lock-up period, we estimate that approximately shares will be available for sale in the public market, subject in some cases to applicable volume limitations under Rule 144.

In addition, of the shares of our common stock that were subject to stock options outstanding as of December 31, 2014, options to purchase shares of common stock were vested as of December 31, 2014 and, upon exercise, these shares will be eligible for sale subject to the lock—up agreements described below and Rules 144 and 701 promulgated under the Securities Act.

# **Lock-Up Agreements**

We and each of our directors and executive officers and holders of substantially all of our outstanding capital stock, have agreed that, without the prior written consent of Goldman, Sachs & Co. and BofA Merrill Lynch, on behalf of the underwriters, we and they will not, subject to limited exceptions described below, during the period ending 180 days after the date of this prospectus:

- Ÿ offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, or publicly disclose an intention to take any such actions with respect to, any shares of our common stock, or any options or warrants to purchase any shares of our common stock, or any securities convertible into, exchangeable for or that represent the right to receive shares of our common stock, whether now owned or hereinafter acquired, owned directly or indirectly; or
- Ÿ request, make any demand for or exercise any right with respect to, the registration of any of our common stock or any security convertible into or exercisable or exchangeable for our common stock,

whether any transaction described above is to be settled by delivery of our common stock or such other securities, in cash or otherwise.

In the case of our officers, directors and stockholders, these lock-up restrictions are subject to certain exceptions, including transfers (i) made as bona fide gifts; (ii) for the primary purpose of satisfying exercise price and/or tax withholding obligations upon the vesting or exercise of an option, or other award granted under a stock incentive plan or stock purchase plan of the company; (iii) acquired in open market transactions; (iv) as part of a distribution, transfer or disposition without consideration to a holder's limited or general partners; and (v) in connection with the establishment of a trading plan pursuant to 10b5-1 under the Exchange Act.

Upon the expiration of the applicable lock-up periods, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

#### **Rule 144**

#### Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- Y 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; or
- Ÿ the average weekly trading volume in our common stock on on Form 144 with respect to such sale.

during the four calendar weeks preceding the filing of a notice

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of \$50,000, the seller must file a notice on Form 144 with the Securities and Exchange Commission and concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

# Non-Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the nine months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

# **Rule 701**

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act

is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The Securities and Exchange Commission has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

# **Equity Plans**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our stock plans. We expect to file the registration statement covering shares offered pursuant to our stock plans shortly after the date of this prospectus, permitting the resale of such shares by nonaffiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.

# **Registration Rights**

Upon the closing of this offering, the holders of shares of common stock, which includes all of the shares of common stock issuable upon the automatic conversion of our preferred stock upon the closing of this offering, or their transferees will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See "Description of Capital Stock—Registration Rights" for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement.

# MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or foreign tax laws are not discussed. This discussion is based on the Internal Revenue Code of 1986, as amended, or Code, Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or IRS, in effect as of the date of this offering. These authorities may change or be subject to differing interpretations. Any such change may be applied retroactively in a manner that could adversely affect a non-U.S. holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to non-U.S. holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a non-U.S. holder's particular circumstances, including the impact of the unearned income Medicare contribution tax. In addition, it does not address consequences relevant to non-U.S. holders subject to particular rules, including, without limitation:

- Ÿ U.S. expatriates and certain former citizens or long-term residents of the United States;
- Ÿ persons subject to the alternative minimum tax;
- Ÿ persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- $\ddot{Y}$  banks, insurance companies and other financial institutions;
- Ÿ real estate investment trusts or regulated investment companies;
- Ÿ brokers, dealers or traders in securities;
- Ÿ "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax:
- Ÿ S corporations, partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes;
- Ÿ tax-exempt organizations or governmental organizations;
- Ÿ persons deemed to sell our common stock under the constructive sale provisions of the Code;
- Ÿ persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation; and
- Ÿ tax-qualified retirement plans.

If a partnership (or other entity treated as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT INTENDED AS TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

#### Definition of a Non-U.S. Holder

For purposes of this discussion, a "non-U.S. holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor a partnership for United States federal income tax purposes. A U.S. person is any of the following:

- Ÿ an individual who is a citizen or resident of the United States;
- Ÿ a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- Ÿ an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- Ÿ a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more United States persons (within the meaning of Section 7701(a)(30) of the Code), or (2) has made a valid election under applicable Treasury Regulations to continue to be treated as a United States person.

#### **Distributions**

As described in the section titled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions on our common stock, such distributions of cash or property on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a non-U.S. holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below in the section relating to the sale or disposition of our common stock.

Subject to the discussion below on backup withholding and foreign accounts, dividends paid to a non-U.S. holder of our common stock that are not effectively connected with the non-U.S. holder's conduct of a trade or business within the United States will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty).

Non-U.S. holders will be entitled to a reduction in or an exemption from withholding on dividends as a result of either (a) an applicable income tax treaty or (b) the non-U.S. holder holding our common stock in connection with the conduct of a trade or business within the United States and dividends being paid in connection with that trade or business. To claim such a reduction in or exemption from withholding, the non-U.S. holder must provide the applicable withholding agent with a properly executed (a) IRS Form W-8BEN claiming an exemption from or reduction of the withholding tax under the benefit of an income tax treaty between the United States and the country in which the non-U.S. holder resides or is established, or (b) IRS Form W-8ECI stating that the dividends are not subject to

withholding tax because they are effectively connected with the conduct by the non-U.S. holder of a trade or business within the United States, as may be applicable. These certifications must be provided to the applicable withholding agent prior to the payment of dividends and must be updated periodically. Non-U.S. holders that do not timely provide the applicable withholding agent with the required certification, but that qualify for a reduced rate under an applicable income tax treaty, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

Subject to the discussion below on backup withholding and foreign accounts, if dividends paid to a non-U.S. holder are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such dividends are attributable), then, although exempt from U.S. federal withholding tax (provided the non-U.S. holder provides appropriate certification, as described above), the non-U.S. holder will be subject to U.S. federal income tax on such dividends on a net income basis at the regular graduated U.S. federal income tax rates. In addition, a non-U.S. holder that is a corporation may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits for the taxable year that are attributable to such dividends, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

# Sale or Other Taxable Disposition

Subject to the discussions below on backup withholding and foreign accounts, a non-U.S. holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- Ÿ the gain is effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such gain is attributable);
- Ÿ the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- Ÿ our common stock constitutes a U.S. real property interest, or USRP, by reason of our status as a U.S. real property holding corporation, or a "USRPHC", for U.S. federal income tax purposes.

Gain described in the first bullet point above will generally be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates. A non-U.S. holder that is a foreign corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) of a portion of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on any gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder (even though the individual is not considered a resident of the United States) provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we are not currently and do not anticipate becoming a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our other business assets and our non-U.S. real property interests, however, there can be no assurance we are not a USRPHC or will not

become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a non-U.S. holder of our common stock will not be subject to U.S. federal income tax if such class of stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such non-U.S. holder owned, actually or constructively, 5% or less of such class of our stock throughout the shorter of the five-year period ending on the date of the sale or other disposition or the non-U.S. holder's holding period for such stock.

Non-U.S. holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

# Information Reporting and Backup Withholding

Subject to the discussion below on foreign accounts, a non-U.S. holder will not be subject to backup withholding with respect to payments of dividends on our common stock we make to the non-U.S. holder, provided the applicable withholding agent does not have actual knowledge or reason to know such holder is a United States person and the holder certifies its non-U.S. status, such as by providing a valid IRS Form W-8BEN or W-8ECI, or other applicable certification. However, information returns will be filed with the IRS in connection with any dividends on our common stock paid to the non-U.S. holder, regardless of whether any tax was actually withheld. Copies of these information returns may also be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the non-U.S. holder resides or is established.

Information reporting and backup withholding may apply to the proceeds of a sale of our common stock within the United States, and information reporting may (although backup withholding generally will not) apply to the proceeds of a sale of our common stock outside the United States conducted through certain U.S.-related financial intermediaries, in each case, unless the beneficial owner certifies under penalty of perjury that it is a non-U.S. holder on IRS Form W-8BEN or other applicable form (and the payor does not have actual knowledge or reason to know that the beneficial owner is a U.S. person) or such owner otherwise establishes an exemption.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

# Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under the Foreign Account Tax Compliance Act, FATCA, on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on payments to non-compliant foreign financial institutions and certain other account holders.

The withholding provisions described above will generally apply to payments of dividends made on or after January 1, 2014 and to payments of gross proceeds from a sale or other disposition of stock on or after January 1, 2017. Because we may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of these withholding rules we may treat the entire distribution as a dividend. Prospective investors should consult their tax advisors regarding these withholding provisions.

# **UNDERWRITING**

We and the underwriters named below will enter into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter shall severally agreed to purchase the number of shares indicated in the following table. Goldman, Sachs & Co. and Merrill Lynch, Pierce, Fenner & Smith Incorporated are the representatives of the underwriters.

<u>Underwriters</u>	Number of Shares
Goldman, Sachs & Co.	
Merrill Lynch, Pierce, Fenner & Smith	
Incorporated	
Leerink Partners LLC	
Canaccord Genuity Inc	
Total	

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid by us to the underwriters. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

Paid by the Company_	No Exercise	Full Exercise
Per Share	\$	\$
Total	\$	\$

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to \$ per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We and our officers, directors and holders of substantially all of our outstanding capital stock have agreed with the underwriters, subject to certain exceptions, we and they will not dispose of or hedge any of our or their capital stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of the representatives. For more information, see "Shares Eligible for Future Sale—Lock Up Agreements".

Prior to the offering, there has been no public market for our shares. The initial public offering price will be negotiated among us and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

An application will be made to list our common stock on the

under the symbol "MCRB."

In connection with the offering, the underwriters may purchase and sell shares of common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A "covered short position" is a short position that is not greater than the amount of additional shares for which the underwriters' option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. "Naked" short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of the company's stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on , in the over-the-counter market or otherwise.

The underwriters do not expect sales to discretionary accounts to exceed five percent of the total number of shares offered.

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately million. We have agreed to reimburse the underwriters for expenses relating to clearance of this offering with the Financial Industry Regulatory Authority (in an amount not to exceed \$ ).

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with the issuer. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

# **Selling Restrictions**

# European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State), each underwriter has represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date) it has not made and will not make an offer of shares to the public in that Relevant Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of shares to the public in that Relevant Member State at any time:

- to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- (b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;
- (c) to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of the representatives for any such offer; or
- (d) in any other circumstances which do not require the publication by the Issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer of shares to the public" in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

Each underwriter has represented and agreed that:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act, or FSMA) received by it in connection with the issue or sale of the shares in circumstances in which Section 21(1) of the FSMA does not apply to the Issuer; and

(b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

### Hong Kong

The shares may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), or (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

# Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 by a relevant person which is: (a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for 6 months after that corporation or that trust has acquired the shares under Section 275 except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; or (3) by operation of law.

# Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and each underwriter has agreed that it will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

#### **LEGAL MATTERS**

The validity of the shares of common stock offered hereby will be passed upon for us by Latham & Watkins LLP. Certain legal matters will be passed upon for the underwriters by Ropes & Gray LLP.

#### **EXPERTS**

The financial statements as of December 31, 2013 and 2012 and for each of the two years in the period ended December 31, 2013 included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

### WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. Upon the closing of this offering, we will be required to file periodic reports, proxy statements, and other information with the Securities and Exchange Commission pursuant to the Securities Exchange Act of 1934. You may read and copy this information at the Public Reference Room of the Securities and Exchange Commission, 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the public reference rooms by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission also maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the Securities and Exchange Commission. The address of that site is www.sec.gov.

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### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Seres Health, Inc.

In our opinion, the accompanying balance sheets and the related statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' deficit and of cash flows present fairly, in all material respects, the financial position of Seres Health, Inc. at December 31, 2013 and 2012, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2013, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts December 11, 2014

# SERES HEALTH, INC. BALANCE SHEETS

(In thousands, except share and per share data)

	December 31,		September 30,	Pro Forma September 30,	
	2012	2013	2014	2014	
Acceto			(unaudited)	(unaudited)	
Assets Current assets:					
Cash and cash equivalents	\$ 6,215	\$ 1,654	\$ 7,120	\$ 7,120	
Prepaid expenses and other current assets	30	51	289	289	
Total current assets	6,245	1,705	7,409	7,409	
Property and equipment, net	266	352	866	866	
Restricted cash	27	37	139	139	
Deferred offering costs			122	122	
Deferred financing costs	<u> </u>	31	17	17	
Total assets	\$ 6,538	\$ 2,125	\$ 8,553	\$ 8,553	
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)	<u>Ψ 0,330</u>	<u> </u>	<u>Ψ 0,555</u>	Ψ 0,000	
Current liabilities:					
Accounts payable	\$ 112	\$ 393	\$ 1,009	\$ 1,009	
Accrued expenses and other current liabilities	66	263	568	568	
Notes payable, current portion		400	1,200	1,200	
Total current liabilities	178	1,056	2,777	2,777	
Notes payable, net of discount	_	438	1,588	1,588	
Preferred stock warrant liability		<u> 164</u>	668		
Total liabilities	178	1,658	5,033	4,365	
Commitments and contingencies (Note 12)					
Redeemable convertible preferred stock (Series A, A-2 and B), \$0.001 par value; 10,478,189, 11,806,272 and 15,401,675 shares authorized at December 31, 2012 and 2013 and September 30, 2014 (unaudited), respectively; 10,478,189 shares issued and outstanding at December 31, 2012 and 2013 and 15,309,548 shares issued and outstanding at September 30, 2014 (unaudited); aggregate liquidation preference of \$11,653 and \$23,301 at December 31, 2013 and September 30, 2014 (unaudited), respectively; no shares issued or outstanding pro forma at September 30, 2014 (unaudited) Stockholders' equity (deficit):	10,708	11,583	23,160	_	
Common stock, \$0.001 par value; 21,000,000, 24,500,000 and					
28,000,000 shares authorized at December 31, 2012 and 2013 and September 30, 2014 (unaudited), respectively; 7,590,000, 6,855,000 and 6,884,187 shares issued and outstanding at December 31, 2012 and 2013 and September 30, 2014 (unaudited), respectively; 22,193,735 shares issued and	7	7	7	22	
outstanding, pro forma at September 30, 2014 (unaudited)	7	7	7 3	22	
Additional paid-in capital Accumulated deficit	— (4,355)	(11 122)		23,816	
		(11,123)	(19,650)	(19,650)	
Total stockholders' equity (deficit)	(4,348)	(11,116)	(19,640)	4,188	
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 6,538	<u>\$ 2,125</u>	<u>\$ 8,553</u>	\$ 8,553	

# SERES HEALTH, INC. STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

		Ended nber 31,	Nine Months Ended September 30,			
	2012	2013	2013	2014		
Revenue	\$ —	\$ —	(unau	dited)		
. 10 10 101	<u> Ф —</u>	<u> Ф —</u>	<u>ф —</u>	<u> Ф</u>		
Operating expenses:  Research and development expenses	2,077	4,805	3,288	5,658		
General and administrative expenses	956	1,247	859	2,211		
·		6,052				
Total operating expenses	3,033		4,147	7,869		
Loss from operations	(3,033)	(6,052)	(4,147)	(7,869)		
Other income (expense):	(0.0)	(40)	(0)	(4 = 4)		
Interest income (expense), net	(93)	(42)	(6)	(154)		
Revaluation of preferred stock warrant liability		(8)		(504)		
Total other income (expense), net	(93)	(50)	(6)	(658)		
Net loss and comprehensive loss	(3,126)	(6,102)	(4,153)	(8,527)		
Accretion of redeemable convertible preferred stock						
to redemption value	(276)	(875)	(654)	(1,019)		
Net loss attributable to common stockholders	\$ (3,402)	\$ (6,977)	\$ (4,807)	\$ (9,546)		
Net loss per share attributable to common stockholders,		<del></del>	<del></del>			
basic and diluted	\$ (0.59)	\$ (1.09)	\$ (0.76)	\$ (1.42)		
Weighted average common shares outstanding, basic	<u></u> /		<u></u>			
and diluted	5,725,120	6,394,916	6,330,706	6,731,724		
	3,123,120	0,004,010	0,000,700	0,731,724		
Pro forma net loss per share attributable to common		φ (0.2 <b>c</b> )		ф (O 41)		
stockholders, basic and diluted (unaudited)		<u>\$ (0.36</u> )		<u>\$ (0.41)</u>		
Pro forma weighted average common shares		40.000.405		40 -00 455		
outstanding, basic and diluted (unaudited)		<u>16,873,105</u>		19,536,123		

# SERES HEALTH, INC. STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

(In thousands, except share data)

	Series A, A-2 and B Redeemable Convertible Preferred Stock		Common Stock Par		Additional Paid-in	Accumulated	Total Stockholders'	
Balance at December 31, 2011	Shares	Amount \$ —	Shares	Value	<u>Capital</u>	Deficit (001)	Deficit (070)	
Issuance of common stock	_	<b>э</b> —	2,400,000 3,000,000	\$ 2 3	\$ —	\$ (981)	\$ (979) 3	
Issuance of Series A redeemable convertible	<u> </u>	_	3,000,000	3		<del>_</del>	3	
preferred stock, net of issuance costs of \$70	6,329,114	4,930	_	_	_	_	_	
Conversion of promissory notes and accrued interest into Series A redeemable convertible preferred stock	1,901,883	1,502						
Issuance of Series A-2 redeemable	1,901,003	1,302					_	
convertible preferred stock	2,247,192	4,000		_				
Issuance of restricted common stock	2,241,132	4,000	2,440,000	2				
Repurchase of unvested restricted common			2,440,000					
stock	_	_	(250,000)	_			<u></u>	
Stock-based compensation expense	_	_	(200,000)	_	28	<u></u>	28	
Accretion of redeemable convertible preferred					20		20	
stock to redemption value	_	276	_	_	(28)	(248)	(276)	
Net loss	_		_	_	( <u>_</u>	(3,126)	(3,126)	
Balance at December 31, 2012	10,478,189	10,708	7,590,000	7		(4,355)	(4,348)	
Repurchase of unvested restricted common	10, 110,100	20,100	1,000,000	•		(1,000)	(1,010)	
stock	_	_	(735,000)	_	_	_	_	
Stock-based compensation expense	_	_	(: 55,555)	_	209	_	209	
Accretion of redeemable convertible preferred								
stock to redemption value	_	875	_	_	(209)	(666)	(875)	
Net loss	_	_	_	_	`—	(6,102)	(6,102)	
Balance at December 31, 2013	10,478,189	11,583	6,855,000	7		(11,123)	(11,116)	
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of		·					,	
\$71	4,831,359	10,558	_	_	_	_	_	
Issuance of common stock upon exercise of stock options	_	_	29,187	_	5	_	5	
Issuance of common stock warrant	_	_	-	_	317	_	317	
Stock-based compensation expense	_	_	_	_	700	_	700	
Accretion of redeemable convertible preferred								
stock to redemption value	_	1,019	_	_	(1,019)	_	(1,019)	
Net loss						(8,527)	(8,527)	
Balance at September 30, 2014 (unaudited)	15,309,548	\$ 23,160	6,884,187	<u>\$ 7</u>	\$ 3	\$ (19,650)	<u>\$ (19,640)</u>	

# SERES HEALTH, INC. STATEMENTS OF CASH FLOWS (In thousands)

	Year Ended December 31,		Nine Months Ended September 30,	
	2012	2013	2013 (unau	2014
Cash flows from operating activities:			(unau	uiteuj
Net loss	\$(3,126)	\$(6,102)	\$(4,153)	\$ (8,527)
Adjustments to reconcile net loss to net cash used in operating activities:	+ (=,===)	+ (=,===)	+(:,===)	+ (5,521)
Stock-based compensation expense	28	209	160	700
Depreciation and amortization expense	25	88	62	113
Loss from revaluation of preferred stock warrant liability	_	8	_	504
Licensing fees paid in common stock warrant	_	_	_	317
Non-cash interest expense	_	19	4	64
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(29)	(21)	(25)	(238)
Accounts payable	103	281	153	519
Accrued expenses and other current liabilities	74	197	112	305
Net cash used in operating activities	(2,925)	(5,321)	(3,687)	(6,243)
Cash flows from investing activities:				
Purchases of property and equipment	(292)	(174)	(140)	(627)
Changes in restricted cash	(27)	(10)	(10)	(102)
Net cash used in investing activities	(319)	(184)	(150)	(729)
Cash flows from financing activities:				
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	8,930	_	_	10,558
Proceeds from issuance of promissory notes	500	_	_	_
Proceeds from issuance of notes payable and preferred stock warrant, net of issuance costs	_	944	944	2,000
Proceeds from exercise of stock options	_	_	_	5
Proceeds from issuance of common stock and restricted common stock	5	_	_	_
Repayment of notes payable	_	_	_	(100)
Payments of initial public offering costs	_	_	_	(25)
Net cash provided by financing activities	9,435	944	944	12,438
Net increase (decrease) in cash and cash equivalents	6,191	(4,561)	(2,893)	5,466
Cash and cash equivalents at beginning of period	24	6,215	6,215	1,654
Cash and cash equivalents at end of period	\$ 6,215	\$ 1,654	\$ 3,322	\$ 7,120
Supplemental disclosure of cash flow information:				
Cash paid for interest	\$ —	\$ 20	\$ 4	\$ 93
Supplemental disclosure of non-cash investing and financing activities:				
Conversion of promissory notes and accrued interest into shares of redeemable convertible				
preferred stock	\$ 1,502	\$ —	\$ —	\$ —
Accretion of redeemable convertible preferred stock to redemption value	\$ 276	\$ 875	\$ 654	\$ 1,019
Issuance of preferred stock warrant in connection with notes payable	\$ —	\$ 156	\$ 156	\$ — \$ 97
Deferred offering costs included in accounts payable	\$ —	\$ —	\$ —	\$ 97

# SERES HEALTH, INC. NOTES TO FINANCIAL STATEMENTS

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited)
(Amounts in thousands, except share and per share data)

#### Nature of the Business and Basis of Presentation

Seres Health, Inc. (the "Company") was incorporated under the laws of the State of Delaware on October 18, 2010. The Company is 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. The Company's lead product candidate, SER-109, is designed to prevent further recurrences of *Clostridium difficile* infection ("CDI"), a debilitating infection of the colon, by treating the dysbiosis of the colonic microbiome and, if approved by the FDA, could be a first-in-field drug. Using its microbiome therapeutics platform, the Company is developing additional product candidates, including SER-262 to prevent an initial recurrence of primary CDI and other product candidates to treat enteric pathogens, such as drug-resistant bacteria and metabolic diseases, such as early-stage, non-insulin dependent diabetes and inflammatory diseases, such as Crohn's disease and infections related to antibiotic use, cancer chemotherapy and immune suppression.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities.

The Company's product candidates are in the development stage. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

The Company's financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. The Company has experienced negative cash flows and had an accumulated deficit of \$11,123 as of December 31, 2013 and \$19,650 as of September 30, 2014. Subsequent to September 30, 2014, the Company received gross proceeds of \$48,000 from the sale of 3,946,328 shares of Series C convertible preferred stock in November 2014 (see Note 16) and the Company received aggregate gross proceeds of \$65,000 from the sale of 2,222,222 shares of Series D convertible preferred stock and 1,388,889 shares of Series D-1 convertible preferred stock in December 2014 (unaudited) (see Note 17). The Company expects that the proceeds from this sale of Series C convertible preferred stock in November 2014, together with its cash and cash equivalents at September 30, 2014 of \$7,120, will enable it to fund its operating expense and capital expenditure requirements through at least December 31, 2015. The future viability of the Company is dependent on its ability to generate cash from operating activities or to raise additional capital to finance its operations. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies.

# SERES HEALTH, INC. NOTES TO FINANCIAL STATEMENTS

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited)
(Amounts in thousands, except share and per share data)

The Company is seeking to complete an initial public offering of its common stock. Upon the closing of a qualified public offering with net proceeds of not less than \$35,000 and a price of at least \$9.00 per share, subject to certain terms, the Company's outstanding redeemable convertible preferred stock will automatically convert into shares of common stock (see Note 16).

In the event the Company does not complete an initial public offering, the Company expects to seek additional funding through private financings, debt financing, collaboration agreements or government grants. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaboration arrangements or obtain government grants. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP").

# 2. Summary of Significant Accounting Policies

#### **Use of Estimates**

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the accrual of research and development expenses and the valuation of common stock, stock-based awards and preferred stock warrant liability. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

### **Unaudited Interim Financial Information**

The accompanying balance sheet as of September 30, 2014, the statements of operations and comprehensive loss and of cash flows for the nine months ended September 30, 2013 and 2014, and the statement of redeemable convertible preferred stock and stockholders' deficit for the nine months ended September 30, 2014 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2014 and the results of its operations and its cash flows for the nine months ended September 30, 2013 and 2014. The financial data and other information disclosed in these notes related to the nine months ended September 30, 2013 and 2014 are unaudited. The results for the nine months ended September 30, 2014 are not necessarily indicative of results to be expected for the year ending December 31, 2014, any other interim periods, or any future year or period.

# SERES HEALTH, INC. NOTES TO FINANCIAL STATEMENTS

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited)
(Amounts in thousands, except share and per share data)

#### **Unaudited Pro Forma Information**

The accompanying unaudited pro forma balance sheet as of September 30, 2014 has been prepared to give effect to the automatic conversion of all outstanding shares of redeemable convertible preferred stock into 15,309,548 shares of common stock and the warrant to purchase Series A-2 redeemable convertible preferred stock outstanding as of September 30, 2014 becoming a warrant to purchase 92,127 shares of common stock (see Note 7) as if the proposed initial public offering had occurred on September 30, 2014. The unaudited pro forma balance sheet as of September 30, 2014 does not give effect to the automatic cashless exercise of a warrant to purchase 454,545 shares of common stock (see Note 9), which will also occur upon the proposed initial public offering, because the number of shares to be issued upon exercise will be determined based on the initial public offering price.

In the accompanying statements of operations, unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2013 and the nine months ended September 30, 2014 have been prepared to give effect to the automatic conversion of all outstanding shares of redeemable convertible preferred stock into shares of common stock and the outstanding warrant to purchase Series A-2 redeemable convertible preferred stock becoming a warrant to purchase shares of common stock (see Note 7) as if the proposed initial public offering had occurred on the later of January 1, 2013 or the issuance date of the redeemable convertible preferred stock. Unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2013 and the nine months ended September 30, 2014 does not give effect to the automatic cashless exercise of a warrant to purchase 454,545 shares of common stock (see Note 9), which will also occur upon the proposed initial public offering, because the number of shares to be issued upon exercise will be determined based on the initial public offering price.

# **Cash Equivalents**

The Company considers all short-term, highly liquid investments with original maturities of ninety days or less at acquisition date to be cash equivalents. Cash equivalents, which consist of money market accounts, are stated at fair value.

### **Restricted Cash**

As of December 31, 2012 and 2013 and September 30, 2014, the Company held cash of \$27, \$37 and \$139, respectively, in a separate restricted bank account as a security deposit for the lease of the Company's facilities. The Company has classified this deposit as long-term restricted cash on its balance sheet.

# Concentration of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company has all cash and cash equivalents balances at one accredited financial institution, in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party manufacturers to supply products for research and development activities of its programs, including pre-clinical and clinical testing. These programs could be adversely affected by a significant interruption in the supply of such drug substance products.

# SERES HEALTH, INC. NOTES TO FINANCIAL STATEMENTS

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited)
(Amounts in thousands, except share and per share data)

#### **Fair Value Measurements**

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Ÿ Level 1—Quoted prices in active markets for identical assets or liabilities.
- Y Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Ÿ Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and its preferred stock warrant liability are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of the Company's accounts payable and accrued expenses approximate their fair value due to the short-term nature of these liabilities. The carrying value of the Company's outstanding debt approximates fair value based on the variable interest rate for the borrowings outstanding as well as short duration of the term of the note (See Note 6).

# **Deferred Offering Costs**

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs (non-current) until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. As of September 30, 2014, the Company had recorded \$122 of deferred offering costs in contemplation of a probable 2015 equity financing. Should the equity financing no longer be considered probable of being consummated, all deferred offering costs will be charged to operating expenses in the statement of operations. The Company did not record any deferred offering costs as of December 31, 2012 or 2013.

# **Property and Equipment**

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the useful life of the asset. Laboratory equipment is depreciated over five years. Computer equipment and furniture and office equipment are depreciated over three years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the related asset. Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

# SERES HEALTH, INC. NOTES TO FINANCIAL STATEMENTS

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited)
(Amounts in thousands, except share and per share data)

# Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

### **Research and Development Costs**

Research and development costs are expensed as incurred. Research and development expenses include salaries, stock-based compensation and benefits of employees, third-party license fees and other operational costs related to the Company's research and development activities, including allocated facility-related expenses and external costs of outside vendors engaged to conduct both pre-clinical studies and clinical trials.

### **Research Contract Costs and Accruals**

The Company has entered into various research and development contracts with research institutions and other companies. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

### **Patent Costs**

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

# **Accounting for Stock-Based Compensation**

The Company measures all stock options and other stock-based awards granted to employees and directors based on the fair value on the date of the grant and recognizes compensation expense of those awards, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues stock options and restricted stock awards with only service-based vesting conditions and records the expense for these awards using the straight-line method.

# SERES HEALTH, INC. NOTES TO FINANCIAL STATEMENTS

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited)
(Amounts in thousands, except share and per share data)

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

The Company classifies stock-based compensation expense in its statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

The Company recognizes compensation expense for only the portion of awards that are expected to vest. In developing a forfeiture rate estimate, the Company has considered its historical experience to estimate pre-vesting forfeitures for service-based awards. The impact of a forfeiture rate adjustment will be recognized in full in the period of adjustment, and if the actual forfeiture rate is materially different from the Company's estimate, the Company may be required to record adjustments to stock-based compensation expense in future periods.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to nonemployees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

#### **Income Taxes**

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

# SERES HEALTH, INC. NOTES TO FINANCIAL STATEMENTS

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited) (Amounts in thousands, except share and per share data)

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

#### Warrant to Purchase Redeemable Convertible Preferred Stock

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

The Company uses the Black-Scholes option-pricing model, which incorporates assumptions and estimates, to value the preferred stock warrant. The Company has assessed these assumptions and 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 redeemable convertible preferred stock, the remaining contractual term of the warrant, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying preferred stock. The Company determines the fair value per share of the underlying preferred stock by taking into consideration the most recent sales of its redeemable convertible preferred stock, results obtained from third-party valuations and additional factors that are deemed relevant. The Company historically has been a private company and lacks company-specific historical and implied volatility information of its stock. Therefore, it estimates its expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrant. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrant. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

# **Segment Data**

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is on developing Ecobiotic microbiome therapeutics to treat dysbiosis in the colonic microbiome. No revenue has been generated since inception, and all tangible assets are held in the United States.

# SERES HEALTH, INC. NOTES TO FINANCIAL STATEMENTS

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited)
(Amounts in thousands, except share and per share data)

# **Comprehensive Loss**

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. There was no difference between net loss and comprehensive loss for each of the periods presented in the accompanying financial statements.

# Net Loss per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the sum of the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options and warrants and unvested restricted stock. The Company applies the two-class method to calculate its basic and diluted net loss per share attributable to common stockholders, as its redeemable convertible preferred stock and common stock are participating securities. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. However, the two-class method does not impact the net loss per share of common stock as the Company was in a net loss position for each of the periods presented and preferred stockholders do not participate in losses.

The Company's redeemable convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Similarly, restricted stock awards granted by the Company entitle the holder of such awards to dividends declared or paid by the board of directors, regardless of whether such awards are unvested, as if such shares were outstanding common shares at the time of the dividend. However, the unvested restricted stock awards are not entitled to share in the residual net assets (deficit) of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

### **Recently Issued and Adopted Accounting Pronouncements**

In June 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-10, *Development Stage Entities*. The amendments in this update removed all incremental financial reporting requirements, including inception-to-date information and certain other disclosures currently required under GAAP, in the financial statements of development stage companies. The amendments are effective for annual reporting periods beginning after December 15, 2014 and interim reporting periods beginning after December 15, 2015. Early adoption is permitted. The Company elected to early adopt this guidance and, therefore, has not presented inception-to-date disclosures in its financial statements.

In July 2013, the FASB issued changes to the presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. These changes require an entity to present an unrecognized tax benefit as a liability in the financial statements if (i) a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available at the

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reporting date under the tax law of the applicable jurisdiction to settle any additional income taxes that would result from the disallowance of a tax position, or (ii) the tax law of the applicable jurisdiction does not require the entity to use, and the entity does not intend to use, the deferred tax asset to settle any additional income taxes that would result from the disallowance of a tax position. Otherwise, an unrecognized tax benefit is required to be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward. These changes became effective for the Company as of January 1, 2014 and the adoption of this guidance did not have a significant impact on its financial statements.

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

#### 3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's assets and liabilities as of December 31, 2013 and September 30, 2014 that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

Fair Value Measurements as of December 31, 2013 Using:

	ran v	Fair value Measurements as of December 31, 2013 Using.								
	Level 1	Level 2	Level 3	Total						
Assets:										
Cash equivalents	\$ —	\$ 1,301	<u> </u>	\$ 1,301						
	\$ —	\$ 1,301	\$ —	\$ 1,301						
Liabilities:	<del></del>		<del></del>	<del></del>						
Liability for preferred stock warrant	\$ —	\$ —	\$ 164	\$ 164						
	\$	\$ —	\$ 164	\$ 164						
	Fair V	Fair Value Measurements as of September 30, 2014 Using: (unaudited)								
	Level 1	Level 2	Level 3	Total						
Assets:			·	<u> </u>						
Cash equivalents	\$ <u>—</u>	\$ 6,030	\$ <u> </u>	\$ 6,030						
	\$ <u> </u>	\$ 6,030	\$ —	\$ 6,030						
Liabilities:	<del></del>	<del></del>	<del></del>							
LIADIIIIES.										
Liability for preferred stock warrant	\$ —	\$ —	\$ 668	\$ 668						

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited) (Amounts in thousands, except share and per share data)

As of December 31, 2013 and September 30, 2014, the Company's cash equivalents that were invested in money market funds were valued based on Level 2 inputs. During the year ended December 31, 2013 and the nine months ended September 30, 2013 and 2014, there were no transfers between Level 1, Level 2 and Level 3. As of and during year ended December 31, 2012, the Company did not have any assets and liabilities that were measured at fair value on a recurring basis.

The warrant liability in the table above is comprised of the values of a warrant for the purchase of Series A-2 redeemable convertible preferred stock (see Note 7) and is based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

#### 4. Property and Equipment, Net

Property and equipment, net consisted of the following:

	Decen	nber 31,	September 30,
	2012	2013	2014
			(unaudited)
Laboratory equipment	\$249	\$ 402	\$ 834
Computer equipment	15	29	106
Furniture and office equipment	10	12	50
Leasehold improvements	<u>17</u>	22	83
	291	465	1,073
Less: Accumulated depreciation and amortization	(25)	(113)	(207)
	\$266	\$ 352	\$ 866

Depreciation and amortization expense was \$25 and \$88 for the years ended December 31, 2012 and 2013, respectively, and \$62 and \$113 for the nine months ended September 30, 2013 and 2014, respectively.

#### Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

Decen	December 31,		1ber 30,
2012	2013		14
		(unau	idited)
\$18	\$ 22	\$	22
33	226		248
15	15		298
\$66	\$263	\$	568
	\$18 33 15	2012     2013       \$18     \$ 22       33     226       15     15	2012     2013     20       \$18     \$ 22     \$       33     226       15     15

#### 6. Notes Payable

On September 9, 2013, the Company entered into a loan and security agreement with Comerica Bank, which provided for borrowings of up to \$3,000 through August 2014. On September 9, 2013, the Company received \$1,000 from borrowings under the agreement, and from March to August 2014, the Company received \$2,000 from additional borrowings under the agreement. Through September 30,

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2014, the Company borrowed the full \$3,000 available under the loan and security agreement and had made \$100 of scheduled principal repayments. Borrowings under the loan and security agreement are collateralized by substantially all of the Company's assets, except for its intellectual property.

In accordance with the terms of the loan and security agreement, the Company is obligated to make monthly, interest-only payments on any term loans funded under the agreement until August 1, 2014. Thereafter, the Company is obligated to pay 30 consecutive, equal monthly installments of principal and interest from September 1, 2014 through February 1, 2017, the maturity date. Term loans under the loan and security agreement bear interest at an annual rate equal to 3.0% plus the greater of (1) the bank's prime rate and (2) the LIBOR rate plus 2.5% (which equated to 6.25% at December 31, 2013 and September 30, 2014). In addition, a final payment of \$60 is due upon the earlier of the maturity date, acceleration of the term loans or prepayment of all or part of the term loans. That amount is being recorded as additional interest expense over the term of the loan and security agreement, using the effective interest method.

In connection with entering into the loan and security agreement, the Company granted to the lender a warrant to purchase 92,127 shares of Series A-2 redeemable convertible preferred stock at an exercise price of \$1.78 per share (see Note 7). The Company recorded the grant date fair value of the warrant of \$156 as a debt discount and as a preferred stock warrant liability on the grant date. The debt discount, which also reflected \$26 of fees paid to the lender, is being accreted to the carrying value of the debt, using the effective interest method.

Accretion of the debt discount recorded as additional interest expense was \$19 for the year ended December 31, 2013 and \$4 and \$49 for the nine months ended September 30, 2013 and 2014, respectively. As of December 31, 2013 and September 30, 2014, the unamortized debt discount was \$162 and \$113, respectively.

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

As of December 31, 2013, annual principal repayment requirements under the loan and security agreement were \$400 during the year ending December 31, 2014, \$1,200 during each of the years ending December 31, 2015 and 2016, and \$200 during the year ending December 31, 2017.

#### 7. Preferred Stock Warrant Liability

In September 2013, the Company issued a warrant to purchase 92,127 shares of Series A-2 redeemable convertible preferred stock in connection with a loan and security agreement (see Note 6). The warrant was immediately exercisable at an exercise price of \$1.78 per share and has a contractual term of ten years from issuance. The fair value of the warrant at issuance was estimated to be \$156 and was recorded as a debt discount and as a preferred stock warrant liability.

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The Company remeasures the fair value of the liability for this preferred stock warrant at each reporting date from its grant date, with any adjustments being recorded as a component of other income (expense), net in the Company's statement of operations and comprehensive loss. For the year ended December 31, 2013 and for the nine months ended September 30, 2013 and 2014, the Company recorded losses of \$8, \$0 and \$504, respectively, to reflect the change in fair value of this preferred stock warrant.

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

	Year Ended		Nine Months En	ded Septemb	September 30,	
	December 31, 2013		 2013		2014	
			 (una	udited)		
Risk-free interest rate		3.20%	2.80%		2.60%	
Expected term (in years)		9.7	10.0		8.9	
Expected volatility		86.0%	86.0%		86.0%	
Expected dividend yield		0%	0%		0%	
Fair value of Series A-2 redeemable convertible preferred						
stock	\$	2.07	\$ 1.97	9	\$ 7.82	

The following table provides a rollforward of the fair value of the Company's preferred stock warrant liability:

	Fair	<b>Value</b>
Balance as of December 31, 2012	\$	_
Issuance of Series A-2 preferred stock warrant		156
Loss on revaluation		8
Balance as of December 31, 2013		164
Loss on revaluation		504
Balance as of September 30, 2014 (unaudited)	\$	668

Upon the closing of an initial public offering in which the Series A-2 redeemable convertible preferred stock is converted into common stock, the preferred stock warrant will become exercisable for common stock instead of preferred stock, and the preferred stock warrant liability, remeasured at fair value at that time, will be reclassified to additional paid-in capital.

#### 8. Redeemable Convertible Preferred Stock

The Company has issued Series A, Series A-2 and Series B redeemable convertible preferred stock (collectively, the "Redeemable Preferred Stock"). The Redeemable Preferred Stock is classified outside of stockholders' equity (deficit) because the shares contain redemption features that are not solely within the control of the Company. As of December 31, 2013 and September 30, 2014, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 11,806,272 shares and 15,401,675 shares, respectively, of \$0.001 par value preferred stock.

# SERES HEALTH, INC. NOTES TO FINANCIAL STATEMENTS

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In June 2012, the Company issued 3,797,468 shares of Series A redeemable convertible preferred stock at an issuance price of \$0.79 per share in exchange for \$3,000, net of issuance costs of \$70. At that same time, convertible promissory notes in the amount of \$1,400 and accrued interest of \$102 were converted into 1,901,883 shares of Series A redeemable convertible preferred stock.

In October 2012, the Company issued 2,531,646 shares of Series A redeemable convertible preferred stock at an issuance price of \$0.79 per share in exchange for \$2,000.

In November 2012, the Company issued 2,247,192 shares of Series A-2 redeemable convertible preferred stock at an issuance price of \$1.78 per share in exchange for \$4,000.

In May 2014, the Company issued 4,831,359 shares of Series B redeemable convertible preferred stock at an issuance price of \$2.20 per share in exchange for \$10,558, net of issuance costs of \$71.

Redeemable Preferred Stock consisted of the following:

	December 31, 2012							
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion			
Series A redeemable convertible preferred stock	8,230,997	8,230,997	\$ 6,678	\$ 6,748	8,230,997			
Series A-2 redeemable convertible preferred stock	2,247,192	2,247,192	4,030	4,030	2,247,192			
	10,478,189	10,478,189	\$10,708	\$ 10,778	10,478,189			
		Dec	cember 31, 2013					
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion			
Series A redeemable convertible preferred stock	8,230,997	8,230,997	\$ 7,231	\$ 7,301	8,230,997			
Series A-2 redeemable convertible preferred stock	3,575,275	2,247,192	4,352	4,352	2,247,192			
	11 806 272	10 478 189	\$11 583	\$ 11.653	10 478 189			

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	September 30, 2014 (unaudited)								
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion				
Series A redeemable convertible preferred stock	8,230,997	8,230,997	\$ 7,678	\$ 7,748	8,230,997				
Series A-2 redeemable convertible preferred stock	2,339,319	2,247,192	4,612	4,612	2,247,192				
Series B redeemable convertible preferred stock	4,831,359	4,831,359	10,870	10,941	4,831,359				
	15,401,675	15,309,548	\$23,160	\$ 23,301	15,309,548				

The holders of the Redeemable Preferred Stock have the following rights and preferences:

#### **Voting Rights**

The holders of Redeemable Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote. Holders of all Redeemable Preferred Stock have the right to vote the number of shares equal to the number of shares of common stock into which such Redeemable Preferred Stock could convert on the record date for determination of stockholders entitled to vote.

#### **Dividends**

The holders of Redeemable Preferred Stock are entitled to receive dividends in preference to any dividend on common stock at the rate of 8% of the Original Issue Price (as defined below) per share, per annum compounded. Dividends are payable only when, as, and if declared by the board of directors. As of December 31, 2013 and September 30, 2014, no dividends had been declared or paid by the Company. The Original Issue Price for Series A, Series A-2 and Series B redeemable convertible preferred stock is \$0.79, \$1.78 and \$2.20, respectively, per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Redeemable Preferred Stock.

#### **Liquidation Preference**

In the event of any liquidation, voluntary or involuntary, dissolution or winding up of the Company or Deemed Liquidation Event (as defined below), holders of Redeemable Preferred Stock are entitled to receive, in preference to all other stockholders, and to the extent available, an amount equal to the Original Issue Price per share, adjusted for any stock dividends, stock splits or reclassifications, plus any accruing dividends accrued but unpaid, whether or not declared, together with any other dividends declared but unpaid. In the event that proceeds are not sufficient to permit payment in full to these holders, the proceeds will be ratably distributed among the holders of redeemable convertible preferred stock on a pari passu basis to the full preferential amount each such holder is otherwise entitled to receive.

After payments have been made in full to the holders of redeemable convertible preferred stock, then, to the extent available, holders of the common stock will receive the remaining amounts available

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for distribution ratably in proportion to the number of common shares held by them provided, however, if the holders of any series of redeemable convertible preferred stock would receive a greater amount of the proceeds if they had converted their shares of redeemable convertible preferred stock, then such holders shall not receive any proceeds under the preceding paragraph and will receive proceeds on an as converted to common stock basis.

Unless the holders of at least 60% of the then outstanding shares of the Redeemable Preferred Stock, voting together as a single class on an as-converted basis, elect otherwise, a Deemed Liquidation Event shall include a merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company.

#### Conversion

Each share of Redeemable Preferred Stock is convertible into common stock at the option of the stockholder at any time after the date of issuance. Each share of the Redeemable Preferred Stock will automatically be converted into shares of common stock, at the applicable Series A, Series A-2 and Series B redeemable convertible preferred stock conversion ratio then in effect, upon a qualified public offering with net proceeds of not less than \$35,000 and a price of at least \$9.00 per share, subject to appropriate adjustment for any stock dividend, stock split, combination or other similar recapitalization (see Note 16).

The conversion ratio of each series of Redeemable Preferred Stock is determined by dividing the Original Issue Price of each series of preferred stock by the Conversion Price of each series. The Conversion Price of each series is \$0.79 for Series A, \$1.78 for Series A-2 and \$2.20 for Series B and is subject to adjustment as set forth in the Company's certificate of incorporation, as amended and restated, unless the holders of at least 60% of the outstanding Redeemable Preferred Stock agree that no such adjustment shall be made. As of December 31, 2013 and September 30, 2014, all outstanding shares of Series A, Series A-2 and Series B redeemable convertible preferred stock are convertible into common stock on a 1-for-1 basis.

#### **Redemption Rights**

At the written election of at least 60% of the holders of the outstanding Redeemable Preferred Stock, voting together as a single class on an as-converted basis, the shares of Redeemable Preferred Stock outstanding shall be redeemed at any time on or after January 1, 2019, in three equal annual installments commencing sixty days after receipt of the required vote at the Original Issue Price per share of Series A, Series A-2 and Series B redeemable convertible preferred stock plus all accruing dividends accrued thereon, whether or not declared, together with any other dividends declared but unpaid thereon.

The carrying values of the Series A, Series A-2 and Series B redeemable convertible preferred stock are being accreted to their redemption values through January 1, 2019 (see Note 16).

#### Reissuance

Shares of any series of Redeemable Preferred Stock that are redeemed or converted will be retired or canceled and cannot be reissued by the Company.

# SERES HEALTH, INC. NOTES TO FINANCIAL STATEMENTS

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited)
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#### Stockholders' Equity (Deficit)

#### **Common Stock**

As of December 31, 2013 and September 30, 2014, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 24,500,000 shares and 28,000,000 shares, respectively, of \$0.001 par value common stock.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of the Redeemable Preferred Stock. When dividends are declared on shares of common stock, the Company must declare at the same time a dividend payable to the holders of Redeemable Preferred Stock equivalent to the dividend amount they would receive if each preferred share were converted into common stock. The Company may not pay dividends to common stockholders until all dividends accrued or declared but unpaid on the Redeemable Preferred Stock have been paid in full. No dividends had been declared to date.

As of December 31, 2013 and September 30, 2014, the Company had reserved 11,832,152 shares and 19,672,959 shares, respectively, for the conversion of the outstanding shares of Redeemable Preferred Stock (see Note 8), the exercise of outstanding stock options and the number of shares remaining available for future grant under the Company's 2012 Plan, the exercise of outstanding common stock warrants, and the exercise of an outstanding warrant to purchase Series A-2 redeemable convertible preferred stock assuming it becomes a warrant to purchase common stock (see Note 7).

#### **Common Stock Warrants**

In June 2014, the Company entered into a research agreement under which it acquired a license to intellectual property. In exchange for the license, the Company issued to the research institution a warrant to purchase 454,545 shares of common stock at an exercise price of \$0.01 per share, which was immediately exercisable. Upon issuance of the warrant, the Company recorded research and development expense of \$317 for the fair value of the warrant, determined using the following assumptions in the Black-Scholes option-pricing model: expected volatility of 86.0%, risk-free interest rate of 2.3%, expected term of seven years (equaling the contractual term of the warrant) and no expected dividends. Because this warrant is indexed to the Company's stock and can only be settled by gross physical delivery of shares or net share settlement, the Company has determined that this warrant qualifies for equity classification. Unless earlier exercised or terminated, the warrant will be automatically exercised upon the closing of an initial public offering by the Company in a cashless exercise, with shares issued being determined based on the initial public offering price.

Also in connection with the research agreement, in June 2014, the Company issued a warrant to purchase up to 284,090 shares of common stock at an exercise price equal to the per share price at which the Company most recently sold shares of its preferred stock (which was \$2.20 as of September 30, 2014 and \$12.1632 as of November 24, 2014), which is exercisable for a number of shares to be determined by the Company's board of directors from time to time, upon achieving specified milestones related to up to five indications. No portion of the warrant was exercisable as of September 30, 2014. Unless the milestones are achieved and the warrant is earlier exercised, this

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warrant will be terminated upon the closing of an initial public offering by the Company. Because achievement of the specified milestones was not deemed probable as of September 30, 2014, the Company did not record any expense for this warrant from date of issuance through September 30, 2014.

#### 2012 Stock Incentive Plan

The Company's 2012 Stock Incentive Plan, as amended, (the "2012 Plan") provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors and consultants of the Company. The 2012 Plan is administered by the board of directors, or at the discretion of the board of directors, by a committee of the board. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or their committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years. The Company generally grants stock-based awards with service conditions only ("service-based" awards).

Stock options granted under the 2012 Plan generally vest over four years and expire after ten years, although options have been granted with vesting terms less than four years.

The total number of shares of common stock that may be issued under the 2012 Plan was 1,261,836 shares as of December 31, 2013, none of which shares remained available for future grant at December 31, 2013. On May 23, 2014, the Company effected an increase in the number of shares of common stock reserved for issuance under the 2012 Plan by 2,300,000 shares. The total number of shares of common stock that may be issued under the 2012 Plan was 3,561,836 shares as of September 30, 2014, of which 475,844 shares remained available for future grant at September 30, 2014.

As required by the 2012 Plan, the exercise price for stock options granted is not to be less than the fair value of common shares as determined by the Company as of the date of grant. The Company values its common stock by taking into consideration its most recently available valuation of common shares performed by management and the board of directors as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant.

#### **Stock Option Valuation**

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

	Year Ended Dec	ember 31,	Nine Months Ended Se	ıded September 30,	
	2012	2012 2013		2014	
			(unaudited)	_	
Risk-free interest rate	0.92%	1.27%	1.08%	1.84%	
Expected term (in years)	6.0	6.0	6.0	6.0	
Expected volatility	109.4%	85.9%	86.5%	84.1%	
Expected dividend yield	0%	0%	0%	0%	

# SERES HEALTH, INC. NOTES TO FINANCIAL STATEMENTS

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited) (Amounts in thousands, except share and per share data)

#### **Stock Options**

The following table summarizes the Company's stock option activity since January 1, 2012:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2012	_	\$ —	<u> </u>	\$ —
Granted	317,836	0.10		
Exercised	_	_		
Forfeited		_		
Outstanding as of December 31, 2012	317,836	\$ 0.10	9.65	\$ —
Granted	999,000	0.48		
Exercised	_	_		
Forfeited	(55,000)	0.10		
Outstanding as of December 31, 2013	1,261,836	\$ 0.40	9.34	\$ 100
Granted	1,835,251	0.71		
Exercised	(29,187)	0.16		
Forfeited	(11,095)	0.44		
Outstanding as of September 30, 2014 (unaudited)	3,056,805	\$ 0.59	9.35	\$ 18,681
Options vested and expected to vest as of December 31, 2013	1,261,836	\$ 0.40	9.34	\$ 100
Options exercisable as of December 31, 2013	303,961	\$ 0.31	9.05	\$ 52
Options vested and expected to vest as of September 30, 2014 (unaudited)	3,056,805	\$ 0.59	9.35	\$ 18,681
Options exercisable as of September 30, 2014 (unaudited)	546,732	\$ 0.37	8.50	\$ 3,460

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2012 and 2013 and the nine months ended September 30, 2014 was \$0.09, \$0.35 and \$3.92 per share, respectively. The total intrinsic value of stock options exercised during the nine months ended September 30, 2014 was \$122.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

During the nine months ended September 30, 2014, the Company granted performance-based stock options to employees for the purchase an aggregate of 60,000 shares of common stock with a grant date fair value of \$3.92 per share. These stock options are exercisable only upon achievement of specified performance targets in each option agreement. As of September 30, 2014, none of these

# SERES HEALTH, INC. NOTES TO FINANCIAL STATEMENTS

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options were exercisable because none of the specified performance targets had been achieved. Because achievement of the specified performance targets was not deemed probable as of September 30, 2014, the Company did not record any expense for these stock options from date of issuance through September 30, 2014.

As of December 31, 2013 and September 30, 2014, there were outstanding unvested service-based stock options held by nonemployees for the purchase of 135,961 and 78,896 shares, respectively, of common stock.

#### **Restricted Common Stock**

The Company has granted restricted common stock with time-based vesting conditions. Unvested shares of restricted common stock may not be sold or transferred by the holder. These restrictions lapse according to the time-based vesting conditions of each award. The table below summarizes the Company's restricted stock activity since January 1, 2012:

	Number of Shares	Aver	eighted age Grant Fair Value
Unvested restricted common stock as of January 1, 2012	400,000	\$	0.001
Issued	2,440,000	\$	0.001
Vested	(981,250)	\$	0.001
Forfeited and repurchased	(250,000)	\$	0.001
Unvested restricted common stock as of December 31, 2012	1,608,750	\$	0.001
Vested	(675,000)	\$	0.001
Forfeited and repurchased	(735,000)	\$	0.001
Unvested restricted common stock as of December 31, 2013	198,750	\$	0.001
Vested	(120,625)	\$	0.001
Unvested restricted common stock as of September 30, 2014 (unaudited)	78,125	\$	0.001

During the years ended December 31, 2012 and 2013, the Company reacquired, at their original issuance price, 250,000 shares and 735,000 shares, respectively, of restricted common stock that were forfeited by former employees.

The aggregate intrinsic value of restricted stock awards that vested during the years ended December 31, 2012 and 2013 and the nine months ended September 30, 2014 was \$33, \$185 and \$223, respectively.

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited) (Amounts in thousands, except share and per share data)

#### **Stock-based Compensation**

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

	Year Ended December 31,				Nine Mont	hs Ended Septem	ber 30,	
		2012		2013		2013		2014
					_		(unaudited)	<u> </u>
Research and development expenses	\$	26	\$	177	\$	137	\$	344
General and administrative expenses		2		32		23		356
	\$	28	\$	209	\$	160	\$	700

As of December 31, 2013, the Company had an aggregate of \$315 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.3 years. As of September 30, 2014, the Company had an aggregate of \$7,393 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 3.4 years.

#### 10. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Year Ended Do	ecember 31,	Nine Months End	ed September 30, 2014
	2012	2013	2013	
			(unau	idited)
Numerator:				
Net loss	\$ (3,126)	\$ (6,102)	\$ (4,153)	\$ (8,527)
Accretion of redeemable convertible preferred stock to				
redemption value	(276)	(875)	(654)	(1,019)
Net loss attributable to common stockholders	\$ (3,402)	\$ (6,977)	\$ (4,807)	\$ (9,546)
Denominator:				
Weighted average common shares outstanding, basic				
and diluted	5,725,120	6,394,916	6,330,706	6,731,724
Net loss per share attributable to common stockholders,				
basic and diluted	\$ (0.59)	\$ (1.09)	\$ (0.76)	\$ (1.42)

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited) (Amounts in thousands, except share and per share data)

The Company's potential dilutive securities, which include stock options, unvested restricted common stock, redeemable convertible preferred stock and warrants to purchase redeemable convertible preferred stock or common stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The following common stock equivalents, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31,		Nine Months Ended September 30,	
	2012	2013	2013	2014
			(unaud	dited)
Stock options to purchase common stock	317,836	1,261,836	962,836	3,056,805
Unvested restricted common stock	1,608,750	198,750	268,125	78,125
Warrants for the purchase of redeemable convertible preferred stock	_	92,127	92,127	92,127
Warrants for the purchase of common stock	_	_	_	738,635
Redeemable convertible preferred stock (as converted to common stock)	10,478,189	10,478,189	10,478,189	15,309,548
	12,404,775	12,030,902	11,801,277	19,275,240

#### 11. Unaudited Pro Forma Net Loss per Share

The unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2013 and the nine months ended September 30, 2014 gives effect to adjustments arising upon the closing of a qualified initial public offering. The unaudited pro forma net loss attributable to common stockholders used in the calculation of unaudited basic and diluted pro forma net loss per share attributable to common stockholders does not include the effects of the accretion of redeemable convertible preferred stock to redemption value or loss from revaluation of preferred stock warrant liability because the calculation assumes that the conversion of redeemable convertible preferred stock into common stock had occurred on the later of January 1, 2013 or the issuance date of the redeemable convertible preferred stock.

The unaudited pro forma basic and diluted weighted average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2013 and the nine months ended September 30, 2014 give effect to the automatic conversion upon a qualified initial public offering of all outstanding shares of redeemable convertible preferred stock as of December 31, 2013 and September 30, 2014 into 10,478,189 and 15,309,548 shares of common stock, respectively, as if the conversion had occurred on the later of January 1, 2013 or the issuance date of the redeemable convertible preferred stock.

# SERES HEALTH, INC. NOTES TO FINANCIAL STATEMENTS

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited) (Amounts in thousands, except share and per share data)

The computation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders is as follows:

	De	Year Ended cember 31, 2013	1	 Months Ended otember 30, 2014
			(unaudited)	
Numerator:				
Net loss attributable to common stockholders	\$	(6,977)	9	\$ (9,546)
Accretion of redeemable convertible preferred stock to redemption value		875		1,019
Loss from revaluation of preferred stock warrant liability		8	_	504
Pro forma net loss attributable to common stockholders	\$	(6,094)	Ş	\$ (8,023)
Denominator:			=	
Weighted average common shares outstanding, basic and diluted		6,394,916		6,731,724
Pro forma adjustment for assumed automatic conversion of all outstanding shares of redeemable convertible preferred stock upon the closing of the				
proposed initial public offering		10,478,189	_	12,804,399
Pro forma weighted average common shares outstanding, basic and diluted		16,873,105		19,536,123
Pro forma net loss per share attributable to common stockholders, basic and diluted	\$	(0.36)	5	\$ (0.41)

#### 12. Commitments and Contingencies

#### Leases

The Company leases office and laboratory space under an operating lease agreement. The lease expires in January 2018 with no extension periods. The Company does have a right of expansion over the term as additional space becomes available but not an obligation. During the years ended December 31, 2012 and 2013, the Company recognized \$99 and \$152, respectively, of rental expense related to office and laboratory space. During the nine months ended September 30, 2013 and 2014, the Company recognized \$124 and \$343, respectively, of rental expense related to office and laboratory space.

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited) (Amounts in thousands, except share and per share data)

Future minimum lease payments for this operating lease as of December 31, 2013 were as follows:

Year Ending December 31,	
2014	\$ 380
2015	681
2016 2017	695
2017	709
2018	60
Total	60 \$2,525

#### **Indemnification Agreements**

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its financial statements as of December 31, 2012 or 2013 or September 30, 2014.

#### 13. Income Taxes

During the years ended December 31, 2012 and 2013 and the nine months ended September 30, 2013 and 2014, the Company recorded no income tax benefits for the net operating losses incurred in each year or interim period, due to its uncertainty of realizing a benefit from those items.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

Year Ended December 31,	
2012	2013
(34.0)%	(34.0)%
(1.1)	(6.1)
(5.3)	(5.3)
1.7	1.2
0.2	_
38.5	44.2
<u> </u>	<u> </u>
	2012 (34.0)% (1.1) (5.3) 1.7 0.2 38.5

# SERES HEALTH, INC. NOTES TO FINANCIAL STATEMENTS

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited)
(Amounts in thousands, except share and per share data)

Net deferred tax assets as of December 31, 2012 and 2013 consisted of the following:

	Decem	December 31,	
	2012 2013		
Deferred tax assets:			
Net operating loss carryforwards	\$ 736	\$ 3,076	
Research and development tax credit carryforwards	45	419	
Capitalized organization costs	659	615	
Capitalized research and development expenses	157	147	
Stock-based compensation expense		16	
Other		46	
Total deferred tax assets		4,319	
Deferred tax liabilities:			
Depreciation and amortization		(25)	
Total deferred tax liabilities		(25)	
Valuation allowance		(4,294)	
Net deferred tax assets	\$ —	\$ —	

As of December 31, 2013, the Company had net operating loss carryforwards for federal and state income tax purposes of \$7,854 and \$7,673, respectively, which begin to expire in 2031 and 2031, respectively. As of December 31, 2013, the Company also had available research and development tax credit carryforwards for federal and state income tax purposes of \$312 and \$163, respectively, which begin to expire in 2031 and 2026, respectively. Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed and any limitation is know

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited)
(Amounts in thousands, except share and per share data)

from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2012 and 2013 and September 30, 2014. Management reevaluates the positive and negative evidence at each reporting period.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2012 and 2013 related primarily to the increases in net operating loss carryforwards and research and development tax credit carryforwards and were as follows:

	Year Ended D	Year Ended December 31,	
	2012	2013	
Valuation allowance at beginning of year	\$ (394)	\$ (1,599)	
Decreases recorded as benefit to income tax provision	<del></del>	_	
Increases recorded to income tax provision	(1,205)	(2,695)	
Valuation allowance as of end of year	<u>\$ (1,599)</u>	\$ (4,294)	

#### 14. Related Party Transactions

In October 2010, the Company entered into a services agreement with Flagship Ventures Management, Inc., an affiliate of one of its stockholders, Flagship Venture Funds, to provide general and administrative services to the Company, including the employer portions of employee health and dental benefit plans for Seres Health employees and consulting services. The Company made payments under the agreement of \$528, \$391, \$244 and \$362 during the years ended December 31, 2012 and 2013 and the nine months ended September 30, 2013 and 2014, respectively. Amounts due to Flagship Ventures Management, Inc. related to the services agreement were \$0, \$0 and \$20 as of December 31, 2012 and 2013 and September 30, 2014, respectively.

#### 15. 401(k) Savings Plan

The Company has a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Company contributions to the plan may be made at the discretion of the Company's board of directors. The Company has not made any contributions to date under the 401(k) Savings Plan.

#### 16. Subsequent Events

For its financial statements as of December 31, 2013 and for the year then ended, the Company evaluated subsequent events through December 11, 2014, the date on which those financial statements were issued.

#### **Issuance of Series C Preferred Stock**

On November 24, 2014, the Company issued 3,946,328 shares of Series C convertible preferred stock ("Series C preferred stock") at a price of \$12.1632 per share for gross proceeds of \$48,000. The rights and preferences of the Series C preferred stock are similar to those of the Series A, Series A-2 and Series B redeemable convertible preferred stock, except that (1) the Original Issue Price for Series C preferred stock is \$12.1632 per share, (2) the holders of the Series C preferred stock do not

# SERES HEALTH, INC. NOTES TO FINANCIAL STATEMENTS

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited)
(Amounts in thousands, except share and per share data)

have redemption rights and (3) the holders of the Series C have specified protective rights not held by the holders of the Series A, Series A-2 and Series B redeemable convertible preferred stock.

In conjunction with the closing of the Series C preferred stock financing, the redemption rights of the Series A, Series A-2 and Series B preferred stock were removed at that time. As a result of the removal of the redemption rights, as of November 24, 2014, the Company ceased the periodic recording of adjustments to accrete the carrying values of Series A, Series A-2 and Series B preferred stock to their respective redemption values through January 1, 2019. Also in connection with the closing, the terms of a qualified public offering requiring the mandatory conversion of all shares of the Company's preferred stock into common stock were changed to be any listing of the Company's common stock on the NYSE or NASDAQ, replacing the previous minimum thresholds of \$35,000 in net proceeds and a price of at least \$9.00 per share.

#### Increase in Authorized Shares of Common Stock and Preferred Stock

On November 24, 2014, the Company effected an increase in the number of authorized shares of its common stock from 28,000,000 shares to 32,000,000 shares and an increase in the number of authorized shares of its preferred stock from 15,401,675 shares to 19,348,003 shares.

#### Increase in Shares Reserved for Issuance under the 2012 Plan

On December 9, 2014, the Company effected an increase in the number of shares of common stock reserved for issuance under the 2012 Plan to 3,608,029 shares (see Note 9).

#### 17. Subsequent Events (unaudited)

For its interim financial statements as of September 30, 2014 and for the nine months then ended, the Company evaluated subsequent events through December 11, 2014, the date on which those financial statements were issued.

#### Issuance of Series D Preferred Stock

On December 19, 2014, the Company issued 2,222,222 shares of Series D convertible preferred stock ("Series D preferred stock") and 1,388,889 shares of Series D-1 convertible preferred stock ("Series D-1 preferred stock") at a price of \$18.00 per share for aggregate gross proceeds of \$65,000. The rights and preferences of the Series D preferred stock and Series D-1 preferred stock are similar to those of the Series A, Series A-2, Series B and Series C preferred stock, except that (1) the Original Issue Price for Series D preferred stock and Series D-1 preferred stock is \$18.00 per share, (2) the holders of the Series D-1 preferred stock do not have the right to vote for the election of directors and do not have the right to voluntarily convert their shares to common stock, (3) the shares of Series D-1 preferred stock shall automatically convert into shares of Series D preferred stock upon the occurrence of certain events and (4) the holders of the Series D preferred stock and Series D-1 preferred stock have specified protective rights not held by the holders of the Series A-2, Series B and Series C preferred stock.

# SERES HEALTH, INC. NOTES TO FINANCIAL STATEMENTS

(Information as of September 30, 2014 and for the nine months ended September 30, 2013 and 2014 is unaudited) (Amounts in thousands, except share and per share data)

#### Increase in Authorized Shares of Common Stock and Preferred Stock

On December 19, 2014, the Company effected an increase in the number of authorized shares of its common stock from 32,000,000 shares to 38,000,000 shares and effected an increase in the number of authorized shares of its preferred stock from 19,348,003 shares to 24,348,003 shares, of which 3,611,111 shares were designated as Series D preferred stock and 1,388,889 shares were designated as Series D-1 preferred stock.

**Shares** 

Common Stock



# Goldman, Sachs & Co. BofA Merrill Lynch

Leerink Partners
Canaccord Genuity

Through and including , 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.

#### **PART II**

#### **INFORMATION NOT REQUIRED IN PROSPECTUS**

#### Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the issuance and distribution of the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the listing fee.

	Amou	unt
Securities and Exchange Commission registration fee	\$	*
FINRA filing fee		*
Initial listing fee		*
Accountants' fees and expenses		*
Legal fees and expenses		*
Blue Sky fees and expenses		*
Transfer Agent's fees and expenses		*
Printing and engraving expenses		*
Miscellaneous		*
Total expenses	\$	*

<sup>\*</sup> To be filed by amendment.

#### Item 14. Indemnification of Directors and Officers.

Section 102 of the General Corporation Law of the State of Delaware permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our restated certificate of incorporation provides that no director of the Registrant shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with any threatened, ending or completed action, suit or proceeding to which he was or is a party or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case,

such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Our restated certificate of incorporation provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our restated certificate of incorporation provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

We have entered into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act of 1933, as amended, or the Securities Act, against certain liabilities.

#### Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding shares of capital stock issued by us within the past three years. Also included is the consideration received by us for such shares and information relating to the

section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

- (a) Issuance of Capital Stock.
- Ÿ On June 1, 2012, the registrant issued 3,797,468 shares of Series A Preferred Stock for aggregate consideration of \$3.0 million to accredited investors and 1,901,833 shares of Series A Preferred Stock in converted promissory notes upon the cancellation of debt totaling \$1,400,000 in principal plus \$102,493 of accrued interest pursuant to Section 4(a)(2) of the Securities Act and Rule 506 as a transactions not involving a public offering.
- Ÿ On October 30, 2012, the registrant issued 2,531,646 shares of Series A Preferred Stock for aggregate consideration of \$2.0 million to accredited investors pursuant to Section 4(a)(2) of the Securities Act and Rule 506 as transaction not involving a public offering.
- Ÿ On November 27, 2012, the registrant issued 2,247,192 shares of Series A-2 Preferred Stock for aggregate consideration of \$4.0 million to accredited investors pursuant to Section 4(a)(2) of the Securities Act and Rule 506 as a transaction not involving a public offering.
- Ÿ On May 23, 2014, the registrant issued 4,831,359 shares of Series B Preferred Stock for aggregate consideration of \$10.6 million to accredited investors pursuant to Section 4(a)(2) of the Securities Act and Rule 506 as a transaction not involving a public offering.
- Ÿ On November 24, 2014, the registrant issued 3,946,328 shares of Series C Preferred Stock for aggregate consideration of \$48.0 million to accredited investors pursuant to Section 4(a)(2) of the Securities Act and Rule 506 as a transaction not involving a public offering.
- Ÿ On December 19, 2014, the registrant issued 2,222,222 shares of Series D Preferred Stock and 1,388,889 Shares of Series D-1 Preferred Stock for aggregate consideration of \$65.0 million to an accredited investor pursuant to Section 4(a)(2) of the Securities Act and Rule 506 as a transaction not involving a public offering.
- (b) Stock Option Grants.
- Ÿ From September 30, 2011 through January 27, 2015, the registrant granted stock options to purchase an aggregate of 3,678,779 shares of its common stock with exercise prices ranging from \$0.10 to \$7.79 per share, to certain employees, non-employees and directors in connection with services provided to the registrant by such parties.
- (c) Warrants
- Ÿ On September 9, 2013, the registrant issued a warrant to purchase 92,127 shares of Series A-2 Preferred Stock to an accredited investor pursuant to Section 4(a)(2) of the Securities Act and Rule 506 as a transaction not involving a public offering.
- Ÿ On June 6, 2014, the registrant issued a warrant to purchase 454,545 shares of common stock and a warrant to purchase up to 284,090 shares of common stock to an accredited investor pursuant to Section 4(a)(2) of the Securities Act and Rule 506 as a transaction not involving a public offering.

#### Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Number	Description of Exhibit
1.1*	Form of Underwriting Agreement
3.1*	Certificate of Incorporation of the Registrant, as amended (currently in effect)
3.2**	Bylaws of the Registrant (currently in effect)

Exhibit Number

	the production of the contract
3.3*	Form of Restated Certificate of Incorporation of the Registrant (to be effective upon the closing of this offering)
3.4*	Form of Restated Bylaws of the Registrant (to be effective upon the closing of this offering)
4.1	Amended and Restated Investors' Rights Agreement, dated December 19, 2014, by and among the Registrant and each of the investors listed on Schedule A thereto
4.2*	Specimen Stock Certificate evidencing the shares of common stock
4.3**	Warrant to Purchase Stock, dated September 9, 2013, issued by the Registrant to Comerica Bank
4.4**	Common Stock Purchase Warrant, dated June 6, 2014, issued by the Registrant to Mayo Foundation for Medical Education and Research
4.5**	Common Stock Purchase Warrant, dated June 6, 2014, issued by the Registrant to Mayo Foundation for Medical Education and Research
5.1*	Opinion of Latham & Watkins LLP
10.1#**	2012 Stock Incentive Plan, as amended, and forms of option agreements thereunder
10.2#*	2015 Incentive Award Plan and forms of option agreements thereunder
10.3#*	2015 Employee Stock Purchase Plan
10.4#*	Non-Employee Director Compensation Program
10.5#*	Form of Indemnification Agreement for Directors and Officers
10.6#**	Offer Letter, dated April 23, 2014, by and between the Registrant and Roger J. Pomerantz, M.D.
10.7#**	Offer Letter, dated October 29, 2014, by and between the Registrant and Eric D. Shaff
10.8#**	Offer Letter, dated October 4, 2012, by and between the Registrant and David Cook
10.9#**	Offer Letter, dated October 18, 2012, by and between the Registrant and John Aunins
10.10#	Offer Letter, dated December 23, 2014, by and between the Registrant and Michele Trucksis, M.D.
10.11	Loan and Security Agreement, dated September 9, 2013, by and between the Registrant and Comerica Bank, as amended.
10.12*	Lease Agreement, dated June 24, 2012, by and between the Registrant and ARE-MA Region No. 21, LLC, as amended
21.1	Subsidiaries of Seres Health, Inc.
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
23.2*	Consent of Latham & Watkins LLP (included in Exhibit 5.1)
24.1**	Power of Attorney (included on signature page)

Description of Exhibit

- \* To be filed by amendment.\*\* Previously filed.

- # Indicates management contract or compensatory plan.
  † Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.

(b) Financial Statement Schedules. Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

#### Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriter, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) For the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- (4) In a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
  - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

- (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

#### **SIGNATURES**

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cambridge, Commonwealth of Massachusetts, on this day of , 2015.

SERES HEALTH, INC.

By:

Roger J. Pomerantz, M.D.
President, Chief Executive Officer and Chairman of the Board

#### SIGNATURES AND POWER OF ATTORNEY

We, the undersigned officers and directors of Seres Health, Inc., hereby severally constitute and appoint Roger J. Pomerantz, M.D. and Eric D. Shaff, and each of them singly (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for him and in his name, place and stead, and in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement (or any other registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
Roger J. Pomerantz, M.D.	President, Chief Executive Officer and Chairman of the Board (principal executive officer)	, 2015
Eric D. Shaff	Chief Financial Officer and Executive Vice President (principal financial and accounting officer)	, 2015
Noubar B. Afeyan, Ph.D.	Director	, 2015
Grégory Behar	Director	, 2015
David A. Berry, M.D., Ph.D.	Director	, 2015
Werner Cautreels, Ph.D.	Director	, 2015
Peter Barton Hutt	Director	, 2015
Richard N. Kender	Director	, 2015
Lorence B. Kim, M.D.	Director	, 2015

#### **Exhibit Index**

Exhibit	Description of Exhibit
Number 1.1*	Description of Exhibit Form of Underwriting Agreement
3.1*	Certificate of Incorporation of the Registrant, as amended (currently in effect)
3.2**	Bylaws of the Registrant (currently in effect)
3.3*	Form of Restated Certificate of Incorporation of the Registrant (to be effective upon the closing of this offering)
3.4*	Form of Restated Bylaws of the Registrant (to be effective upon the closing of this offering)
4.1	Amended and Restated Investors' Rights Agreement, dated December 19, 2014, by and among the Registrant and each of the investors listed on Schedule A thereto
4.2*	Specimen Stock Certificate evidencing the shares of common stock
4.3**	Warrant to Purchase Stock, dated September 9, 2013, issued by the Registrant to Comerica Bank
4.4**	Common Stock Purchase Warrant, dated June 6, 2014, issued by the Registrant to Mayo Foundation for Medical Education and Research
4.5**	Common Stock Purchase Warrant, dated June 6, 2014, issued by the Registrant to Mayo Foundation for Medical Education and Research
5.1*	Opinion of Latham & Watkins LLP
10.1#**	2012 Stock Incentive Plan, as amended, and forms of option agreements thereunder
10.2#*	2015 Incentive Award Plan and forms of option agreements thereunder
10.3#*	2015 Employee Stock Purchase Plan
10.4#*	Non-Employee Director Compensation Program
10.5#*	Form of Indemnification Agreement for Directors and Officers
10.6#**	Offer Letter, dated April 23, 2014, by and between the Registrant and Roger J. Pomerantz, M.D.
10.7#**	Offer Letter, dated October 29, 2014, by and between the Registrant and Eric D. Shaff
10.8#**	Offer Letter, dated October 4, 2012, by and between the Registrant and David Cook
10.9#**	Offer Letter, dated October 18, 2012, by and between the Registrant and John Aunins
10.10#	Offer Letter, dated December 23, 2014, by and between the Registrant and Michele Trucksis, M.D.
10.11	Loan and Security Agreement, dated September 9, 2013, by and between the Registrant and Comerica Bank, as amended.
10.12*	Lease Agreement, dated June 24, 2012, by and between the Registrant and ARE-MA Region No. 21, LLC, as amended
21.1	Subsidiaries of Seres Health, Inc.
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
23.2*	Consent of Latham & Watkins LLP (included in Exhibit 5.1)
24.1**	Power of Attorney (included on signature page)

- \* To be filed by amendment.

- \*\* Previously filed.

  # Indicates management contract or compensatory plan.

  † Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.

#### AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT

THIS AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT is made as of the 19th day of December, 2014, by and among Seres Health, Inc., a Delaware corporation (the "**Company**"), and each of the investors listed on <u>Schedule A</u> hereto, each of which is referred to in this Agreement as an "**Investor**."

#### **RECITALS**

**WHEREAS**, certain of the Investors (the "**Existing Investors**") possess registration rights, information rights, rights of first offer, and other rights pursuant to an Amended and Restated Investors' Rights Agreement dated as of November 24, 2014, between the Company and such Investors (as amended, the "**Prior Agreement**");

**WHEREAS**, the Existing Investors desire to amend and restate the Prior Agreement in its entirety and to accept the rights created pursuant to this Agreement in lieu of the rights granted to them under the Prior Agreement; and

**WHEREAS,** one of the Investors is a party to that certain Series D Preferred Stock Purchase Agreement of even date herewith between the Company and such Investor (the "**Purchase Agreement**"), under which certain of the Company's and such Investor's obligations are conditioned upon the execution and delivery of this Agreement by the parties hereto;

**NOW, THEREFORE**, the Company and the Existing Investors hereby agree to amend and restate the Prior Agreement in its entirety as set forth herein, and all of the parties hereto further agree as follows:

- 1. <u>Definitions</u>. For purposes of this Agreement:
- 1.1 "Affiliate" means, with respect to any specified Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such Person, including without limitation any general partner, managing member, officer or director of such Person or any venture capital or other investment fund now or hereafter existing that is controlled by one or more general partners or managing members of, or shares the same management company or investment advisor with, such Person.
  - 1.2 "Common Stock" means shares of the Company's common stock, par value \$0.001 per share.
- 1.3 "Damages" means any loss, damage, or liability (joint or several) to which a party hereto may become subject under the Securities Act, the Exchange Act, or other federal or state law, insofar as such loss, damage, or liability (or any action in respect thereof) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in any registration statement of the Company, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto; (ii) an omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading; or (iii) any violation or alleged violation by the indemnifying party (or any of its agents or Affiliates) of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act, or any state securities law.

- 1.4 "**Derivative Securities**" means any securities or rights convertible into, or exercisable or exchangeable for (in each case, directly or indirectly), Common Stock, including options and warrants.
  - 1.5 "Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.
- 1.6 "Excluded Registration" means (i) a registration relating to the sale of securities to employees of the Company or a subsidiary pursuant to a stock option, stock purchase, or similar plan; (ii) a registration relating to an SEC Rule 145 transaction; (iii) a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the Registrable Securities; or (iv) a registration in which the only Common Stock being registered is Common Stock issuable upon conversion of debt securities that are also being registered.
- 1.7 **"Form S-1"** means such form under the Securities Act as in effect on the date hereof or any successor registration form under the Securities Act subsequently adopted by the SEC.
- 1.8 "**Form S-3**" means such form under the Securities Act as in effect on the date hereof or any registration form under the Securities Act subsequently adopted by the SEC that permits incorporation of substantial information by reference to other documents filed by the Company with the SEC.
  - 1.9 "GAAP" means generally accepted accounting principles in the United States.
  - 1.10 "Holder" means any holder of Registrable Securities who is a party to this Agreement.
- 1.11 "Immediate Family Member" means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, of a natural person referred to herein.
  - 1.12 "Initiating Holders" means, collectively, Holders who properly initiate a registration request under this Agreement.
  - 1.13 "IPO" means the Company's first underwritten public offering of its Common Stock under the Securities Act.
- 1.14 "**Key Employee**" means any executive-level employee (including division director and vice president-level positions) as well as any employee who, either alone or in concert with others, develops, invents, programs, or designs any Company Intellectual Property (as defined in the Purchase Agreement).

- 1.15 "**Major Investor**" means (i) any Investor that, individually or together with such Investor's Affiliates, holds at least 281,000 shares of Registrable Securities (as adjusted for any stock split, stock dividend, combination, or other recapitalization or reclassification effected after the date hereof) and (ii) any Investor that, individually or together with such Investor's Affiliates, holds at least 164,430 shares of Series C Preferred Stock (as adjusted for any stock split, stock dividend, combination, or other recapitalization or reclassification effected after the date hereof).
- 1.16 "**New Securities**" means, collectively, equity securities of the Company, whether or not currently authorized, as well as rights, options, or warrants to purchase such equity securities, or securities of any type whatsoever that are, or may become, convertible or exchangeable into or exercisable for such equity securities.
  - 1.17 "Person" means any individual, corporation, partnership, trust, limited liability company, association or other entity.
- 1.18 "**Preferred Director**" means the director of the Company that the holders of record of the Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock are entitled to elect pursuant to the Company's Certificate of Incorporation.
- 1.19 "**Preferred Stock**" means shares of Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock.
- 1.20 "Registrable Securities" means (i) the Common Stock issuable or issued upon conversion of the Preferred Stock; (ii) the Common Stock held by Flagship VentureLabs IV LLC as of the date of the Prior Agreement (including without limitation and for the avoidance of doubt the Common Stock acquired by Nestlé Health Science US Holdings, Inc. ("Nestlé") pursuant to the Stock Purchase Agreement dated as of December 19, 2014, by and between Flagship VentureLabs IV LLC and Nestlé (the "Common Stock Purchase Agreement"); (iii) any Common Stock issued as (or issuable upon the conversion or exercise of any warrant, right, or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the shares referenced in clause (i) and (ii) above; and (iv) the Common Stock issued or issuable to Comerica Ventures Incorporated, its successors and assigns, upon conversion of shares of any securities of the Company (including without limitation Series A-2 Preferred Stock) issuable upon exercise of the warrant issued by the Company to Comerica Bank pursuant to that certain Loan and Security Agreement, dated as of September 9, 2013, between the Company and Comerica Bank, as may be amended and/or restated from time to time; excluding in all cases, however, any Registrable Securities sold by a Person in a transaction in which the applicable rights under this Agreement are not assigned pursuant to Subsection 6.1, and excluding for purposes of Section 2 any shares for which registration rights have terminated pursuant to Subsection 2.13 of this Agreement.
- 1.21 "**Registrable Securities then outstanding**" means the number of shares determined by adding the number of shares of outstanding Common Stock that are Registrable Securities and the number of shares of Common Stock issuable (directly or indirectly) pursuant to then exercisable and/or convertible securities that are Registrable Securities.

- 1.22 "**Restricted Securities**" means the securities of the Company required to bear the legend set forth in Subsection 2.12(b) hereof.
- 1.23 "SEC" means the Securities and Exchange Commission.
- 1.24 "SEC Rule 144" means Rule 144 promulgated by the SEC under the Securities Act.
- 1.25 "SEC Rule 145" means Rule 145 promulgated by the SEC under the Securities Act.
- 1.26 "Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.
- 1.27 "**Selling Expenses**" means all underwriting discounts, selling commissions, and stock transfer taxes applicable to the sale of Registrable Securities, and fees and disbursements of counsel for any Holder, except for the fees and disbursements of the Selling Holder Counsel borne and paid by the Company as provided in Subsection 2.6.
  - 1.28 "Series A Preferred Stock" means shares of the Company's Series A Preferred Stock, par value \$0.001 per share.
  - 1.29 "Series A-2 Preferred Stock" means shares of the Company's Series A-2 Preferred Stock, par value \$0.001 per share.
  - 1.30 "Series B Preferred Stock" means shares of the Company's Series B Preferred Stock, par value \$0.001 per share.
  - 1.31 "Series C Preferred Stock" means shares of the Company's Series C Preferred Stock, par value \$0.001 per share.
- 1.32 "**Series C Purchase Agreement**" means that certain Series C Preferred Stock Purchase Agreement, dated as of November 24, 2014, by and among the Company and the purchasers named therein.
  - 1.33 "Series D Preferred Stock" means shares of the Company's Series D Preferred Stock, par value \$0.001 per share.
  - 1.34 "Series D-1 Preferred Stock" means shares of the Company's Series D-1 Preferred Stock, par value \$0.001 per share.
  - 2. Registration Rights. The Company covenants and agrees as follows:
    - 2.1 Demand Registration.

(a) <u>Form S-1 Demand</u>. If at any time after the earlier of (i) five (5) years after the date of this Agreement or (ii) one hundred eighty (180) days after the effective date of the registration statement for the IPO, the Company receives a request from Holders of a

majority of the Registrable Securities then outstanding that the Company file a Form S-1 registration statement for which the anticipated aggregate offering price would exceed \$10,000,000, then the Company shall (i) within ten (10) days after the date such request is given, give notice thereof (the "**Demand Notice**") to all Holders other than the Initiating Holders; and (ii) as soon as practicable, and in any event within sixty (60) days after the date such request is given by the Initiating Holders, file a Form S-1 registration statement under the Securities Act covering all Registrable Securities that the Initiating Holders requested to be registered and any additional Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within twenty (20) days of the date the Demand Notice is given, and in each case, subject to the limitations of Subsection 2.1(c) and Subsection 2.3.

(b) <u>Form S-3 Demand</u>. If at any time when it is eligible to use a Form S-3 registration statement, the Company receives a request from Holders of at least thirty percent (30%) of the Registrable Securities then outstanding that the Company file a Form S-3 registration statement with respect to outstanding Registrable Securities of such Holders having an anticipated aggregate offering price of at least \$5,000,000, then the Company shall (i) within ten (10) days after the date such request is given a Demand Notice to all Holders other than the Initiating Holders; and (ii) as soon as practicable, and in any event within forty-five (45) days after the date such request is given by the Initiating Holders, file a Form S-3 registration statement under the Securities Act covering all Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within twenty (20) days of the date the Demand Notice is given, and in each case, subject to the limitations of <u>Subsection 2.1(c)</u> and <u>Subsection 2.3</u>.

(c) Notwithstanding the foregoing obligations, if the Company furnishes to Holders requesting a registration pursuant to this <u>Subsection 2.1</u> a certificate signed by the Company's chief executive officer stating that in the good faith judgment of the Company's Board of Directors it would be materially detrimental to the Company and its stockholders for such registration statement to either become effective or remain effective for as long as such registration statement otherwise would be required to remain effective, because such action would (i) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving the Company; (ii) require premature disclosure of material information that the Company has a bona fide business purpose for preserving as confidential; or (iii) render the Company unable to comply with requirements under the Securities Act or Exchange Act, then the Company shall have the right to defer taking action with respect to such filing, and any time periods with respect to filing or effectiveness thereof shall be tolled correspondingly, for a period of not more than ninety (90) days after the request of the Initiating Holders is given; <u>provided, however</u>, that the Company may not invoke this right more than once in any twelve (12) month period; and <u>provided further</u> that the Company shall not register any securities for its own account or that of any other stockholder during such ninety (90) day period other than an Excluded Registration.

(d) The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to <u>Subsection 2.1(a)</u> (i) during the period that is sixty (60) days before the Company's good faith estimate of the date of filing of, and ending on a date that is one hundred eighty (180) days after the effective date of, a Company-initiated registration,

provided, that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; (ii) after the Company has effected two registrations pursuant to Subsection 2.1(a); or (iii) if the Initiating Holders propose to dispose of shares of Registrable Securities that may be immediately registered on Form S-3 pursuant to a request made pursuant to Subsection 2.1(b). The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Subsection 2.1(b) (i) during the period that is thirty (30) days before the Company's good faith estimate of the date of filing of, and ending on a date that is ninety (90) days after the effective date of, a Company-initiated registration, provided, that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; or (ii) if the Company has effected two registrations pursuant to Subsection 2.1(b) within the twelve (12) month period immediately preceding the date of such request. A registration shall not be counted as "effected" for purposes of this Subsection 2.1(d) until such time as the applicable registration statement has been declared effective by the SEC, unless the Initiating Holders withdraw their request for such registration, elect not to pay the registration expenses therefor, and forfeit their right to one demand registration statement pursuant to Subsection 2.6, in which case such withdrawn registration statement shall be counted as "effected" for purposes of this Subsection 2.1(d).

2.2 <u>Company Registration</u>. If the Company proposes to register (including, for this purpose, a registration effected by the Company for stockholders other than the Holders) any of its securities under the Securities Act in connection with the public offering of such securities solely for cash (other than in an Excluded Registration or the IPO), the Company shall, at such time, promptly give each Holder notice of such registration. Upon the request of each Holder given within twenty (20) days after such notice is given by the Company, the Company shall, subject to the provisions of <u>Subsection 2.3</u>, cause to be registered all of the Registrable Securities that each such Holder has requested to be included in such registration. The Company shall have the right to terminate or withdraw any registration initiated by it under this <u>Subsection 2.2</u> before the effective date of such registration, whether or not any Holder has elected to include Registrable Securities in such registration. The expenses (other than Selling Expenses) of such withdrawn registration shall be borne by the Company in accordance with <u>Subsection 2.6</u>.

#### 2.3 Underwriting Requirements.

(a) If, pursuant to <u>Subsection 2.1</u>, the Initiating Holders intend to distribute the Registrable Securities covered by their request by means of an underwriting, they shall so advise the Company as a part of their request made pursuant to <u>Subsection 2.1</u>, and the Company shall include such information in the Demand Notice. The underwriter(s) will be selected by a majority in interest of the Initiating Holders, subject only to the reasonable approval of the Company. In such event, the right of any Holder to include such Holder's Registrable Securities in such registration shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting to the extent provided herein. All Holders proposing to distribute their securities through such underwriting shall (together with the Company as provided in <u>Subsection 2.4(e)</u>) enter into an underwriting agreement in customary form with the underwriter(s) selected for such underwriting. Notwithstanding any other provision of this <u>Subsection 2.3</u>, if the managing underwriter(s) advise(s) the Initiating Holders in writing that marketing factors require a limitation on the number of shares to be underwritten, then the Initiating Holders shall so advise all Holders of Registrable Securities that otherwise would be underwritten pursuant

hereto, and the number of Registrable Securities that may be included in the underwriting shall be allocated among such Holders of Registrable Securities, including the Initiating Holders, in proportion (as nearly as practicable) to the number of Registrable Securities owned by each Holder or in such other proportion as shall mutually be agreed to by all such selling Holders; provided, however, that the number of Registrable Securities held by the Holders to be included in such underwriting shall not be reduced unless all other securities are first entirely excluded from the underwriting. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest 100 shares.

(b) In connection with any offering involving an underwriting of shares of the Company's capital stock pursuant to Subsection 2.2, the Company shall not be required to include any of the Holders' Registrable Securities in such underwriting unless the Holders accept the terms of the underwriting as agreed upon between the Company and its underwriters, and then only in such quantity as the underwriters in their sole discretion determine will not jeopardize the success of the offering by the Company. If the total number of securities, including Registrable Securities, requested by stockholders to be included in such offering exceeds the number of securities to be sold (other than by the Company) that the underwriters in their reasonable discretion determine is compatible with the success of the offering, then the Company shall be required to include in the offering only that number of such securities, including Registrable Securities, which the underwriters and the Company in their sole discretion determine will not jeopardize the success of the offering. If the underwriters determine that less than all of the Registrable Securities requested to be registered can be included in such offering, then the Registrable Securities that are included in such offering shall be allocated among the selling Holders in proportion (as nearly as practicable to) the number of Registrable Securities owned by each selling Holder or in such other proportions as shall mutually be agreed to by all such selling Holders. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest 100 shares. Notwithstanding the foregoing, in no event shall (i) the number of Registrable Securities included in the offering be reduced unless all other securities (other than securities to be sold by the Company) are first entirely excluded from the offering, and (ii) the number of Registrable Securities included in the offering be reduced below thirty percent (30%) of the total number of securities included in such offering. For purposes of the provision in this Subsection 2.3(b) concerning apportionment, for any selling Holder that is a partnership, limited liability company, or corporation, the partners, members, retired partners, retired members, stockholders, and Affiliates of such Holder, or the estates and Immediate Family Members of any such partners, retired partners, members, and retired members and any trusts for the benefit of any of the foregoing Persons, shall be deemed to be a single "selling Holder," and any pro rata reduction with respect to such "selling Holder" shall be based upon the aggregate number of Registrable Securities owned by all Persons included in such "selling Holder," as defined in this sentence.

(c) For purposes of <u>Subsection 2.1</u>, a registration shall not be counted as "effected" if, as a result of an exercise of the underwriter's cutback provisions in <u>Subsection 2.3(a)</u>, fewer than fifty percent (50%) of the total number of Registrable Securities that Holders have requested to be included in such registration statement are actually included.

- 2.4 <u>Obligations of the Company</u>. Whenever required under this <u>Section 2</u> to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:
- (a) prepare and file with the SEC a registration statement with respect to such Registrable Securities and use its commercially reasonable efforts to cause such registration statement to become effective and, upon the request of the Holders of a majority of the Registrable Securities registered thereunder, keep such registration statement effective for a period of up to one hundred twenty (120) days or, if earlier, until the distribution contemplated in the registration statement has been completed; provided, however, that (i) such one hundred twenty (120) day period shall be extended for a period of time equal to the period the Holder refrains, at the request of an underwriter of Common Stock (or other securities) of the Company, from selling any securities included in such registration, and (ii) in the case of any registration of Registrable Securities on Form S-3 that are intended to be offered on a continuous or delayed basis, subject to compliance with applicable SEC rules, such one hundred twenty (120) day period shall be extended, if necessary, to keep the registration statement effective until all such Registrable Securities are sold;
- (b) prepare and file with the SEC such amendments and supplements to such registration statement, and the prospectus used in connection with such registration statement, as may be necessary to comply with the Securities Act in order to enable the disposition of all securities covered by such registration statement;
- (c) furnish to the selling Holders such numbers of copies of a prospectus, including a preliminary prospectus, as required by the Securities Act, and such other documents as the Holders may reasonably request in order to facilitate their disposition of their Registrable Securities;
- (d) use its commercially reasonable efforts to register and qualify the securities covered by such registration statement under such other securities or blue-sky laws of such jurisdictions as shall be reasonably requested by the selling Holders; provided that the Company shall not be required to qualify to do business or to file a general consent to service of process in any such states or jurisdictions, unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act;
- (e) in the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the underwriter(s) of such offering;
- (f) use its commercially reasonable efforts to cause all such Registrable Securities covered by such registration statement to be listed on a national securities exchange or trading system and each securities exchange and trading system (if any) on which similar securities issued by the Company are then listed;
- (g) provide a transfer agent and registrar for all Registrable Securities registered pursuant to this Agreement and provide a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration;

- (h) promptly make available for inspection by the selling Holders, any managing underwriter(s) participating in any disposition pursuant to such registration statement, and any attorney or accountant or other agent retained by any such underwriter or selected by the selling Holders, all financial and other records, pertinent corporate documents, and properties of the Company, and cause the Company's officers, directors, employees, and independent accountants to supply all information reasonably requested by any such seller, underwriter, attorney, accountant, or agent, in each case, as necessary or advisable to verify the accuracy of the information in such registration statement and to conduct appropriate due diligence in connection therewith;
- (i) notify each selling Holder, promptly after the Company receives notice thereof, of the time when such registration statement has been declared effective or a supplement to any prospectus forming a part of such registration statement has been filed; and
- (j) after such registration statement becomes effective, notify each selling Holder of any request by the SEC that the Company amend or supplement such registration statement or prospectus.

In addition, the Company shall ensure that, at all times after any registration statement covering a public offering of securities of the Company under the Securities Act shall have become effective, its insider trading policy shall provide that the Company's directors may implement a trading program under Rule 10b5-1 of the Exchange Act.

- 2.5 <u>Furnish Information</u>. It shall be a condition precedent to the obligations of the Company to take any action pursuant to this <u>Section 2</u> with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself, the Registrable Securities held by it, and the intended method of disposition of such securities as is reasonably required to effect the registration of such Holder's Registrable Securities.
- 2.6 Expenses of Registration. All expenses (other than Selling Expenses) incurred in connection with registrations, filings, or qualifications pursuant to Section 2, including all registration, filing, and qualification fees; printers' and accounting fees; fees and disbursements of counsel for the Company; and the reasonable fees and disbursements of one counsel for the selling Holders selected by the Holders of a majority of the Registrable Securities to be registered ("Selling Holder Counsel"), shall be borne and paid by the Company; provided, however, that the Company shall not be required to pay for any expenses of any registration proceeding begun pursuant to Subsection 2.1 if the registration request is subsequently withdrawn at the request of the Holders of a majority of the Registrable Securities to be registered (in which case all selling Holders shall bear such expenses pro rata based upon the number of Registrable Securities that were to be included in the withdrawn registration), unless the Holders of a majority of the Registrable Securities agree to forfeit their right to one registration pursuant to Subsection 2.1(a) or Subsection 2.1(b), as the case may be; provided further that if, at the time of such withdrawal, the Holders shall have learned of a material adverse change in the condition, business, or prospects of the Company from that known to the Holders at the time of their request and have withdrawn the request with reasonable promptness after learning of such information then the Holders shall not be required to pay any of such

expenses and shall not forfeit their right to one registration pursuant to <u>Subsection 2.1(a)</u> or <u>Subsection 2.1(b)</u>. All Selling Expenses relating to Registrable Securities registered pursuant to this <u>Section 2</u> shall be borne and paid by the Holders pro rata on the basis of the number of Registrable Securities registered on their behalf.

2.7 <u>Delay of Registration</u>. No Holder shall have any right to obtain or seek an injunction restraining or otherwise delaying any registration pursuant to this Agreement as the result of any controversy that might arise with respect to the interpretation or implementation of this <u>Section 2</u>.

2.8 Indemnification. If any Registrable Securities are included in a registration statement under this Section 2:

(a) To the extent permitted by law, the Company will indemnify and hold harmless each selling Holder, and the partners, members, officers, directors, and stockholders of each such Holder; legal counsel, accountants and investment advisors for each such Holder; any underwriter (as defined in the Securities Act) for each such Holder; and each Person, if any, who controls such Holder or underwriter within the meaning of the Securities Act or the Exchange Act, against any Damages, and the Company will pay to each such Holder, underwriter, controlling Person, or other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Subsection 2.8(a) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Company, which consent shall not be unreasonably withheld, nor shall the Company be liable for any Damages to the extent that they arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of any such Holder, underwriter, controlling Person, or other aforementioned Person expressly for use in connection with such registration.

(b) To the extent permitted by law, each selling Holder, severally and not jointly, will indemnify and hold harmless the Company, and each of its directors, each of its officers who has signed the registration statement, each Person (if any), who controls the Company within the meaning of the Securities Act, legal counsel and accountants for the Company, any underwriter (as defined in the Securities Act), any other Holder selling securities in such registration statement, and any controlling Person of any such underwriter or other Holder, against any Damages, in each case only to the extent that such Damages arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of such selling Holder expressly for use in connection with such registration; and each such selling Holder will pay to the Company and each other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Subsection 2.8(b) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Holder, which consent shall not be unreasonably withheld; and provided further that in no event shall the aggregate amounts payable by any Holder by way of indemnity or contribution under Subsections 2.8(b) and 2.8(d) exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of fraud or willful misconduct by such Holder.

(c) Promptly after receipt by an indemnified party under this <u>Subsection 2.8</u> of notice of the commencement of any action (including any governmental action) for which a party may be entitled to indemnification hereunder, such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this <u>Subsection 2.8</u>, give the indemnifying party notice of the commencement thereof. The indemnifying party shall have the right to participate in such action and, to the extent the indemnifying party so desires, participate jointly with any other indemnifying party to which notice has been given, and to assume the defense thereof with counsel mutually satisfactory to the parties; <u>provided</u>, <u>however</u>, that an indemnified party (together with all other indemnified parties that may be represented without conflict by one counsel) shall have the right to retain one separate counsel, with the fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such action. The failure to give notice to the indemnifying party within a reasonable time of the commencement of any such action shall relieve such indemnifying party of any liability to the indemnifying party's ability to defend such action. The failure to give notice to the indemnifying party will not relieve it of any liability that it may have to any indemnified party otherwise than under this <u>Subsection 2.8</u>.

(d) To provide for just and equitable contribution to joint liability under the Securities Act in any case in which either (i) any party otherwise entitled to indemnification hereunder makes a claim for indemnification pursuant to this Subsection 2.8 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case, notwithstanding the fact that this Subsection 2.8 provides for indemnification in such case, or (ii) contribution under the Securities Act may be required on the part of any party hereto for which indemnification is provided under this Subsection 2.8, then, and in each such case, such parties will contribute to the aggregate losses, claims, damages, liabilities, or expenses to which they may be subject (after contribution from others) in such proportion as is appropriate to reflect the relative fault of each of the indemnifying party and the indemnified party in connection with the statements, omissions, or other actions that resulted in such loss, claim, damage, liability, or expense, as well as to reflect any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or allegedly untrue statement of a material fact, or the omission or alleged omission of a material fact, relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission; provided, however, that, in any such case, (x) no Holder will be required to contribute any amount in excess of the public offering price of all such Registrable Securities offered and sold by such Holder pursuant to such registration statement, and (y) no Person guilty of fraudulent misrepresentation (

fraudulent misrepresentation; and <u>provided further</u> that in no event shall a Holder's liability pursuant to this <u>Subsection 2.8(d)</u>, when combined with the amounts paid or payable by such Holder pursuant to <u>Subsection 2.8(b)</u>, exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of willful misconduct or fraud by such Holder.

- (e) Notwithstanding the foregoing, to the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with the underwritten public offering are in conflict with the foregoing provisions, the provisions in the underwriting agreement shall control.
- (f) Unless otherwise superseded by an underwriting agreement entered into in connection with the underwritten public offering, the obligations of the Company and Holders under this <u>Subsection 2.8</u> shall survive the completion of any offering of Registrable Securities in a registration under this <u>Section 2</u>, and otherwise shall survive the termination of this Agreement.
- 2.9 <u>Reports Under Exchange Act</u>. With a view to making available to the Holders the benefits of SEC Rule 144 and any other rule or regulation of the SEC that may at any time permit a Holder to sell securities of the Company to the public without registration or pursuant to a registration on Form S-3, the Company shall:
- (a) make and keep available adequate current public information, as those terms are understood and defined in SEC Rule 144, at all times after the effective date of the registration statement filed by the Company for the IPO;
- (b) use commercially reasonable efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after the Company has become subject to such reporting requirements); and
- (c) furnish to any Holder, so long as the Holder owns any Registrable Securities, forthwith upon request (i) to the extent accurate, a written statement by the Company that it has complied with the reporting requirements of SEC Rule 144 (at any time after ninety (90) days after the effective date of the registration statement filed by the Company for the IPO), the Securities Act, and the Exchange Act (at any time after the Company has become subject to such reporting requirements), or that it qualifies as a registrant whose securities may be resold pursuant to Form S 3 (at any time after the Company so qualifies); (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company; and (iii) such other information as may be reasonably requested in availing any Holder of any rule or regulation of the SEC that permits the selling of any such securities without registration (at any time after the Company has become subject to the reporting requirements under the Exchange Act) or pursuant to Form S-3 (at any time after the Company so qualifies to use such form).
- 2.10 <u>Limitations on Subsequent Registration Rights</u>. From and after the date of this Agreement, the Company shall not, without the prior written consent of the Holders of a

majority of the Registrable Securities then outstanding, enter into any agreement with any holder or prospective holder of any securities of the Company that (i) would provide to such holder the right to include securities in any registration on other than a subordinate basis after all Holders have had the opportunity to include in the registration and offering all shares of Registrable Securities that they wish to so include or (ii) allow such holder or prospective holder to initiate a demand for registration of any securities held by such holder or prospective holder.

2.11 "Market Stand off" Agreement. Each Holder hereby agrees that it will not, without the prior written consent of the managing underwriter, during the period commencing on the date of the final prospectus relating to the IPO and ending on the date specified by the Company and the managing underwriter (such period not to exceed one hundred eighty (180) days), (i) lend; offer; pledge; sell; contract to sell; sell any option or contract to purchase; purchase any option or contract to sell; grant any option, right, or warrant to purchase; or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Stock held immediately before the effective date of the registration statement for such offering or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or other securities, in cash, or otherwise. The foregoing provisions of this Subsection 2.11 shall apply only to the IPO, shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement for such IPO, and shall be applicable to the Holders only if all officers and directors of the Company and holders of at least one percent (1%) of the outstanding Common Stock (after giving effect to conversion into Common Stock of all outstanding shares of Preferred Stock) are subject to the same restrictions. The underwriters in connection with such registration are intended third party beneficiaries of this Subsection 2.11 and shall have the right, power, and authority to enforce the provisions hereof as though they were a party hereto. Each Holder further agrees to execute such agreements as may be reasonably requested by the underwriters in connection with such registration that are consistent with this Sub

#### 2.12 Restrictions on Transfer.

(a) The Preferred Stock and the Registrable Securities shall not be sold, pledged, or otherwise transferred in violation of this Agreement, and the Company shall not recognize and shall issue stop-transfer instructions to its transfer agent with respect to any such sale, pledge, or transfer, except upon the conditions specified in this Agreement, which conditions are intended to ensure compliance with the provisions of the Securities Act. A transferring Holder will cause any proposed purchaser, pledgee, or transferee of the Preferred Stock and the Registrable Securities held by such Holder to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Agreement. Notwithstanding the foregoing, the Company shall not require any transferee of Registrable Securities pursuant to an effective registration statement under the Securities Act or, following the IPO, SEC Rule 144 to be bound by the terms of this <u>Subsection 2.12</u> if the transferred securities do not remain Registrable Securities hereunder following such transfer.

(b) Each certificate or instrument representing (i) the Preferred Stock, (ii) the Registrable Securities, and (iii) any other securities issued in respect of the securities referenced in clauses (i) and (ii), upon any stock split, stock dividend, recapitalization, merger, consolidation, or similar event, shall (unless otherwise permitted by the provisions of <u>Subsection 2.12(c)</u>) be stamped or otherwise imprinted with a legend substantially in the following form:

THE SECURITIES REPRESENTED HEREBY HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. SUCH SHARES MAY NOT BE SOLD, PLEDGED, OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR A VALID EXEMPTION FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SAID ACT.

THE SECURITIES REPRESENTED HEREBY MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF AN AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.

The Holders consent to the Company making a notation in its records and giving instructions to any transfer agent of the Restricted Securities in order to implement the restrictions on transfer set forth in this <u>Subsection 2.12</u>.

(c) The holder of each certificate representing Restricted Securities, by acceptance thereof, agrees to comply in all respects with the provisions of this Section 2. Before any proposed sale, pledge, or transfer of any Restricted Securities, unless there is in effect a registration statement under the Securities Act covering the proposed transaction or, following the IPO, the transfer is made pursuant to SEC Rule 144, the Holder thereof shall give notice to the Company of such Holder's intention to effect such sale, pledge, or transfer. Each such notice shall describe the manner and circumstances of the proposed sale, pledge, or transfer in sufficient detail and, if reasonably requested by the Company, shall be accompanied at such Holder's expense by either (i) a written opinion of legal counsel who shall, and whose legal opinion shall, be reasonably satisfactory to the Company, addressed to the Company, to the effect that the proposed transaction may be effected without registration under the Securities Act; (ii) a "no action" letter from the SEC to the effect that the proposed sale, pledge, or transfer of such Restricted Securities without registration will not result in a recommendation by the staff of the SEC that action be taken with respect thereto; or (iii) any other evidence reasonably satisfactory to counsel to the Company to the effect that the proposed sale, pledge, or transfer of the Restricted Securities may be effected without registration under the Securities Act, whereupon the Holder of such Restricted Securities shall be entitled to sell, pledge, or transfer such Restricted Securities in accordance with the terms of the notice given by the Holder to the Company. The Company will not require such a legal opinion or "no action" letter (x) in any transaction in compliance with SEC Rule 144 or (y) in any transaction in which such Holder distributes Restricted Securities to an Affiliate of such Holder for no consideration; provided that, with respect to transfers following the IPO under the foregoing clause (y), each transferee agrees in writing to be subject to the terms of this Subsection 2.12. Each certificate or instrument evidencing the Restricted Securities transferred as above provided shall bear, except if such transfer is made pursuant to SEC Rule 144 or pursuant to an effective registration statement under the Securities Act, the appropriate restrictive legend set forth in Subsection 2.12(b), except that such certificate shall not bear such restrictive legend if, in the opinion of counsel for such Holder and the Company, such legend is not required in order to establish compliance with any provisions of the Securities Act.

- 2.13 <u>Termination of Registration Rights</u>. The right of any Holder to request registration or inclusion of Registrable Securities in any registration pursuant to <u>Subsection 2.1</u> or <u>Subsection 2.2</u> shall terminate upon the earliest to occur of:
  - (a) the closing of a Deemed Liquidation Event, as such term is defined in the Company's Certificate of Incorporation;
- (b) such time after the IPO as SEC Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such Holder's shares without limitation during a three-month period without registration; and
  - (c) the fifth (5th) anniversary of the IPO.

## 3. Information Rights.

- 3.1 <u>Delivery of Financial Statements</u>. The Company shall deliver to each Major Investor and each Investor owning shares of Series C Preferred Stock purchased from the Company pursuant to the Series C Purchase Agreement, <u>provided that</u> the Board of Directors has not reasonably determined that such Major Investor or Investor, as the case may be, is a competitor of the Company:
- (a) as soon as practicable, but in any event within one hundred twenty (120) days after the end of each fiscal year of the Company, (i) a balance sheet as of the end of such year, (ii) statements of income and of cash flows for such year and (iii) a statement of stockholders' equity as of the end of such year, all such financial statements audited and certified by independent public accountants selected by the Company and approved by the Board of Directors, including the Preferred Director;
- (b) as soon as practicable, but in any event within forty-five (45) days after the end of each of the first three (3) quarters of each fiscal year of the Company, unaudited statements of income and of cash flows for such fiscal quarter, and an unaudited balance sheet and a statement of stockholders' equity as of the end of such fiscal quarter, all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments and (ii) not contain all notes thereto that may be required in accordance with GAAP);
- (c) as soon as practicable, but in any event within forty-five (45) days after the end of each of the first three (3) quarters of each fiscal year of the Company, a statement showing the number of shares of each class and series of capital stock and securities convertible into or exercisable for shares of capital stock outstanding at the end of the period, the Common Stock issuable upon conversion or exercise of any outstanding securities convertible or exercisable for Common Stock and the exchange ratio or exercise price applicable thereto, and the number of shares of issued stock options and stock options not yet issued but reserved for issuance, if any, all in sufficient detail as to permit any Major Investor to calculate its percentage equity ownership in the Company, and certified by the chief financial officer or chief executive officer of the Company as being true, complete, and correct; and

(d) such other information relating to the financial condition, business, prospects, or corporate affairs of the Company as any Major Investor may from time to time reasonably request; <u>provided</u>, <u>however</u>, that the Company shall not be obligated under this <u>Subsection 3.1</u> to provide information (i) that the Company reasonably determines in good faith to be confidential information (unless covered by an enforceable confidentiality agreement, in form acceptable to the Company) or a trade secret or (ii) the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

If, for any period, the Company has any subsidiary whose accounts are consolidated with those of the Company, then in respect of such period the financial statements delivered pursuant to the foregoing sections shall be the consolidated and consolidating financial statements of the Company and all such consolidated subsidiaries.

Notwithstanding anything else in this <u>Subsection 3.1</u> to the contrary, the Company may cease providing the information set forth in this <u>Subsection 3.1</u> during the period starting with the date sixty (60) days before the Company's good-faith estimate of the date of filing of a registration statement if it reasonably concludes it must do so to comply with the SEC rules applicable to such registration statement and related offering; provided that the Company's covenants under this <u>Subsection 3.1</u> shall be reinstated at such time as the Company is no longer actively employing its commercially reasonable efforts to cause such registration statement to become effective.

Notwithstanding anything else in this <u>Subsection 3.1</u> to the contrary, (x) the Company shall not be obligated to provide any information under <u>Subsection 3.1(d)</u> to the Major Investor that purchased Series D Preferred Stock from the Company pursuant to the Purchase Agreement, or any of its permitted transferees, and (y) the Company shall not be obligated to provide any information under <u>Subsection 3.1</u> to the Major Investor that purchased Series D Preferred Stock from the Company pursuant to the Purchase Agreement, or any of its permitted transferees, unless such Major Investor continues to own shares representing at least fifty percent (50%) of the combined aggregate voting power of (1) the shares of Series D Preferred Stock and Series D-1 Preferred Stock purchased by such Major Investor pursuant to the Purchase Agreement and (2) the shares of Common Stock purchased by such Major Investor pursuant to the Stock Purchase Agreement, dated as of December 19, 2014, by and between the Flagship VentureLabs IV LLC and such Major Investor.

3.2 <u>Inspection</u>. The Company shall permit each Major Investor (provided that the Board of Directors has not reasonably determined that such Major Investor is a competitor of the Company), at such Major Investor's expense, to visit and inspect the Company's properties; examine its books of account and records; and discuss the Company's affairs, finances, and accounts with its officers, during normal business hours of the Company as may be reasonably requested by the Major Investor; <u>provided</u>, <u>however</u>, that the Company shall not be obligated pursuant to this <u>Subsection 3.2</u> to provide access to any information that it reasonably and in good faith considers to be confidential information (unless covered by an enforceable confidentiality agreement, in form acceptable to the Company) or a trade secret or the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

- 3.3 <u>Termination of Information Rights</u>. The covenants set forth in <u>Subsection 3.1</u> and <u>Subsection 3.2</u> shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO, (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act, or (iii) upon a Deemed Liquidation Event, as such term is defined in the Company's Certificate of Incorporation, unless the consideration received by the Investors is in the form of securities that are privately held, whichever event occurs first.
- 3.4 <u>Confidentiality</u>. Each Investor agrees that such Investor will keep confidential and will not disclose, divulge, or use for any purpose (other than to monitor its investment in the Company) any confidential information obtained from the Company pursuant to the terms of this Agreement (including notice of the Company's intention to file a registration statement), unless such confidential information (a) is known or becomes known to the public in general (other than as a result of a breach of this <u>Subsection 3.4</u> by such Investor), (b) is or has been independently developed or conceived by any Investor without use of the Company's confidential information, or (c) is or has been made known or disclosed to any Investor by a third party without a breach of any obligation of confidentiality such third party may have to the Company; <u>provided</u>, <u>however</u>, that an Investor may disclose confidential information: (i) to its attorneys, accountants, consultants, and other professionals to the extent necessary to obtain their services in connection with monitoring its investment in the Company; (ii) to any prospective purchaser of any Registrable Securities from such Investor, if such prospective purchaser agrees to be bound by the provisions of this <u>Subsection 3.4</u>; (iii) to any existing or prospective Affiliate, partner, member, stockholder, or wholly owned subsidiary of such Investor in the ordinary course of business, <u>provided that</u> such Investor informs such Person that such information is confidential and directs such Person to maintain the confidentiality of such information; or (iv) as may otherwise be required by law, <u>provided that</u> such Investor promptly notifies the Company of such disclosure and takes reasonable steps to minimize the extent of any such required disclosure.

## 4. Rights to Future Stock Issuances.

- 4.1 <u>Right of First Offer</u>. Subject to the terms and conditions of this <u>Subsection 4.1</u> and applicable securities laws, if the Company proposes to offer or sell any New Securities, the Company shall first offer such New Securities to each Major Investor. A Major Investor shall be entitled to apportion the right of first offer hereby granted to it among itself and its Affiliates in such proportions as it deems appropriate.
- (a) The Company shall give notice (the "**Offer Notice**") to each Major Investor, stating (i) its bona fide intention to offer such New Securities, (ii) the number of such New Securities to be offered, and (iii) the price and terms, if any, upon which it proposes to offer such New Securities.
- (b) By notification to the Company within twenty (20) days after the Offer Notice is given, each Major Investor may elect to purchase or otherwise acquire, at the

price and on the terms specified in the Offer Notice, up to that portion of such New Securities which equals the proportion that the Common Stock issued and held, or issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of the Preferred Stock and any other Derivative Securities then held, by such Major Investor bears to the total Common Stock of the Company then outstanding (assuming full conversion and/or exercise, as applicable, of all Preferred Stock and other Derivative Securities). At the expiration of such twenty (20) day period, the Company shall promptly notify each Major Investor that elects to purchase or acquire all the shares available to it (each, a "Fully Exercising Investor") of any other Major Investor's failure to do likewise. During the ten (10) day period commencing after the Company has given such notice, each Fully Exercising Investor may, by giving notice to the Company, elect to purchase or acquire, in addition to the number of shares specified above, up to that portion of the New Securities for which Major Investors were entitled to subscribe but that were not subscribed for by the Major Investors which is equal to the proportion that the Common Stock issued and held, or issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of Preferred Stock and any other Derivative Securities then held, by such Fully Exercising Investor bears to the Common Stock issued and held, or issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of the Preferred Stock and any other Derivative Securities then held, by all Fully Exercising Investors who wish to purchase such unsubscribed shares. The closing of any sale pursuant to this Subsection 4.1(b) shall occur within the later of ninety (90) days of the date that the Offer Notice is given and the date of initial sale of New Securities pursuant to Subsection 4.1(c).

- (c) If all New Securities referred to in the Offer Notice are not elected to be purchased or acquired as provided in <u>Subsection 4.1(b)</u>, the Company may, during the ninety (90) day period following the expiration of the periods provided in <u>Subsection 4.1(b)</u>, offer and sell the remaining unsubscribed portion of such New Securities to any Person or Persons at a price not less than, and upon terms no more favorable to the offeree than, those specified in the Offer Notice. If the Company does not enter into an agreement for the sale of the New Securities within such period, or if such agreement is not consummated within thirty (30) days of the execution thereof, the right provided hereunder shall be deemed to be revived and such New Securities shall not be offered unless first reoffered to the Major Investors in accordance with this <u>Subsection 4.1</u>.
- (d) The right of first offer in this <u>Subsection 4.1</u> shall not be applicable to (i) Exempted Securities (as defined in the Company's Certificate of Incorporation); or (ii) shares of Common Stock issued in the IPO.
- 4.2 <u>Termination</u>. The covenants set forth in <u>Subsection 4.1</u> shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO, (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act, or (iii) upon a Deemed Liquidation Event, as such term is defined in the Company's Certificate of Incorporation, whichever event occurs first.

#### 5. Additional Covenants.

5.1 <u>Insurance</u>. The Company shall use its commercially reasonable efforts to (i) maintain Directors and Officers liability insurance and (ii) upon the request of the Board of

Directors or the holders of a majority of the Registrable Securities then outstanding, term "key person" insurance on the Chief Executive Officer of the Company, in each case from financially sound and reputable insurers and in an amount and on terms and conditions satisfactory to the Board of Directors. The Company will use commercially reasonable efforts to cause such insurance policies to be maintained until such time as the Board of Directors determines that such insurance should be discontinued. The "key person" policy shall name the Company as loss payee and neither policy shall be cancelable by the Company without prior approval by the Board of Directors, including the Preferred Director.

- 5.2 Employee Agreements. The Company will cause (i) each person now or hereafter employed by it or by any subsidiary (or engaged by the Company or any subsidiary as a consultant/independent contractor) with access to confidential information and/or trade secrets to enter into a nondisclosure and proprietary rights assignment agreement and (ii) each Key Employee to enter into a one (1) year noncompetition and nonsolicitation agreement, each in a form acceptable to the Investors. In addition, the Company shall not amend, modify, terminate, waive, or otherwise alter, in whole or in part, any of the above-referenced agreements or any restricted stock agreement between the Company and any employee, without the consent of the Preferred Director.
- 5.3 Employee Stock. Unless otherwise approved by the Board of Directors, including the approval of the Preferred Director, all future employees and consultants of the Company who purchase, receive options to purchase, or receive awards of shares of the Company's capital stock after the date hereof shall be required to execute restricted stock or option agreements, as applicable, providing for (i) vesting of shares over a four (4) year period, with the first twenty-five percent (25%) of such shares vesting following twelve (12) months of continued employment or service, and the remaining shares vesting in equal quarterly installments over the following thirty-six (36) months, and (ii) a market stand-off provision substantially similar to that in Subsection 2.11. In addition, unless otherwise approved by the Board of Directors, including the Preferred Director, the Company shall retain a "right of first refusal" on employee transfers until the Company's IPO and shall have the right to repurchase unvested shares at cost upon termination of employment of a holder of restricted stock.
- 5.4 <u>Qualified Small Business Stock</u>. The Company shall use commercially reasonable efforts to cause the shares of Preferred Stock issued pursuant to the Series C Purchase Agreement, as well as any shares into which such shares are converted, within the meaning of Section 1202(f) of the United States Internal Revenue Code of 1986 (as amended, the "Code"), to constitute "qualified small business stock" as defined in Section 1202(c) of the Code; <u>provided, however</u>, that such requirement shall not be applicable if the Board of Directors of the Company determines, in its good-faith business judgment, that such qualification is inconsistent with the best interests of the Company. The Company shall submit to its stockholders (including the Investors) and to the Internal Revenue Service any reports that may be required under Section 1202(d)(1)(C) of the Code and the regulations promulgated thereunder. In addition, within twenty (20) business days after any Investor's written request therefor, the Company shall, at its option, either (i) deliver to such Investor a written statement indicating whether (and what portion of) such Investor's interest in the Company constitutes "qualified small business stock" as defined in Section 1202(c) of the Code or (ii) deliver to such Investor such factual information in the Company's possession as is reasonably necessary to enable such Investor to determine whether (and what portion of) such Investor's interest in the Company constitutes "qualified small business stock" as defined in Section 1202(c) of the Code.

- 5.5 <u>Matters Requiring Investor Director Approval</u>. So long as the holders of Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock are entitled to elect a Preferred Director, the Company hereby covenants and agrees with the Investors holding shares of Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock that it shall not, nor shall it permit any subsidiary to, without approval of the Board of Directors, which approval must include the affirmative vote of the Preferred Director:
- (a) make any loan or advance to, or own any stock or other securities of, any subsidiary or other corporation, partnership, or other entity unless it is wholly owned by the Company;
- (b) make any loan or advance to any Person, including, without limitation, any employee or director of the Company or any subsidiary, except advances and similar expenditures in the ordinary course of business or under the terms of an employee stock or option plan approved by the Board of Directors, including the Preferred Director;
- (c) guarantee, directly or indirectly, any indebtedness except for trade accounts of the Company or any subsidiary arising in the ordinary course of business:
  - (d) make any investment inconsistent with any investment policy approved by the Board of Directors;
- (e) incur any aggregate indebtedness in excess of \$250,000 that is not already included in a budget approved by the Board of Directors, other than trade credit incurred in the ordinary course of business;
- (f) otherwise enter into or be a party to any transaction with any director, officer, or employee of the Company or any "associate" (as defined in Rule 12b-2 promulgated under the Exchange Act) of any such Person, except for transactions contemplated by this Agreement and the Purchase Agreement; transactions resulting in payments to or by the Company in an aggregate amount less than \$100,000 per year; or transactions made in the ordinary course of business and pursuant to reasonable requirements of the Company's business and upon fair and reasonable terms that are approved by a majority of the Board of Directors;
- (g) hire, terminate, or change the compensation of the executive officers, including approving any option grants or stock awards to executive officers;
  - (h) change the principal business of the Company, enter new lines of business, or exit the current line of business;
- (i) sell, assign, license, pledge, or encumber material technology or intellectual property, other than licenses granted in the ordinary course of business;
- (j) increase the shares of Common Stock reserved for issuance under the Company's 2012 Stock Incentive Plan or adopt any other equity incentive plan; or

(k) enter into any corporate strategic relationship involving the payment, contribution, or assignment by the Company or to the Company of money or assets greater than \$250,000.

- 5.6 <u>Board Matters</u>. Unless otherwise determined by the vote of a majority of the directors then in office, the Board of Directors shall meet at least quarterly in accordance with an agreed-upon schedule, unless agreed by a majority of the Board of Directors, including the Preferred Director. The Company shall reimburse the nonemployee directors for all reasonable out-of-pocket travel expenses incurred (consistent with the Company's travel policy) in connection with attending meetings of the Board of Directors. The Company shall cause to be established, as soon as practicable after such request, and will maintain, an audit and compensation committee, each of which shall consist solely of non-management directors. Each non-employee director shall be entitled in such person's discretion to be a member of any Board committee. Each committee of the Board shall include the Preferred Director.
- 5.7 <u>Successor Indemnification</u>. If the Company or any of its successors or assignees consolidates with or merges into any other Person and is not the continuing or surviving corporation or entity of such consolidation or merger, then to the extent necessary, proper provision shall be made so that the successors and assignees of the Company assume the obligations of the Company with respect to indemnification of members of the Board of Directors as in effect immediately before such transaction, whether such obligations are contained in the Company's Bylaws, its Certificate of Incorporation, or elsewhere, as the case may be.
- 5.8 <u>Termination of Covenants</u>. The covenants set forth in this <u>Section 5</u>, except for <u>Subsection 5.7</u>, shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO, (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act, or (iii) upon a Deemed Liquidation Event, as such term is defined in the Company's Certificate of Incorporation, whichever event occurs first.

#### 6. Miscellaneous.

6.1 <u>Successors and Assigns</u>. The rights under this Agreement may be assigned (but only with all related obligations) by a Holder to a transferee of Registrable Securities that (i) is an Affiliate of a Holder; (ii) is a Holder's Immediate Family Member or trust for the benefit of an individual Holder or one or more of such Holder's Immediate Family Members; or (iii) after such transfer, holds at least 100,000 shares of Registrable Securities (subject to appropriate adjustment for stock splits, stock dividends, combinations, and other recapitalizations); provided, however, that (x) the Company is, within a reasonable time after such transfer, furnished with written notice of the name and address of such transferee and the Registrable Securities with respect to which such rights are being transferred; and (y) such transferee agrees in a written instrument delivered to the Company to be bound by and subject to the terms and conditions of this Agreement, including the provisions of <u>Subsection 2.11</u>. For the purposes of determining the number of shares of Registrable Securities held by a transferee, the holdings of a transferee (1) that is an Affiliate or stockholder of a Holder; (2) who is a Holder's Immediate Family Member; or (3) that is a trust for the benefit of an individual Holder or such

Holder's Immediate Family Member shall be aggregated together and with those of the transferring Holder; provided further that all transferees who would not qualify individually for assignment of rights shall have a single attorney-in-fact for the purpose of exercising any rights, receiving notices, or taking any action under this Agreement. The terms and conditions of this Agreement inure to the benefit of and are binding upon the respective successors and permitted assignees of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assignees any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided herein. Notwithstanding anything to the contrary in this <u>Subsection 6.1</u>, Comerica Ventures, and its successors and assigns, may transfer and assign its rights under the Agreement (together with all related obligations): (a) to any transferee irrespective of the minimum share requirement set forth in clause (iii) of this <u>Subsection 6.1</u>; and (b) to any of its Affiliates, partners or stockholders without compliance with the notice and delivery requirements set forth in clauses (x) and (y) in the proviso at the end of the first sentence of this <u>Subsection 6.1</u> of the Agreement (but only to the extent such transferee remains bound by the restrictions and obligations of the transferor under the Agreement).

- 6.2 <u>Governing Law</u>. This Agreement and any controversy arising out of or relating to this Agreement shall be governed by and construed in accordance with the internal laws of the Commonwealth of Massachusetts, without regard to conflict of law principles that would result in the application of any law other than the law of the Commonwealth of Massachusetts.
- 6.3 <u>Counterparts</u>. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.
- 6.4 <u>Titles and Subtitles</u>. The titles and subtitles used in this Agreement are for convenience only and are not to be considered in construing or interpreting this Agreement.
- 6.5 Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt or: (i) personal delivery to the party to be notified; (ii) when sent, if sent by electronic mail or facsimile during the recipient's normal business hours, and if not sent during normal business hours, then on the recipient's next business day; (iii) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (iv) one (1) business day after the business day of deposit with a nationally recognized overnight courier, freight prepaid, specifying next-day delivery, with written verification of receipt. All communications shall be sent to the respective parties at their addresses as set forth on Schedule A hereto, or to the principal office of the Company at 161 First Street, Suite 2C, Cambridge, MA 02142, Attention: Chief Executive Officer, in the case of the Company, or to such email address, facsimile number, or address as subsequently modified by written notice given in accordance with this Subsection 6.5. If notice is given to the Company, a copy shall also be given to Latham & Watkins LLP, John Hancock Tower, 27th Floor, 200 Clarendon Street, Boston, MA 02116, Attention Peter N. Handrinos, Esq.

6.6 Amendments and Waivers. Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance, and either retroactively or prospectively) only with the written consent of the Company and the holders of a majority of the Registrable Securities then outstanding; provided that the Company may in its sole discretion waive compliance with Subsection 2.12(c) (and the Company's failure to object promptly in writing after notification of a proposed assignment allegedly in violation of Subsection 2.12(c) shall be deemed to be a waiver); provided further that any provision hereof may be waived by any waiving party on such party's own behalf, without the consent of any other party. Notwithstanding the foregoing, this Agreement may not be amended or terminated and the observance of any term hereof may not be waived with respect to any Investor without the written consent of such Investor, unless such amendment, termination, or waiver applies to all Investors in the same fashion (it being agreed that a waiver of the provisions of Section 4 with respect to a particular transaction shall be deemed to apply to all Investors in the same fashion if such waiver does so by its terms, notwithstanding the fact that certain Investors may nonetheless, by agreement with the Company, purchase securities in such transaction). The Company shall give prompt notice of any amendment or termination hereof or waiver hereunder to any party hereto that did not consent in writing to such amendment, termination, or waiver. Any amendment, termination, or waiver effected in accordance with this Subsection 6.6 shall be binding on all parties hereto, regardless of whether any such party has consented thereto; provided, however, that no such amendment shall be binding on Nestlé or any of its Affiliates if such amendment (1) is not entered into or approved in writing by Nestlé or such Affiliate (provided that, for the avoidance of doubt, any such entry into or approval in writing that occurs through the exercise of any right or the enforcement of any obligation arising under Section 4 of the Common Stock Purchase Agreement shall not be deemed for any purpose to constitute an entry into or an approval in writing by Nestlé or such Affiliate for this purpose) and (2)(i) imposes an obligation on Nestlé or such Affiliate that is unrelated to (x) the subject matter of this Agreement or the Purchase Agreement, or the transactions contemplated hereby or thereby, (y) Nestlé's investment in the Company or (z) Nestlé's ownership of securities of the Company or (ii) imposes any restriction on the conduct by Nestlé or any of its Affiliates of its business. No waivers of or exceptions to any term, condition, or provision of this Agreement, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, condition, or provision.

- 6.7 <u>Severability</u>. In case any one or more of the provisions contained in this Agreement is for any reason held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement, and such invalid, illegal, or unenforceable provision shall be reformed and construed so that it will be valid, legal, and enforceable to the maximum extent permitted by law.
- 6.8 <u>Aggregation of Stock</u>. All shares of Registrable Securities held or acquired by Affiliates shall be aggregated together for the purpose of determining the availability of any rights under this Agreement and such Affiliated persons may apportion such rights as among themselves in any manner they deem appropriate.
- 6.9 Entire Agreement. This Agreement (including any Schedules hereto) constitutes the full and entire understanding and agreement among the parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof existing between the parties is expressly canceled.

6.10 <u>Dispute Resolution</u>. The parties (a) hereby irrevocably and unconditionally submit to the jurisdiction of the state courts of the Commonwealth of Massachusetts and to the jurisdiction of the United States District Court for the District of Massachusetts for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (b) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in the state courts of the Commonwealth of Massachusetts or the United States District Court for the District of Massachusetts, and (c) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court.

WAIVER OF JURY TRIAL: EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, THE OTHER TRANSACTION DOCUMENTS, THE SECURITIES OR THE SUBJECT MATTER HEREOF OR THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS TRANSACTION, INCLUDING, WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER WARRANTS AND REPRESENTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.

6.11 <u>Delays or Omissions</u>. No delay or omission to exercise any right, power, or remedy accruing to any party under this Agreement, upon any breach or default of any other party under this Agreement, shall impair any such right, power, or remedy of such nonbreaching or nondefaulting party, nor shall it be construed to be a waiver of or acquiescence to any such breach or default, or to any similar breach or default thereafter occurring, nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default thereafter occurring. All remedies, whether under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

6.12 <u>Further Assurances</u>. At any time or from time to time after the date hereof, the parties agree to cooperate with each other, and at the request of any other party, to execute and deliver any further instruments or documents and to take all such further action as the other party may reasonably request in order to evidence or effectuate the consummation of the transactions contemplated hereby and to otherwise carry out the intent of the parties hereunder.

- 6.13 <u>Acknowledgment</u>. The Company acknowledges that each Investor is in the business of venture capital investing and therefore review the business plans and related proprietary information of many enterprises, including enterprises which may have products or services which compete directly or indirectly with those of the Company. Nothing in this Agreement shall preclude or in any way restrict any Investor from investing or participating in any particular enterprise whether or not such enterprise has products or services which compete with those of the Company.
- 6.14 <u>Massachusetts Business Trust</u>. A copy of the Agreement and Declaration of Trust of each Investor affiliated with Fidelity Management & Research Company is on file with the Secretary of State of the Commonwealth of Massachusetts and notice is hereby given that this Agreement is executed on behalf of the trustees of such Investor or any affiliate thereof as trustees and not individually and that the obligations of this Agreement are not binding on any of the trustees, officers or stockholders of such Investor or any affiliate thereof individually but are binding only upon such Investor or any affiliate thereof and its assets and property.
- 6.15 <u>Series D-1 Preferred Stock</u>. For all purposes of this Agreement, all outstanding shares of Series D-1 Preferred Stock shall be deemed to have been converted into Series D Preferred Stock and each reference herein to "Preferred Stock" shall be deemed to refer to and include to such shares.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties have executed this Amended and Restated Investors' Rights Agreement as of the date first written above.

# SERES HEALTH, INC.

By: /s/ Roger J. Pomerantz
Name: Roger J. Pomerantz, M.D.

Title: President and Chief Executive Officer

# NESTLÉ HEALTH SCIENCE US HOLDINGS, INC.

By: /s/ Andrew Glass
Name: Andrew Glass

Title: Asst Sec

# FIDELITY SELECT PORTFOLIOS: BIOTECHNOLOGY PORTFOLIO

By: /s/Joseph Zambello
Name: Joseph Zambello
Title: Deputy Treasurer

## FIDELITY ADVISOR SERIES VII: FIDELITY ADVISOR BIOTECHNOLOGY FUND

/s/ Joseph Zambello By: Name: Joseph Zambello Title: Deputy Treasurer

# FIDELITY GROWTH COMPANY COMMINGLED POOL

By: /s/ Kenneth B. Robins

Name: Kenneth B. Robins

Title: Treasurer

# FIDELITY MT. VERNON STREET TRUST: FIDELITY SERIES GROWTH COMPANY FUND

By: /s/ Joseph Zambello

Name: Joseph Zambello Title: Deputy Treasurer

# FIDELITY MT. VERNON STREET TRUST: FIDELITY GROWTH COMPANY FUND

By: /s/Joseph Zambello
Name: Joseph Zambello
Title: Deputy Treasurer

## ROCK SPRINGS CAPITAL MASTER FUND LP

By: Rock Springs GP LLC Its: General Partner

/s/ Graham McPhail By: Name: Graham McPhail

Title: Managing Director Rock Springs Capital 650 S. Exeter St., Suite 1070

Baltimore, MD 21202

# BLACKROCK HEALTH SCIENCES TRUST

By: BlackRock Advisors, LLC Its: Investment Adviser

By: /s/ Hongying Xie
Name: Hongying Erin Xie
Title: Managing Director

# BLACKROCK HEALTH SCIENCES OPPORTUNITIES PORTFOLIO, A SERIES OF BLACKROCK FUNDS

By: BlackRock Advisors, LLC Its: Investment Adviser

By: /s/ Hongying Xie
Name: Hongying Erin Xie
Title: Managing Director

## BLACKROCK HEALTH SCIENCES MASTER UNIT TRUST

By: BlackRock Capital Management, Inc. Its: Investment Adviser

/s/ Hongying Xie By: Name: Hongying Erin Xie
Title: Managing Director

# LEERINK HOLDINGS LLC

By: /s/ Timothy R. G. Gerhold

Name: Timothy R. G. Gerhold, General Counsel

Title: Authorized Person

# LEERINK SWANN CO-INVESTMENT FUND, LLC

/s/ Joseph R. Gentile Name: Joseph R. Gentile
Title: Manager

# SOFINNOVA VENTURE PARTNERS IX, L.P.

By: Sofinnova Management IX, L.L.C.

its General Partner

By: /s/ Srinivas Akkaraju

Name: Srinivas Akkaraju
Title: Managing Member

T. Rowe Price Health Sciences Fund, Inc.
TD Mutual Funds – TD Health Sciences Fund
Valic Company I – Health Sciences Fund
T. Rowe Price Health Sciences Portfolio
John Hancock Variable Insurance Trust – Health Sciences
Trust
John Hancock Funds II – Health Sciences Fund,

Each fund, severally and not jointly

By: T. ROWE PRICE ASSOCIATES, INC., Investment Adviser or Subadviser

/s/ Adam Poussard

Name: Adam Poussard
Title: Vice President

# RA CAPITAL HEALTHCARE FUND, LP

By: /s/ Peter Klochinsky
Name: Peter Kolchinsky

Title: Manager

ORBIMED PRIVATE INVESTMENTS V, LP	
By:	OrbiMed Capital GP V LLC, its General Partner
By:	OrbiMed Advisors LLC, is Managing Member
By: Name: Title:	

## FLAGSHIP VENTURES FUND IV, L.P.

By its General Partner Flagship Ventures Fund IV General Partner LLC

By: /s/ Noubar Afeyan

Manager

## FLAGSHIP VENTURES FUND IV-Rx, L.P.

By its General Partner Flagship Ventures Fund IV General Partner LLC

By: /s/ Noubar Afeyan

Manager

## FLAGSHIP VENTURES FUND 2007, L.P.

By its General Partner Flagship Ventures Fund 2007 General Partner LLC

By: /s/ Noubar Afeyan

Manager

## FLAGSHIP VENTURELABS IV LLC

By: FLAGSHIP VENTURES FUND IV, L.P.

its Authorized Member

By: FLAGSHIP VENTURES FUND IV GENERAL

PARTNER LLC its General Partner

By: /s/ Noubar Afeyan

Name: Noubar Afeyan
Title: Manager

INVESTORS:
ENSO VENTURES 2 LIMITED BY INTERLOCK DIRECTOR LTD., DIRECTOR
AUTHORIZED SIGNATORY
AUTHORIZED SIGNATORY

# **INVESTORS:**

# MAYO CLINIC

By: /s/ Harry N. Hoffman, III

Name: Harry N. Hoffman, III

Title: Treasurer and Chief Investment Officer

# **INVESTORS:**

# ALEXANDRIA EQUITIES, LLC,

a Delaware limited liability company

By: ALEXANDRIA REAL ESTATE EQUITIES, INC., a

Maryland corporation, managing member

By: /s/ Dean A. Shigenaga

Name: Dean A. Shigenaga
Title: Executive Vice President

Chief Financial Officer

INV	/F.	ST	O	R	3

/s/ Roger J. Pomerantz

Roger J. Pomerantz, M.D.

By: Name: Jon Favreau Title: Trustee  By: Name: Joya Favreau	FAV	REAU 2008 TRUST, DTD 4-10-2008
Title: Trustee  By:	By:	
Ву:	Nam	: Jon Favreau
	Title	Trustee
	Bv:	
		: Jova Favreau
Title: Trustee		

**INVESTORS:** 

INVESTORS:
/s/ John Aunins
John Aunins

INVESTORS:
/s/ David Cook
David Cook

INVESTORS:
/s/ Matthew Henn
Matthew Henn

#### **SCHEDULE A**

#### **INVESTORS**

#### Name and Address

Nestlé Health Science US Holdings, Inc. 900 Long Ridge Road, Building 2

Stamford, CT 06902

Attention: Andrew Glass, Esq. Email: andrew.glass@us.nestle.com

F: (480) 379-5510

With a copy (which shall not constitute notice) to:

Nestlé Health Science S.A. Avenue Nestlé, 55 1800 Vevey Switzerland Attention: Claudio Kuoni, Esq.

Email: Claudio.Kuoni@nestle.com

F: 41.21.924.2875

Fidelity Select Portfolios: Biotechnology Portfolio

Brown Brothers Harriman & Co.

525 Washington Blvd Jersey City NJ 07310

Attn: Michael Lerman 15th Floor

Corporate Actions

Email: michael.lerman@bbh.com

F: (617) 772-2418

Fidelity Advisor Series VII: Fidelity Advisor

Biotechnology Fund State Street Bank & Trust PO Box 5756

Boston, Massachusetts 02206

Attn: Bangle & Co fbo Fidelity Advisor Series VII:

Fidelity Advisor Biotechnology Fund

Email: SSBCORPACTIONS@StateStreet.com

F: (617) 988-9110

Fidelity Growth Company Commingled Pool

Brown Brothers Harriman & Co.

525 Washington Blvd Jersey City NJ 07310

Attn: Michael Lerman 15th Floor

Corporate Actions

Email: michael.lerman@bbh.com

F: (617) 772-2418

OrbiMed Private Investments V, LP c/o OrbiMed Advisors LLC

Attention: Evan Sotiriou 601 Lexington Ave.

54th Floor

New York, NY 10022

Leerink Swann Co-Investment Fund, LLC

1 Federal Street Boston, MA 02110

Attention: General Counsel

F: (646) 499-7130

Leerink Holdings LLC

1 Federal Street Boston, MA 02110

Attention: General Counsel

F: (646) 499-7130

T. Rowe Price Health Sciences Fund, Inc.

T. Rowe Price Associates, Inc.

100 East Pratt Street Baltimore, MD 21202

Attn: Andrew Baek, Vice President and Senior Legal Counsel

Phone: 410-345-2090

E-mail: andrew\_baek@troweprice.com

Fidelity Mt. Vernon Street Trust: Fidelity Series Growth

Company Fund

State Street Bank & Trust

PO Box 5756

Boston, Massachusetts 02206

Attn: WAVELENGTH + CO Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund Email: SSBCORPACTIONS@StateStreet.com

F: (617) 988-9110

Fidelity Mt. Vernon Street Trust: Fidelity Growth

Company Fund Ball & Co

C/o Citibank N.A/Custody

IC&D Lock Box P.O Box 7247-7057

Philadelphia, P.A 19170-7057

Account #: 206681

Email: fidelity.tpacd@citi.com

F: 813-604-1415

BlackRock Health Sciences Master Unit Trust

c/o BlackRock Advisors, LLC

Fundamental Equity – Global Opportunities Health

& Sciences Team

60 State Street, 19th/20th Floors

Boston, MA 02109

Attn: Erin Xie, Chian Jiang

Email: erin.xie@blackrock.com, chian.jiang@blackrock.com

With a copy (which shall not constitute notice) to:

c/o BlackRock, Inc.

Office of the General Counsel

40 East 52nd Street

New York, NY 10022

Attn: David Maryles and Vincent Taurassi Email: legaltransactions@blackrock.com

BlackRock Health Sciences Trust

c/o BlackRock Advisors, LLC

 $Fundamental\ Equity-Global\ Opportunities\ Health$ 

& Sciences Team

60 State Street, 19th/20th Floors

Boston, MA 02109

Attn: Erin Xie, Chian Jiang

Email: erin.xie@blackrock.com, chian.jiang@blackrock.com

VALIC Company I – Health Sciences Fund

T. Rowe Price Associates, Inc.

100 East Pratt Street Baltimore, MD 21202

Attn: Andrew Baek, Vice President and Senior Legal Counsel

Phone: 410-345-2090

E-mail: andrew\_baek@troweprice.com

TD Mutual Funds – TD Health Sciences Fund

T. Rowe Price Associates, Inc.

100 East Pratt Street

Baltimore, MD 21202

Attn: Andrew Baek, Vice President and Senior Legal Counsel

Phone: 410-345-2090

E-mail: andrew\_baek@troweprice.com

T. Rowe Price Health Sciences Portfolio

T. Rowe Price Associates, Inc.

100 East Pratt Street

Baltimore, MD 21202

Attn: Andrew Baek, Vice President and Senior Legal Counsel

Phone: 410-345-2090

E-mail: andrew\_baek@troweprice.com

John Hancock Variable Insurance Trust – Health Sciences Trust T. Rowe Price Associates. Inc.

100 East Pratt Street

Baltimore, MD 21202

Attn: Andrew Baek, Vice President and Senior Legal Counsel

Phone: 410-345-2090

E-mail: andrew\_baek@troweprice.com

With a copy (which shall not constitute notice) to:

c/o BlackRock, Inc.
Office of the General Counsel
40 East 52nd Street
New York, NY 10022

Attn: David Maryles and Vincent Taurassi Email: legaltransactions@blackrock.com

BlackRock Health Sciences Master Unit Trust c/o BlackRock Advisors, LLC Fundamental Equity – Global Opportunities Health & Sciences Team 60 State Street, 19th/20th Floors Boston, MA 02109 Attn: Erin Xie, Chian Jiang Email: erin.xie@blackrock.com, chian.jiang@blackrock.com

With a copy (which shall not constitute notice) to:

c/o BlackRock, Inc.
Office of the General Counsel
40 East 52nd Street
New York, NY 10022
Attn: David Maryles and Vincent Taurassi
Email: legaltransactions@blackrock.com

Sofinnova Venture Partners IX, L.P. c/o Sofinnova Ventures, Inc.
Attention: Hooman Shahlavi

3000 Sand Hill Road, Bldg 4, Suite 250 Menlo Park, CA 94025

Flagship Ventures Fund IV, L.P. c/o Flagship Ventures One Memorial Drive Cambridge, MA 02142 F: (617) 868 -1115

Flagship Ventures Fund IV-Rx, L.P. c/o Flagship Ventures One Memorial Drive Cambridge, MA 02142 F: (617) 868 -1115

Flagship Ventures Fund 2007, L.P. c/o Flagship Ventures One Memorial Drive Cambridge, MA 02142 F: (617) 868 -1115 John Hancock Funds II – Health Sciences Fund T. Rowe Price Associates, Inc. 100 East Pratt Street Baltimore, MD 21202 Attn: Andrew Baek, Vice President and Senior Legal Counsel Phone: 410-345-2090

E-mail: andrew\_baek@troweprice.com

RA Capital Healthcare Fund, LP c/o RA Capital Management, LLC, Attention: Amanda Daniels 20 Park Plaza, Suite 1200 Boston, MA 02116 F: (617) 778-2510

Rock Springs Capital Master Fund LP Attention: Evans Apeadu 650 South Exeter Street, Suite 1070 Baltimore, MD 21202 Email: evans@rockspringscapital.com

Flagship VentureLabs IV LLC c/o Flagship Ventures One Memorial Drive Cambridge, MA 02142 F: (617) 868 -1115 Enso Ventures 2 Limited

Suite C1 Hirzel Court Hirzel Street St Peter Port Guernsey Channel Islands GY1 2NH F: +44 (0) 1481 755859

Mayo Clinic 200 First Street SW Rochester, MN 55905 F: (507) 538-7802 Alexandria Equities, LLC 385 E. Colorado Blvd. Suite 299 Pasadena, CA 91101 F: (626) 578-0770

For purposes of Section 2.1(b), Section 2.2 through Section 2.12, and Section 6 only:

Comerica Ventures Incorporated 1717 Main St. 5th Floor, MC 6406 Dallas, TX 75201



161 First Street, Suite 2C | Cambridge, MA 02142 | 617-945-9626 | www.sereshealth.com

December 23, 2014

Dr. Michele Trucksis 12 Forest Hill Road Wayland, MA 01778

Dear Dr. Trucksis,

Seres Health, Inc. (the "Company") is pleased to confirm its offer to employ you as a regular, full-time employee on the following terms:

- 1. **Position; start date.** You will serve as the Company's Chief Medical Officer and Executive Vice President. In this capacity you will be reporting to Roger Pomerantz, Chief Executive Officer. Your effective date of hire will be no later than January 15th, 2015. This letter is subject to, and will become effective only upon, your commencing employment with the Company (the date you actually commence employment, the "**Effective Date**").
- 2. **Base salary; work location.** Your base salary for this position will be at the rate of \$320,000 per year. Your base salary will be paid semi-monthly in equal installments and in accordance with the Company's payroll practices and procedures. Your normal place of work will be 161 First Street, Suite 2C, Cambridge, Massachusetts 02142; however, it is understood that the Company may change your normal place of work according to the Company's future needs.
- 3. **Annual bonus.** Beginning with the 2015 fiscal year, you will be eligible to receive an annual bonus with a target amount equal to 30% of your annual base salary, with the actual amount of any such bonus determined at the sole discretion of the Company's Board of Directors or an authorized committee thereof (the "**Board**") based upon both the Company's performance and your individual performance and subject to proration for any partial year of service. Bonuses are intended to retain valuable Company employees, and a bonus is not payable unless you are an employee of the Company on the date that such bonus is paid.
- 4. **Signing bonus.** The Company will pay you a one-time signing bonus in the amount of \$40,000 (the "**Signing Bonus**"), payable on the Company's first ordinary payroll date following your start date and provided you remain continuously employed with the Company through the payment date. In the event that you voluntarily terminate your employment with the Company (other than for Good Reason, as defined below) prior to the first anniversary of the Effective Date, you agree to repay to the Company a pro-rata portion of the Signing Bonus, which pro-rata amount will be determined by multiplying the Signing Bonus by a fraction, the numerator of which is the number of days between your termination date and the first anniversary of the Effective Date, and the denominator of which is 365.

- 5. **Benefits.** You will be eligible to participate in the Company's standard benefit programs, which currently include holidays, 15 days of vacation, 5 days sick leave, medical insurance, dental insurance, 401(k) plan and life insurance, subject to the terms of such programs as in effect from time to time.
- 6. **Equity award.** Subject to the approval of the Board, the Company will grant to you an option (the "**Option**"), intended to qualify to the maximum extent permissible as an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended (the "**Code**"), for the purchase of 339,124 shares of the Company's common stock with an exercise price per share equal to the per share fair market value, as determined by the Board, of the common stock on the date of grant. In all respects, the Option will be governed by the Seres Health, Inc. 2012 Stock Incentive Plan, as amended from time to time, and a stock option agreement to be entered into between you and the Company.
- 7. **Proprietary Information Agreement; Company policies.** As a condition of this offer and your employment, you must sign and abide by the Company's standard Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement (the "**Proprietary Information Agreement**"), a copy of which is enclosed and incorporated herein by reference. As a Company employee, you will be expected to abide by Company policies and procedures as may be in effect from time to time.
- 8. **At-will employment.** It is understood that you are an "at-will" employee. You are not being offered employment for a definite period of time, and either you or the Company may terminate the employment relationship at any time and for any reason without prior notice and without additional compensation to you, except as otherwise specifically provided in this letter.
- 9. **Termination benefits**. In the event of the termination of your employment for any reason, the Company will pay you your base salary plus any accrued but unused vacation through your last day of employment (the "**Date of Termination**"), and the amount of any documented, reimbursable expenses properly incurred by you on behalf of the Company prior to any such termination and not yet reimbursed (collectively, the "**Accrued Obligations**"). In addition, if during the six (6) month period that immediately follows a Sale Event, the Company either (i) terminates your employment without Cause or (ii) you resign from your employment for Good Reason (all as defined below) and provided you enter into within 52 days of the Date of Termination, do not revoke and comply with the terms of a separation agreement in a form provided by the Company, which will include a general release of claims against the Company and related persons and entities, the Company will provide you with the following "**Termination Benefits**": (a) continuation of your base salary for the six (6) month period that immediately follows the Date of Termination (the "**Salary Continuation Payments**"); and (b) if elected, continuation of group health plan benefits to the extent authorized by and consistent with COBRA, with the cost of the regular premium for such benefits shared in the same relative proportion by the Company and you as in effect on the Date Termination, until the earlier of (i) the date that is six (6) months after the Date of Termination; and (ii) the date you become eligible for health benefits through another employer (and you agree to promptly notify the Company of such eligibility) or otherwise become ineligible for COBRA; and (c) any then unvested portion of the Option shall become

fully vested upon the Date of Termination. The Salary Continuation Payments will commence within 60 days after the Date of Termination and shall be made on the Company's regular payroll dates; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Salary Continuation Payments shall begin to be paid in the second calendar year. In the event you miss a regular payroll period between the Date of Termination and first Salary Continuation Payment date, the first Salary Continuation Payment will include a "catch up" payment. Solely for purposes of Section 409A of the Code, each Salary Continuation Payment is considered a separate payment. For the avoidance of doubt, in the event your employment is terminated for any reason prior to a Sale Event, you will be entitled to the Accrued Obligations but you will not be entitled to Termination Benefits.

- 10. **Definitions.** For the purposes of this letter:
- (a) "Cause" means: (i) conduct by you in connection with your service to the Company that is fraudulent, unlawful or grossly negligent; (ii) your material breach of your material responsibilities to the Company or your willful failure to comply with lawful directives of the Board or written policies of the Company; (iii) breach by you of your representations, warranties, covenants and/or obligations under this letter (including the Proprietary Information Agreement); and/or (iv) material misconduct by you which seriously discredits or damages the Company or any of its affiliates.
- (b) "Good Reason" means that you have complied with the "Good Reason Process" (hereinafter defined) following the occurrence of any of the following actions undertaken by the Company without your express prior written consent: (i) the material diminution in your responsibilities, authority and function; or (ii) a material reduction in your base salary; or (iii) a requirement by the Company that you relocate your principal location of employment to a location that is more than fifty (50) miles outside of the greater Boston metropolitan area. "Good Reason Process" means that (i) you have reasonably determined in good faith that a Good Reason condition has occurred; (ii) you have notified the Company in writing of the first occurrence of the Good Reason condition within thirty (30) days of the first occurrence of such condition; (iii) you have cooperated in good faith with the Company's efforts, for a period not less than thirty (30) days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) you terminate your employment within thirty (30) days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.
- (c) "Sale Event" means the consummation of (i) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity, (ii) a merger, reorganization or consolidation involving the Company in which the shares of voting stock of the Company outstanding immediately prior to such transaction represent or are converted into or exchanged for securities of the surviving or resulting entity immediately upon completion of such transaction which represent less than 50 percent of the outstanding voting power of such surviving or resulting entity, (iii) the acquisition of all or a majority of the outstanding voting stock of the Company in a single transaction or a series of related transactions by a person, entity or group of persons or entities, or (iv) any other

acquisition of the business of the Company, as determined by the Board; provided, however, that an initial public offering of the Company's equity securities, any subsequent public offering or another capital raising event, or a merger effected solely to change the Company's domicile shall not constitute a "Sale Event."

- 11. **Taxes**; **Section 409A.** All forms of compensation referred to in this offer letter are subject to reduction to reflect applicable withholding and payroll taxes and other deductions required by law. You hereby acknowledge that the Company does not have a duty to design its compensation policies in a manner that minimizes your tax liabilities, and you will not make any claim against the Company or the Board related to tax liabilities arising from your compensation. Anything in this letter to the contrary notwithstanding, if at the time of your separation from service within the meaning of Section 409A of the Code, the Company determines that you are a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that you become entitled to under this letter on account of your separation from service would be considered deferred compensation subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after your separation from service, or (B) your death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule. To the extent that any payment or benefit described in this letter constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon your termination of employment, then such payments or benefits shall be payable only upon your separation from service. The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h). The Company and you intend that this letter will be administered in accordance with Section 409A of the Code. To the extent that any provision of this letter is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with or are exempt from Section 409A of the Code. The Company makes no representation or warranty and shall have no liability to you or any other person if any provisions of this letter are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.
- 12. **Entire agreement; governing law.** This letter, along with the Proprietary Information Agreement, sets forth the complete and exclusive agreement between you and the Company with regard to your employment with the Company, and supersedes any prior representations or agreements about this matter, whether written or verbal. The terms of this letter and the resolution of any disputes as to the meaning, effect, performance or validity of this letter or arising out of, related to, or in any way connected with this letter, your employment with the Company or any other relationship between you and the Company (the "**Disputes**") will be governed by Massachusetts law, excluding laws relating to

conflicts or choice of law that would result in the application of law other than Massachusetts law. You and the Company submit to the exclusive personal jurisdiction of the federal and state courts located in the Commonwealth of Massachusetts in connection with any Dispute or any claim related to any Dispute.

- 13. **Assignment.** Neither you nor the Company may make any assignment of this letter or any interest in it, by operation of law or otherwise, without the prior written consent of the other; provided, however, that the Company may assign its rights and obligations under this letter (including the Proprietary Information Agreement) without your consent to any affiliate or to any person or entity with whom the Company shall hereafter effect a reorganization, consolidate with, or merge into or to whom it transfers all or substantially all of its properties or assets. This letter shall inure to the benefit of and be binding upon you and the Company, and each of your and its respective successors, executors, administrators, heirs and permitted assigns.
- 14. **Miscellaneous.** This letter may not be modified or amended, and no breach shall be deemed to be waived, except by a written agreement signed by you and an authorized officer of the Company. The headings and captions in this letter are for convenience only and in no way define or describe the scope or content of any provision of this letter. This letter may be executed in two or more counterparts, each of which shall be an original and all of which together shall constitute one and the same instrument.
- 15. **Other terms.** This offer is subject to background and reference checks that are satisfactory to the Company. In making this offer, the Company understands, and in accepting it you represent that you are not under any obligation to any former employer or any person, firm, or corporation which would prevent, limit, or impair in any way the performance by you of your duties as an employee of the Company. The Immigration Reform and Control Act requires employers to verify the employment eligibility and identity of new employees. Enclosed is a copy of the Form I-9 that you will be required to complete. Please bring the appropriate documents listed on that form with you when you report for work. We will not be able to employ you if you fail to comply with this requirement.

Please indicate your acceptance of this offer by returning signed and dated copies of this letter and the Proprietary Information Agreement to Eric Shaff at eshaff@sereshealth.com no later than Tuesday, December 23, 2014, after which date this offer will expire.

We look forward to your joining the Company and are very pleased that you will be working with us.

Very truly yours,

/s/ Roger Pomerantz

Roger Pomerantz President and CEO SERES HEALTH, INC.

Accepted and Agreed:	
/s/ Michele Trucksis	
Michele Trucksis	
12/23/2014	
Date:	

This LOAN AND SECURITY AGREEMENT (this "Agreement") is entered into as of September 9, 2013, by and between COMERICA BANK ("Bank") and SERES HEALTH, INC., a Delaware corporation ("Borrower").

### **RECITALS**

Borrower wishes to obtain credit from time to time from Bank, and Bank desires to extend credit to Borrower. This Agreement sets forth the terms on which Bank will advance credit to Borrower, and Borrower will repay the amounts owing to Bank.

#### **AGREEMENT**

The parties agree as follows:

### 1. DEFINITIONS AND CONSTRUCTION.

- 1.1 <u>Definitions</u>. As used in this Agreement, all capitalized terms shall have the definitions set forth on <u>Exhibit A</u>. Any term used in the Code and not defined herein shall have the meaning given to the term in the Code.
- 1.2 <u>Accounting Terms</u>. Any accounting term not specifically defined on <u>Exhibit A</u> shall be construed in accordance with GAAP and all calculations shall be made in accordance with GAAP. The term "financial statements" shall include the accompanying notes and schedules.

### 2. LOAN AND TERMS OF PAYMENT.

## 2.1 Credit Extensions.

(a) <u>Promise to Pay; Use of Proceeds</u>. Borrower promises to pay to Bank, in lawful money of the United States of America, the aggregate unpaid principal amount of all Credit Extensions made by Bank to Borrower, together with interest on the unpaid principal amount of such Credit Extensions at rates in accordance with the terms hereof. Borrower shall use the proceeds of the Credit Extensions solely as working capital, and to fund its general business requirements, including capital expenditures, and not for personal, family, household or agricultural purposes.

### (b) [Reserved].

#### (c) Growth Capital Advances.

- (i) <u>Availability</u>. Subject to and upon the terms and conditions of this Agreement, Borrower may request, and Bank agrees to make Growth Capital Advances to Borrower. On the Closing Date, or as soon thereafter as may be practical, the initial Growth Capital Advance shall be made in an aggregate principal amount equal to One Million Dollars (\$1,000,000). Thereafter, Borrower may request Growth Capital Advances through Growth Capital Availability End Date. The aggregate principal amount of all Growth Capital Advances shall not, in any event, exceed the Growth Capital Line. Each Growth Capital Advance shall be in a minimum amount of \$500,000.
- (ii) <u>Repayment</u>. Interest shall accrue from the date of each Growth Capital Advance at the rate specified in the Pricing Addendum, and shall be payable in accordance with Section 2.3(b) and on the terms set forth in the Pricing Addendum. Borrower shall make monthly payments of interest-only, commencing on the first day of the month following the funding of such Growth Capital Advance, and continuing on the first day of each successive month thereafter through the Growth Capital Availability End Date. Any Growth Capital Advances that are outstanding on the Growth Capital Availability End Date shall be payable in thirty (30) consecutive equal monthly installments of principal, plus all accrued and unpaid interest, beginning on September 1, 2014, and continuing on the same day of each month thereafter, unless such day is not a Business Day and then on the next Business Day thereafter, until paid in full. Notwithstanding (but without duplication with) the foregoing, on

the Growth Capital Maturity Date, if the Final Payment has not previously been paid in full in connection with the prepayment of the Growth Capital Advances, Borrower shall pay to Bank the Final Payment in respect of each Growth Capital Advance. Growth Capital Advances, once repaid, may not be reborrowed. Borrower may only voluntarily prepay the Growth Capital Advances in accordance with Section 2.1(c)(iv) below.

- (iii) <u>Procedures for Borrowing</u>. Other than on the Closing Date, when Borrower desires to obtain a Growth Capital Advance, Borrower shall notify Bank (which notice shall be irrevocable) by facsimile transmission to be received no later than 3:00 p.m. Eastern Time three (3) Business Days before the day on which the Growth Capital Advance is to be made. Such notice shall be substantially in the form of <u>Exhibit C</u>. The notice shall be signed by a Responsible Officer or its designee. Bank shall be entitled to rely on any facsimile given by a person who Bank reasonably believes to be a Responsible Officer or a designee thereof, and Borrower shall indemnify and hold Bank harmless for any damages or loss suffered by Bank as a result of such reliance.
- (iv) Voluntary Prepayments. Except as set forth in the Pricing Addendum, Borrower shall have the option to prepay all, but not less than all, of the Growth Capital Advances in full, provided Borrower (a) provides written notice to Bank of its election to prepay the Growth Capital Advances at least three (3) days prior to such prepayment, and (b) pays to Bank, on the date of such prepayment, an amount equal to the sum of (1) all outstanding principal of the Growth Capital Advances, plus (2) all accrued and unpaid interest in respect of the Growth Capital Advances and all other unpaid fees and expenses, including Bank Expenses, owing hereunder, plus (3) the Final Payment, plus (4) all other sums, if any, that shall have become due and payable under the Loan Documents, including interest at the Default Rate with respect to any past due amounts.
- (v) <u>Mandatory Prepayment on Acceleration</u>. If the Growth Capital Advances are accelerated following the occurrence of an Event of Default, Borrower shall immediately pay to Bank an amount equal to the sum of: (a) all outstanding principal of the Growth Capital Advances, plus (b) all accrued and unpaid interest thereon through the prepayment date and all other unpaid fees and expenses, including Bank Expenses, owing hereunder, plus (c) the Final Payment, plus (d) all other Obligations that are due and payable under the Loan Documents, including interest at the Default Rate with respect to any past due amounts.
  - 2.2 [Reserved].
  - 2.3 Interest Rates, Payments, and Calculations.
- (a) <u>Interest Rate</u>. The Growth Capital Advances shall bear interest, on the outstanding daily balance thereof, on the terms set forth in the Pricing Addendum.
- (b) <u>Payments</u>. Bank shall, at its option, charge such interest, all Bank Expenses, and all Periodic Payments against any of Borrower's deposit accounts. Any interest not paid when due shall be compounded by becoming a part of the Obligations, and such interest shall thereafter accrue interest at the rate then applicable hereunder. All payments shall be free and clear of any taxes, withholdings, duties, impositions or other charges, to the end that Bank will receive the entire amount of any Obligations payable hereunder, regardless of source of payment.
- 2.4 <u>Crediting Payments</u>. Prior to the occurrence and continuance of an Event of Default, Bank shall credit a wire transfer of funds, check or other item of payment to such deposit account or Obligation as Borrower specifies. After the occurrence and during the continuance of an Event of Default, Bank shall have the right, in its sole discretion, to immediately apply any wire transfer of funds, check, or other item of payment Bank may receive to conditionally reduce Obligations, but such applications of funds shall not be considered a payment on account unless such payment is of immediately available federal funds or unless and until such check or other item of payment is honored when presented for payment. Notwithstanding anything to the contrary contained herein, any wire transfer or payment received by Bank after 12:00 noon Eastern Time shall be deemed to have been received by Bank as of the opening of business on the immediately following Business Day. Whenever any payment to Bank under the Loan Documents would otherwise be due (except by reason of acceleration) on a date that is not a Business Day, such payment shall instead be due on the next Business Day, and additional fees or interest, as the case may be, shall accrue and be payable for the period of such extension.

- 2.5 Fees. Borrower shall pay to Bank the following:
- (a) <u>Facility Fee</u>. On the Closing Date, a facility fee equal to Five Thousand Dollars (\$5,000), which shall be fully-earned and nonrefundable;
- (b) <u>Final Payment Fee</u>. The Final Payment on the earliest to occur of (i) the Growth Capital Maturity Date, (ii) the acceleration of any Growth Capital Advances, or (iii) the prepayment of a Growth Capital Advance pursuant to Section 2.1(c)(iv) or (v); and
- (c) <u>Bank Expenses</u>. On the Closing Date, all Bank Expenses incurred through the Closing Date, and, after the Closing Date, all Bank Expenses, as and when they become due; provided, that Borrower's liability for Bank Expenses incurred prior to and as of the Closing Date in connection with the negotiation and documentation of the Loan Documents shall be limited to Twenty Five Thousand Dollars (\$25,000) provided there is a customary level of negotiation of the Loan Documents.
- 2.6 <u>Term</u>. This Agreement shall become effective on the Closing Date and, subject to Section 13.8, shall continue in full force and effect for so long as any Obligations (other than inchoate indemnity obligations as to which no claim has been asserted or is known to exist) remain outstanding or Bank has any obligation to make Credit Extensions under this Agreement or any other Loan Document (excluding the Warrant). Notwithstanding the foregoing, Bank shall have the right to terminate its obligation to make Credit Extensions under this Agreement immediately and without notice upon the occurrence and during the continuance of an Event of Default.

# 3. CONDITIONS OF LOANS.

- 3.1 <u>Conditions Precedent to Initial Credit Extension</u>. The obligation of Bank to make the initial Credit Extension is subject to the condition precedent that Bank shall have received, in form and substance satisfactory to Bank, the following:
  - (a) this Agreement, duly executed by Borrower;
- (b) an officer's certificate of Borrower with respect to incumbency and resolutions authorizing the execution and delivery of this Agreement and the other Loan Documents;
  - (c) the Pricing Addendum, duly executed by Borrower;
  - (d) a financing statement (Form UCC-1);
  - (e) agreement to furnish insurance, duly executed by Borrower;
  - (f) payment of the fees and Bank Expenses then due specified in Section 2.5;
  - (g) current SOS Reports indicating that except for Permitted Liens, there are no other security interests or Liens of record in the

Collateral;

- (h) current financial statements, including company prepared financial statements for Borrower's most recently ended fiscal year, company prepared consolidated balance sheets and income statements for the most recently ended month in accordance with Section 6.2, and such other updated financial information as Bank may reasonably request;
  - $(i) \ current \ Compliance \ Certificate \ in \ accordance \ with \ Section \ 6.2;$
  - (j) a Warrant in form and substance satisfactory to Bank, duly executed by Borrower;

- (k) a Collateral Information Certificate, duly executed by Borrower;
- (l) an Automatic Loan Payment Authorization, duly executed by Borrower; and
- (m) such other documents, instruments and certificates, and completion of such other matters, as Bank may reasonably deem necessary or appropriate.
- 3.2 <u>Conditions Precedent to all Credit Extensions</u>. The obligation of Bank to make each Credit Extension, including the initial Credit Extension, is further subject to the following conditions:
  - (a) timely receipt by Bank of the Payment/Advance Form as provided in Section 2.1;
- (b) the representations and warranties contained in the Loan Documents shall be true and correct in all material respects on and as of the date of such Payment/Advance Form and on the effective date of each Credit Extension as though made at and as of each such date, and no Event of Default shall have occurred and be continuing, or would exist after giving effect to such Credit Extension (provided, however, that those representations and warranties expressly referring to another date shall be true, correct and complete in all material respects as of such date, and provided further, that that such materiality qualifiers shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof). The making of each Credit Extension shall be deemed to be a representation and warranty by Borrower on the date of such Credit Extension as to the accuracy of the facts referred to in this Section 3.2; and
  - (c) no event or circumstance shall exist or have occurred that has had or could reasonably be expected to have a Material Adverse Effect.

## 4. CREATION OF SECURITY INTEREST.

- 4.1 <u>Grant of Security Interest</u>. Borrower grants and pledges to Bank a continuing security interest in the Collateral to secure prompt repayment of any and all Obligations and to secure prompt performance by Borrower of each of its covenants and duties under the Loan Documents (other than the Warrant). Except as set forth in the Schedule, subject to Permitted Liens of the type described in clauses (c), (f) and (j) of the definition of Permitted Liens that may have superior priority to Bank's Lien under this Agreement, such security interest constitutes a valid, first priority security interest in the presently existing Collateral, and will constitute a valid, first priority security interest in later-acquired Collateral. Borrower also hereby agrees not to sell, transfer, assign, mortgage, pledge, lease, grant a security interest in, or encumber, or allow a Lien on, any of its Intellectual Property, except in connection with Liens of the type described in clauses (b) and (e) of the definition of Permitted Liens and Permitted Transfers. Notwithstanding any termination of this Agreement, Bank's Lien on the Collateral shall remain in effect for so long as any Obligations (other than inchoate indemnity obligations as to which no claim has been asserted or is known to exist) are outstanding or Bank has any obligation to make Credit Extensions under this Agreement or any other Loan Document.
- 4.2 <u>Perfection of Security Interest</u>. Borrower authorizes Bank to file at any time financing statements, continuation statements, and amendments thereto that (i) either specifically describe the Collateral or describe the Collateral as all assets of Borrower of the kind pledged hereunder, and (ii) contain any other information required by the Code for the sufficiency of filing office acceptance of any financing statement, continuation statement, or amendment, including whether Borrower is an organization, the type of organization and any organizational identification number issued to Borrower, if applicable. Any such financing statements may be filed by Bank at any time in any jurisdiction whether or not Division 9 of the Code is then in effect in that jurisdiction. Borrower shall from time to time endorse and deliver to Bank, at the request of Bank, all Negotiable Collateral and other documents that Bank may reasonably request, in form satisfactory to Bank, to perfect and continue perfection of Bank's security interests in the Collateral and in order to fully consummate all of the transactions contemplated under the Loan Documents. Borrower shall have possession of the Collateral, except where expressly otherwise provided in this Agreement or where Bank chooses to perfect its security interest by possession in addition to the filing of a financing statement. Where Collateral with an aggregate book value not to

exceed \$150,000 is in possession of a third party bailee, Borrower shall take such steps as Bank reasonably requests for Bank to (i) obtain an acknowledgment, in form and substance satisfactory to Bank, of the bailee that the bailee holds such Collateral for the benefit of Bank, and (ii) obtain "control" of any Collateral consisting of investment property, deposit accounts, securities accounts, letter-of-credit rights or electronic chattel paper (as such items and the term "control" are defined in Division 9 of the Code) by causing the securities intermediary or depositary institution or issuing bank to execute a control agreement in form and substance satisfactory to Bank subject to the terms therein; provided that control agreements shall not be required during the transition period provided under Section 6.6 so long as Borrower is in compliance with the terms thereof. Borrower will not create any chattel paper without placing a legend on the chattel paper acceptable to Bank indicating that Bank has a security interest in the chattel paper. Borrower from time to time may deposit with Bank specific cash collateral to secure specific Obligations; Borrower authorizes Bank to hold such specific balances in pledge and to decline to honor any drafts thereon or any request by Borrower or any other Person to pay or otherwise transfer any part of such balances for so long as the specific Obligations are outstanding.

- 4.3 <u>Right to Inspect</u>. Bank (through any of its officers, employees, or agents) shall have the right, upon reasonable prior notice, from time to time during Borrower's usual business hours but no more than once each year (unless an Event of Default has occurred and is continuing), to inspect Borrower's Books and to make copies thereof and to check, test, and appraise the Collateral in order to verify Borrower's financial condition or the amount, condition of, or any other matter relating to, the Collateral.
- 4.4 Pledge of Collateral. Borrower hereby pledges, assigns and grants to Bank a security interest in all the Shares, together with all proceeds and substitutions thereof, all cash, stock and other moneys and property paid thereon, all rights to subscribe for securities declared or granted in connection therewith, and all other cash and noncash proceeds of the foregoing, as security for the performance of the Obligations; provided that Bank shall not have a security interest in more than sixty-five percent (65%) of the voting Equity Interests in any Excluded Foreign Subsidiary. On the Closing Date, the certificate or certificates for the pledged Shares, if any, will be delivered to Bank, accompanied by an instrument of assignment duly executed in blank by Borrower. To the extent required by the terms and conditions governing the Shares, Borrower shall cause the books of each entity whose Shares are part of the Collateral and any transfer agent to reflect the pledge of the Shares. Upon the occurrence and during the continuance of an Event of Default hereunder, Bank may effect the transfer of any securities included in the Collateral (including but not limited to the Shares) into the name of Bank and cause new certificates representing such securities to be issued in the name of Bank or its transferee. Borrower will execute and deliver such documents, and take or cause to be taken such actions, as Bank may reasonably request to perfect or continue the perfection of Bank's security interest in the pledged Shares. Unless an Event of Default shall have occurred and be continuing, Borrower shall be entitled to exercise any voting rights with respect to the pledged Shares and to give consents, waivers and ratifications in respect thereof, provided that no vote shall be cast or consent, waiver or ratification given or action taken which would be inconsistent with any of the terms of this Agreement or which would constitute or create any violation of any of such terms and Borrower shall be permitted to receive any cash d

# 5. <u>REPRESENTATIONS AND WARRANTIES</u>.

Borrower represents and warrants as follows:

- 5.1 <u>Due Organization and Qualification</u>. Borrower and each Subsidiary is an entity duly existing under the laws of the jurisdiction in which it is incorporated or organized, as applicable, and qualified and licensed to do business in any state in which the conduct of its business or its ownership of property requires that it be so qualified, except where the failure to do so could not reasonably be expected to cause a Material Adverse Effect.
- 5.2 <u>Due Authorization; No Conflict</u>. The execution, delivery, and performance of the Loan Documents are within Borrower's powers, have been duly authorized, and are not in conflict with nor constitute a breach of any provision contained in Borrower's organizational documents, nor will they constitute an event of default under any material agreement by which Borrower is bound. Borrower is not in default under any agreement by which it is bound, except to the extent such default would not reasonably be expected to cause a Material Adverse Effect.

- 5.3 <u>Collateral</u>. Borrower has rights in or the power to transfer the Collateral, and its title to the Collateral is free and clear of Liens, adverse claims, and restrictions on transfer or pledge except for Permitted Liens. Other than Inventory that is in transit, movable Equipment (such as mobile phones, laptops and the like) with employees and consultants, and Inventory and Equipment at cleaning or repair locations in each case in the ordinary course of business or as permitted pursuant to the terms of this Agreement, all Collateral is located solely in the Collateral States at the locations specified in the Collateral Information Certificate, and at such other locations as may be timely disclosed in writing to Bank pursuant to Section 7.2. The Accounts are bona fide existing obligations of the account debtors. No licenses or agreements giving rise to any Accounts is with any Prohibited Territory or with any Person organized under or doing business in a Prohibited Territory. All Inventory is in all material respects of good and merchantable quality, free from all material defects, except for Inventory for which adequate reserves have been made. Except as set forth in the Schedule or as disclosed in writing from time to time with respect to accounts maintained outside of Bank to the extent expressly permitted under Section 6.6, none of the Collateral consisting of deposit, investment or securities accounts is maintained or invested with a Person other than Bank or Bank's Affiliates.
- 5.4 <u>Intellectual Property</u>. Borrower is the sole owner of the Intellectual Property, except for (i) licenses of the type identified in clause (b) of the definition of Permitted Transfer, and (ii) over the counter software that is commercially available to the public. To the best of Borrower's knowledge, each of the Copyrights, Trademarks and Patents is valid and enforceable, and no part of the Intellectual Property has been judged invalid or unenforceable, in whole or in part, and no claim has been made to Borrower that any part of the Intellectual Property violates the rights of any third party except to the extent such invalidity, unenforceability or claim could not reasonably be expected to cause a Material Adverse Effect. Borrower's rights as a licensee of intellectual property (including trademarks), other than off-the-shelf or shrink-wrap licenses, do not give rise to more than five percent (5%) of its gross revenue in any given month, including without limitation revenue derived from the sale, licensing, rendering or disposition of any product or service.
- 5.5 Name; Location of Chief Executive Office; Location of Inventory and Equipment. Except as disclosed in the Schedule, Borrower has not done business during the five (5) years prior to the Closing Date, under any name other than that specified on the signature page hereof, and its exact legal name is as set forth in the first paragraph of this Agreement. The chief executive office of Borrower is located in the Chief Executive Office State at the address indicated in Section 10 hereof or at such other location as to which Borrower has provided timely written notice in accordance with Section 7.2 hereof. Except as disclosed in the Schedule, all Inventory and Equipment of Borrower in an aggregate book value over \$150,000 is located at the address indicated in Section 10 hereof, or at such other location as to which Borrower has provided timely written notice in accordance with Section 7.10 hereof.
- 5.6 <u>Actions, Suits, Litigation, or Proceedings</u>. Except as set forth in the Schedule, there are no actions, suits, litigation or proceedings, at law or in equity, pending by or against Borrower or any Subsidiary before any court, administrative agency, or arbitrator which could reasonably be expected to have a Material Adverse Effect.
- 5.7 No Material Adverse Change in Financial Statements. All consolidated financial statements related to Borrower and any Subsidiary that are delivered by Borrower to Bank fairly present in all material respects Borrower's consolidated financial condition as of the date thereof and Borrower's consolidated results of operations for the period then ended. As of the Closing Date, the date of delivery of each borrowing request and the date of funding of each Credit Extension, there has not been a material adverse change in the consolidated financial condition of Borrower since the date of the most recent of such financial statements submitted to Bank. As of the date referenced in each Compliance Certificate delivered to Bank, except as set forth in such Compliance certificate, there has not been a material adverse change in the consolidated financial condition of Borrower since the date of the most recent of such financial statements submitted to Bank.
- 5.8 <u>Solvency, Payment of Debts</u>. Borrower is able to pay its debts (including trade debts) as they mature; the fair saleable value of Borrower's assets (including goodwill minus disposition costs) exceeds the fair value of its liabilities; and Borrower is not left with unreasonably small capital after the transactions contemplated by this Agreement.

- 5.9 <u>Compliance with Laws and Regulations</u>. Borrower and each Subsidiary have met the minimum funding requirements of ERISA with respect to any employee benefit plans subject to ERISA. No event has occurred resulting from Borrower's failure to comply with ERISA that is reasonably likely to result in Borrower's incurring any liability that could reasonably be expected to have a Material Adverse Effect. Borrower is not an "investment company" or a company "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940. Borrower is not engaged principally, or as one of the important activities, in the business of extending credit for the purpose of purchasing or carrying margin stock (within the meaning of Regulations T, U, and X of the Board of Governors of the Federal Reserve System). Borrower has complied in all material respects with all the provisions of the Federal Fair Labor Standards Act. Borrower is in compliance with all environmental laws, regulations and ordinances except where the failure to comply is not reasonably likely to have a Material Adverse Effect. Borrower has not violated any statutes, laws, ordinances or rules applicable to it, the violation of which could reasonably be expected to have a Material Adverse Effect. Borrower and each Subsidiary have filed or caused to be filed all tax returns required to be filed, and have paid, or have made adequate provision for the payment of, all taxes reflected therein except those being contested in good faith with adequate reserves under GAAP or where the failure to file such returns or pay such taxes could not reasonably be expected to have a Material Adverse Effect.
- 5.10 <u>Subsidiaries</u>. Borrower does not own any stock, partnership interest or other equity securities of any Person, except for Permitted Investments. As of the Closing Date, Borrower has no Subsidiaries.
- 5.11 <u>Government Consents</u>. Borrower and each Subsidiary have obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all governmental authorities that are necessary for the continued operation of Borrower's business as currently conducted, except where the failure to do so would not reasonably be expected to cause a Material Adverse Effect.
- 5.12 <u>Restricted Agreements</u>. Except as disclosed on the Schedule or as timely disclosed in writing to Bank pursuant to Section 6.9, Borrower is not a party to, nor is bound by, any Restricted Agreement.
- 5.13 Shares. Borrower has full power and authority to create a first lien on the pledged Shares and no disability or contractual obligation exists that would prohibit Borrower from pledging such Shares pursuant to this Agreement. To Borrower's knowledge, there are no subscriptions, warrants, rights of first refusal or other restrictions on transfer relative to, or options exercisable with respect to the pledged Shares. The pledged Shares have been and will be duly authorized and validly issued, and are fully paid and non-assessable. To Borrower's knowledge, the Shares are not the subject of any present or threatened suit, action, arbitration, administrative or other proceeding, and Borrower knows of no reasonable grounds for the institution of any such proceedings.
- 5.14 <u>Full Disclosure</u>. No representation, warranty or other statement made by Borrower in any certificate or written statement furnished to Bank taken together with all such certificates and written statements furnished to Bank contains any untrue statement of a material fact or omits to state a material fact necessary in order to make the statements contained in such certificates or statements not misleading, it being recognized by Bank that the projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not to be viewed as facts and that actual results during the period or periods covered by any such projections and forecasts may differ from the projected or forecasted results.

## 6. AFFIRMATIVE COVENANTS.

Borrower covenants that, until payment and satisfaction in full of all outstanding Obligations (other than inchoate indemnity obligations as to which no claim has been asserted or is known to exist), and for so long as Bank may have any commitment to make a Credit Extension hereunder, Borrower shall, and shall cause each Subsidiary to, do all of the following:

#### 6.1 Good Standing and Government Compliance.

(a) Borrower shall maintain its corporate existence in the Borrower State. Notwithstanding the foregoing, it shall not be deemed a violation of this Section 6.1(a) if Borrower effects a statutory conversion, under and in compliance with Section 214 of the Delaware Limited Liability Company Act, as in effect on the Closing Date, from a Delaware corporation to a Delaware limited liability company, so long as each of the following have occurred or have been satisfied to the satisfaction of Bank: (i) Borrower is the continuing and surviving entity in such conversion, such conversion does not result in a change in Borrower's taxpayer identification number, and such conversion does not result in the creation of a "new debtor" (as such term is defined in the Code); (ii) such conversion has no adverse effect on the validity, enforceability, attachment, perfection or priority of Bank's security interests in the Collateral; (iii) such conversion does not involve a Transfer by Borrower or merger or consolidation involving Borrower; (iv) such conversion is otherwise permitted under this Agreement and the other Loan Documents and would not result in a violation of any covenant or agreement contained herein or therein; (v) no Event of Default, or any event or circumstance that with the giving of notice or the passage of time (or both) could result in an Event of Default, exists at the time of such conversion, or could reasonably be expected to occur immediately following such conversion; (vi) such conversion is permitted under and is effected in compliance with all applicable law, including the Delaware General Corporation Law and the Delaware Limited Liability Company Act: (vii) Borrower shall have delivered to Bank, not less than thirty (30) days' prior to the effective date of such conversion, a certificate of a Responsible Officer of Borrower in form and substance satisfactory to Bank, which shall include but not be limited to: (A) the proposed effective date of such conversion, (B) the exact legal name of Borrower following such conversion, (C) true, correct and complete copies of the certificate of conversion and certificate of formation to be filed with the Delaware Secretary of State, and (D) a true, correct and complete copy of the limited liability company agreement for Borrower to be effective following such conversion; (viii) Borrower shall have delivered to Bank a certificate of a Responsible Officer of Borrower, as of the effective date of such conversion, in form and substance satisfactory to Bank, which shall include but not be limited to certification: (A) certification as to the matters in clauses (i) through (vi) above, and (B) that Borrower has delivered to Bank, true, correct and complete copies of all stockholder and board approvals obtained or required in connection with such conversion and the duly executed limited liability company agreement becoming effective upon such conversion; (ix) Borrower shall have executed and delivered to Bank an amendment to this Agreement (including an assumption and reaffirmation of the Obligations and Bank's Liens and authorizations to file such financing statement amendments or additional financing statements as Bank may require) and an officer's certificate of Borrower with respect to incumbency and resolutions authorizing the execution, delivery and performance of this Agreement and the other Loan Documents with respect to the new name and organizational structure resulting from such conversion, in each case in form and substance satisfactory to Bank; (x) Bank has determined that such conversion does not create any regulatory or legal issues or issues with respect to Bank's customer identification program; (xi) Parent Holding Company shall have assumed the Warrant on terms satisfactory to Bank, and shall have issued to Bank a new warrant agreement on terms reasonably satisfactory to Bank; and (xii) Borrower and Parent Holding Company shall have delivered to Bank such other documents, instruments, agreements, waivers, consents, resolutions, reaffirmations, authorizations, opinions and certificates as Bank may request in connection with such conversion. At all times following the effective date of such conversion, Borrower shall maintain its limited liability company existence in the Borrower State.

(b) Borrower shall maintain its good standing in the Borrower State and shall cause each of its Subsidiaries' to maintain their respective organizational existence and good standing in their respective jurisdictions of organization, shall maintain qualification and good standing in each other jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Effect, and shall furnish to Bank the organizational identification number issued to Borrower or any Subsidiary by the authorities of the jurisdiction in which Borrower or any Subsidiary is organized, if applicable. Borrower shall meet, and shall cause each Subsidiary to meet, the minimum funding requirements of ERISA with respect to any employee benefit plans subject to ERISA. Borrower shall comply in all material respects with all applicable Environmental Laws, and maintain all material permits, licenses and approvals required thereunder where the failure to do so could reasonably be expected to have a Material Adverse Effect. Borrower shall comply, and shall cause each Subsidiary to comply, with all statutes, laws, ordinances and government rules and regulations to which it is subject, and shall maintain, and shall cause each of its Subsidiaries to maintain, in force all licenses, approvals and agreements, the loss of which or failure to comply with which could reasonably be expected to have a Material Adverse Effect.

#### 6.2 Financial Statements, Reports, Certificates. Borrower shall deliver the following to Bank:

(a) (i) as soon as available, but in any event within thirty (30) days after the end of each calendar month, a company prepared consolidated balance sheet and income statement covering Borrower's operations during such period prepared in accordance with GAAP (subject to normal year-end adjustments and without all required footnotes), in a form reasonably acceptable to Bank and certified by a Responsible Officer; (ii) as soon as available, but in any event within one hundred eighty (180) days after the end of Borrower's fiscal year (commencing with the fiscal year ending December 31, 2013), audited consolidated financial statements of Borrower prepared in accordance with GAAP, consistently applied, together with an opinion which is unqualified (except for a going concern comment or qualification related solely the need to raise additional equity capital due to Borrower not having sufficient cash to support 12 months of operations) or otherwise consented to in writing by Bank on such financial statements of an independent certified public accounting firm reasonably acceptable to Bank; (iii) if applicable, copies of all statements, reports and notices sent or made available generally by Borrower to its security holders or to any holders of Subordinated Debt and all reports on Forms 10-K and 10-Q filed with the Securities and Exchange Commission; (iv) promptly upon receipt of notice thereof, a report of any legal actions pending or threatened against Borrower or any Subsidiary that could reasonably be expected to result in damages or costs to Borrower or any Subsidiary of Two Hundred Fifty Thousand Dollars (\$250,000) or more; (v) promptly upon receipt, each management letter prepared by Borrower's independent certified public accounting firm regarding Borrower's management control systems; (vi) as soon as available, but in any event not later than forty-five (45) days after the last day of each fiscal year, Borrower's financial and business projections and budget for the immediately following fiscal year (with quarterly detail), with evidence of approval thereof by Borrower's board of directors; and (vii) such budgets, sales projections, operating plans or other financial information generally prepared by Borrower in the ordinary course of business as Bank may reasonably request from time to time.

# (b) [Reserved].

- (c) Within thirty (30) days after the last day of each month, Borrower shall deliver to Bank with the monthly financial statements a Compliance Certificate certified as of the last day of the applicable month and signed by a Responsible Officer in substantially the form of Exhibit D hereto.
- (d) Immediately upon becoming aware of the occurrence or existence of an Event of Default hereunder, a written statement of a Responsible Officer setting forth details of the Event of Default, and the action which Borrower has taken or proposes to take with respect thereto.
- (e) Bank shall have a right from time to time hereafter to audit Borrower's Accounts and appraise Collateral at Borrower's expense, provided that such audits will be conducted no more often than every twelve (12) months unless an Event of Default has occurred and is continuing.

Borrower may deliver to Bank on an electronic basis any certificates, reports or information required pursuant to this Section 6.2, and Bank shall be entitled to rely on the information contained in the electronic files, provided that Bank in good faith believes that the files were delivered by a Responsible Officer. If Borrower delivers this information electronically, it shall also deliver to Bank by U.S. Mail, reputable overnight courier service, hand delivery, facsimile or .pdf file within five (5) Business Days of submission of the unsigned electronic copy the certification of monthly financial statements, and the Compliance Certificate, each bearing the physical signature of the Responsible Officer.

6.3 <u>Inventory</u>; <u>Returns</u>. Borrower shall keep all Inventory in good and merchantable condition, free from all material defects except for Inventory for which adequate reserves have been made. Returns and allowances, if any, as between Borrower and its account debtors shall be on the same basis and in accordance with the usual customary practices of Borrower, as they exist on the Closing Date. Borrower shall promptly notify Bank of all returns and recoveries and of all disputes and claims with respect to Borrower involving more than Two Hundred Fifty Thousand Dollars (\$250,000).

6.4 <u>Taxes</u>. Borrower shall make, and cause each Subsidiary to make, due and timely payment or deposit of all material federal, state, and local taxes, assessments, or contributions required of it by law, including, but not limited to, those laws concerning income taxes, F.I.C.A., F.U.T.A. and state disability, and will execute and deliver to Bank, on demand, proof satisfactory to Bank indicating that Borrower or a Subsidiary has made such payments or deposits and any appropriate certificates attesting to the payment or deposit thereof; provided that Borrower or a Subsidiary need not make any payment if the amount or validity of such payment is contested in good faith by appropriate proceedings and is reserved against (to the extent required by GAAP) by Borrower.

#### 6.5 Insurance.

- (a) Borrower, at its expense, shall keep the Collateral insured against loss or damage by fire, theft, explosion, sprinklers, and all other hazards and risks, and in such amounts, as ordinarily insured against by other owners in similar businesses conducted in the locations where Borrower's business is conducted on the date hereof. Borrower shall also maintain liability and other insurance in amounts and of a type that are customary to businesses similar to Borrower's.
- (b) All such policies of insurance shall be in such form, with such companies, and in such amounts as are reasonably satisfactory to Bank. All policies of property insurance shall contain a lender's loss payable endorsement, in a form satisfactory to Bank, showing Bank as an additional loss payee, and all liability insurance policies shall show Bank as an additional insured and specify that the insurer must give at least thirty (30) days' notice to Bank before canceling or not renewing its policy for any reason. Upon Bank's request, Borrower shall deliver to Bank certified copies of the policies of insurance and evidence of all premium payments. If no Event of Default has occurred and is continuing, proceeds payable under any casualty policy will, at Borrower's option, be payable to Borrower to replace the property subject to the claim, provided that any such replacement property shall be deemed Collateral in which Bank has been granted a first priority security interest. If an Event of Default has occurred and is continuing, all proceeds payable under any such policy shall, at Bank's option, be payable to Bank to be applied on account of the Obligations.
- 6.6 Accounts. Borrower shall maintain all its, and shall cause all of its Subsidiaries to maintain their, depository, operating, cash management accounts with Bank and all of its and their primary investment and securities accounts with Bank; provided, however, that Borrower shall have until sixty (60) days after the Closing Date to complete the transfer to Bank of its account balances maintained at the other banks and financial institutions in the accounts identified on the Schedule and to close all such accounts, so long as the aggregate amount on deposit in such accounts at no time exceeds One Million Five Hundred Thousand Dollars (\$1,500,000).

# 6.7 [<u>Reserved</u>].

# 6.8 Intellectual Property Rights.

- (a) Borrower shall register or cause to be registered (to the extent not already registered) with the United States Patent and Trademark Office or the United States Copyright Office, as the case may be, those registrable intellectual property rights now owned or hereafter developed or acquired by Borrower, to the extent that Borrower, in its reasonable business judgment, deems it appropriate to so protect such intellectual property rights.
- (b) Borrower shall give Bank prompt written notice of any applications or registrations of intellectual property rights filed with the United States Patent and Trademark Office, including the date of such filing and the registration or application numbers, if any.
- (c) Borrower shall give Bank prompt written notice of the filing of any applications or registrations with the United States Copyright Office, including the title of such intellectual property rights to be registered, as such title will appear on such applications or registrations, and the date such applications or registrations will be filed.

(d) Borrower shall to (i) protect, defend and maintain the validity and enforceability of the Intellectual Property material to Borrower's business, (ii) use commercially reasonable efforts to detect infringements of the Intellectual Property and promptly advise Bank in writing of material infringements detected and (iii) not allow any material Intellectual Property to be abandoned, forfeited or dedicated to the public without the written consent of Bank, which shall not be unreasonably withheld.

6.9 Restricted Agreement Consents. Promptly after entering into or becoming bound by any Restricted Agreement, Borrower shall: (i) provide written notice to Bank of the material terms of such license or agreement with a description of its likely impact on Borrower's business or financial condition; and (ii) use commercially reasonable efforts to take such actions as Bank may reasonably request to obtain the consent of, or waiver by, any person whose consent or waiver is necessary for (A) Borrower's interest in such licenses or contract rights to be deemed Collateral and for Bank to have a security interest in such license or contract right, and to have the power to assign such license or contract rights in connection with an enforcement of remedies, that might otherwise be restricted by the terms of the applicable license or agreement, whether now existing or entered into in the future, and (B) Bank to have the ability in the event of a liquidation of any Collateral to dispose of such Collateral in accordance with Bank's rights and remedies under this Agreement and the other Loan Documents.

6.10 <u>Creation/Acquisition of Subsidiaries</u>. Without limiting the generality of any other provision hereof, in the event Borrower or any Subsidiary creates or acquires any Subsidiary, Borrower and such Subsidiary shall promptly notify Bank of the creation or acquisition of such new Subsidiary and take all such action as may be reasonably required by Bank to cause each such Subsidiary (other than an Excluded Foreign Subsidiary) to guarantee the Obligations of Borrower under the Loan Documents and, in each case, grant a continuing pledge and security interest in and to the property and assets of such Subsidiary (substantially as described on <u>Exhibit B</u> hereto), and Borrower (or any intermediate Subsidiary holding the Equity Interests in such Subsidiary) shall grant and pledge to Bank a perfected security interest in the Equity Interests of such Subsidiary (regardless of whether or not it is an Excluded Foreign Subsidiary); provided that Bank shall not have a security interest in more than sixty-five percent (65%) of the voting Equity Interests of any Excluded Foreign Subsidiary.

6.11 Parent Holding Company. Without limiting the generality of any other provision hereof, not less than thirty (30) days prior to the acquisition by, or transfer to, a Parent Holding Company of Borrower's Equity Interests, Borrower shall provide written notice to Bank of such acquisition or transfer, which notice shall include, but not be limited to, the proposed date for the transaction, a description of the transaction in reasonable detail, certified copies of Parent Holding Company's organizational documents (including its operating agreement if a limited liability company), a pro forma capitalization table for Borrower and such Parent Holding Company as of the date immediately following such transaction, and such other documents, instruments and agreements relating thereto as Bank may require. Prior to or concurrent with such acquisition or transfer, Borrower and Parent Holding Company shall and take all such action as may be required by Bank, including the execution and delivery of such documents, instruments, agreements and certificates as Bank may require, to cause each Parent Holding Company to become a co-borrower hereunder or, at Bank's sole discretion, to unconditionally guarantee the Obligations of Borrower under the Loan Documents, and, in each case, grant a continuing pledge and security interest in and to the property and assets of Parent Holding Company (substantially as described on Exhibit B hereto), including without limitation a pledge of all of the Equity Interests of Borrower and delivery to Bank of original share certificates accompanied by assignments separate from certificate (or other appropriate instruments of transfer) duly executed in blank.

6.12 <u>Further Assurances</u>. At any time and from time to time Borrower shall execute and deliver such further instruments and take such further action as may reasonably be requested by Bank to effect the purposes of this Agreement.

# 7. NEGATIVE COVENANTS.

Borrower covenants and agrees that, so long as any credit hereunder shall be available and until the outstanding Obligations (other than inchoate indemnity obligations as to which no claim has been asserted or is known to exist) are paid and satisfied in full or for so long as Bank may have any commitment to make any Credit Extension, Borrower will not, and will not permit any Subsidiary to, do any of the following without Bank's prior written consent:

- 7.1 <u>Dispositions</u>. Convey, sell, lease, license, transfer or otherwise dispose of (collectively, to "Transfer"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, or subject to Section 6.6 of this Agreement, move cash balances on deposit with Bank to accounts opened at another financial institution, other than Permitted Transfers.
- 7.2 Change in Name, Location, Executive Office, or Executive Management; Change in Business; Change in Fiscal Year; Change in Control. Change its name or the Borrower State without thirty (30) days' prior written notification to Bank; relocate its chief executive office without twenty (20) days' prior written notification to Bank; without at least fifteen (15) days' prior written notice to Bank, add any new offices or business or Collateral locations unless such new offices or locations contain, in the aggregate, less than \$150,000 in Borrower's or such Subsidiaries' assets or property; replace its chief executive officer or chief financial officer, if one exists, without written notification to Bank promptly thereafter; engage in any business, or permit any of its Subsidiaries to engage in any business, other than or reasonably related or incidental to the businesses currently engaged in by Borrower; change its fiscal year end; have a Change in Control.
- 7.3 <u>Mergers or Acquisitions</u>. Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with or into any other business organization (other than mergers or consolidations of a Subsidiary into another Subsidiary or into Borrower), or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock or property of another Person, or enter into any agreement to do any of the same.
- 7.4 <u>Indebtedness</u>. Create, incur, assume, guarantee or be or remain liable with respect to any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness, or prepay any Indebtedness or take any actions which impose on Borrower an obligation to prepay any Indebtedness, except Indebtedness to Bank or as expressly agreed to by, in writing, Bank under the relevant subordination agreement.
- 7.5 Encumbrances. Create, incur, assume or allow any Lien with respect to any of its property, or assign or otherwise convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for (a) with respect to Intellectual Property, Permitted Liens of the type described in clauses (b), (e) and (i) of the definition of Permitted Liens, and (b) with respect to other property, Permitted Liens, or covenant to any other Person that Borrower in the future will refrain from creating, incurring, assuming or allowing any Lien with respect to any of Borrower's property, or permit any Subsidiary to do so.
- 7.6 <u>Distributions</u>. Pay any dividends or make any other distribution or payment on account of or in redemption, retirement or purchase of any Equity Interests, except that, subject to the last sentence of this Section 7.6, Borrower may (a) pay up to One Hundred Thousand Dollars (\$100,000) in the aggregate in any fiscal year to repurchase outstanding capital stock issued by Borrower as required pursuant to customary stock repurchase agreements approved by Borrower's Board of Directors, from former officers, directors or employees upon the death, disability or termination or cessation of employment or service of such officers, directors or employees, (b) pay any dividends or make any distribution solely in common stock of Borrower, provided that such dividends or distributions of such stock or equity do not otherwise violate the terms of this Agreement and no Event of Default has occurred and is continuing at the time of making such dividend or distribution or would result from the making of such dividend or distribution, (c) purchase, redeem, or otherwise acquire shares of its equity interests or warrant or options to acquire any such equity interests from its stockholders consistent with the requirement of existing equity agreements of Borrower to the extent the consideration paid in respect thereof is paid solely in equity interests of Borrower, and (d) make distributions in cash in the aggregate amount not to exceed One Hundred Fifty Thousand Dollars (\$150,000) during the term of this Agreement. Notwithstanding the foregoing, Borrower shall be permitted to make such repurchases only if, at the time of such repurchase, and immediately after giving effect thereto: (i) no Event of Default, or any event or circumstance that with the giving of notice or the passage of time (or both) could result in an Event of Default, exists or could reasonably be expected to occur, (ii) Borrower is solvent, and (iii) such distribution is permitted under and is made in compliance with applicable law, including Sections 170 and 1
- 7.7 <u>Investments</u>. Directly or indirectly acquire or own, or make any Investment in or to any Person, or permit any of its Subsidiaries to do so, other than Permitted Investments, or maintain or invest any of its property with a Person other than Bank or Bank's Affiliates or permit any Subsidiary to do so except as expressly permitted under Section 6.6, or suffer or permit any Subsidiary to be a party to, or be bound by, an agreement that

restricts such Subsidiary from paying dividends or otherwise distributing property to Borrower. Further, Borrower shall not enter into, or permit any Subsidiary or Affiliate to enter into, any license or agreement with any Prohibited Territory or with any Person organized under or doing business in a Prohibited Territory.

- 7.8 <u>Transactions with Affiliates</u>. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower except for: (a) transactions that are in the ordinary course of Borrower's business, upon fair and reasonable terms that are no less favorable to Borrower than would be obtained in an arm's length transaction with a non-affiliated Person, and (b) transactions constituting <u>bona fide</u> rounds of preferred stock financing (or "bridge" convertible Subordinated Debt financing primarily with venture capital or private equity investors) for capital raising purposes, provided that such transactions are approved by Borrower's Board of Directors, including all disinterested directors, do not cause a Change in Control and are otherwise permitted hereunder.
- 7.9 <u>Subordinated Debt</u>. Make any payment in respect of any Subordinated Debt, or permit any of its Subsidiaries to make any such payment, except in compliance with the terms of such Subordinated Debt and the terms of the subordination agreement relating to such Subordinated Debt, or amend any provision of any document evidencing such Subordinated Debt, except in compliance with the terms of the subordination agreement relating to such Subordinated Debt, or amend any provision affecting Bank's rights contained in any documentation relating to the Subordinated Debt without Bank's prior written consent.
- 7.10 Inventory and Equipment. Store, or cause or permit any Subsidiary to store, any Inventory or the Equipment, valued, individually or in the aggregate, in excess of One Hundred Fifty Thousand Dollars (\$150,000), with a bailee, warehouseman, or similar third party unless (a) Borrower shall promptly thereafter give Bank written notice thereof identifying the names and addresses of such third parties and briefly describing the Inventory or Equipment in the possession of such third parties; and (b) the third party has been notified of Bank's security interest and Bank (i) shall have received a duly executed Collateral Access Agreement, including an acknowledgment from the third party that it is holding or will hold the Inventory or Equipment for Bank's benefit, or (ii) is in possession of the warehouse receipt, where negotiable, covering such Inventory or Equipment. Except for such locations as Bank may approve in writing, Borrower shall keep, and shall cause each of its Subsidiaries to keep, its Inventory and Equipment, valued, individually or in the aggregate, in excess of One Hundred Fifty Thousand Dollars (\$150,000), only at the locations set forth in the Schedule delivered by Borrower to Bank prior to the Closing Date, and at such other locations of which Borrower gives Bank prior written notice as required under Section 7.2 and as to which Bank files Security Instruments where needed to perfect its security interests and liens in such Inventory and Equipment and as to which (x) Bank has received a Collateral Access Agreement, and (y) Borrower has taken such actions as Bank reasonably requests to perfect and maintain the perfection and priority of Bank's Lien on the Collateral.
- 7.11 No Investment Company; Margin Regulation. Become or be controlled by an "investment company," within the meaning of the Investment Company Act of 1940, or become principally engaged in, or undertake as one of its important activities, the business of extending credit for the purpose of purchasing or carrying margin stock, or use the proceeds of any Credit Extension for such purpose.

### 8. EVENTS OF DEFAULT.

Any one or more of the following events shall constitute an Event of Default by Borrower under this Agreement:

- 8.1 Payment Default. If Borrower fails to pay any of the Obligations when due;
- 8.2 Covenant Default.
  - (a) If Borrower fails to perform any obligation under Article 6 or violates any of the covenants contained in Article 7 of this Agreement;

- (b) If Borrower fails or neglects to perform or observe any other material term, provision, condition, covenant contained in this Agreement, in any of the Loan Documents, or in any other present or future agreement between Borrower and Bank and as to any default under such other term, provision, condition or covenant that can be cured, has failed to cure such default within ten (10) Business Days after Borrower receives notice thereof or any officer of Borrower becomes aware thereof; provided, however, that if the default cannot by its nature be cured within the ten (10) Business Day period or cannot after diligent attempts by Borrower be cured within such ten (10) Business Day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional reasonable period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, so long as Borrower continues to diligently attempt to cure such default, and within such reasonable time period the failure to have cured such default shall not be deemed an Event of Default but no Credit Extensions will be made;
- 8.3 <u>Investor Support</u>. If Bank reasonably determines, based on indications from Borrower's existing investors, that such investors no longer intend to provide capital to Borrower in amounts and at times sufficient to enable Borrower to satisfy its obligations as they become due, including but not limited to all Obligations owing from Borrower to Bank.
- 8.4 <u>Defective Perfection</u>. If Bank shall receive at any time following the Closing Date an SOS Report indicating that except for Permitted Liens, Bank's security interest in the Collateral is not prior to all other security interests or Liens of record reflected in such SOS Report;
- 8.5 <u>Attachment</u>. If any material portion of Borrower's and/or its Subsidiaries assets is attached, seized, subjected to a writ or distress warrant, or is levied upon, or comes into the possession of any trustee, receiver or person acting in a similar capacity and such attachment, seizure, writ or distress warrant or levy has not been removed, discharged or rescinded within ten (10) days, or if Borrower and/or its Subsidiaries is enjoined, restrained, or in any way prevented by court order from continuing to conduct all or any material part of its business affairs, or if a judgment or other claim becomes a lien or encumbrance upon any material portion of Borrower's and/or its Subsidiaries assets, or if a notice of lien, levy, or assessment is filed of record with respect to any of Borrower's and/or its Subsidiaries assets by the United States Government, or any department, agency, or instrumentality thereof, or by any state, county, municipal, or governmental agency, and the same is not paid within ten (10) days after Borrower and/or its Subsidiaries receives notice thereof, provided that none of the foregoing shall constitute an Event of Default where such action or event is stayed or an adequate bond has been posted pending a good faith contest by Borrower and/or its Subsidiaries (provided that no Credit Extensions will be made during such cure period);
- 8.6 <u>Insolvency</u>. If Borrower and/or its Subsidiaries becomes insolvent, or if an Insolvency Proceeding is commenced by Borrower and/or its Subsidiaries, or if an Insolvency Proceeding is commenced against Borrower and/or its Subsidiaries and is not dismissed or stayed within forty-five (45) days (provided that no Credit Extensions will be made prior to the dismissal of such Insolvency Proceeding);
- 8.7 <u>Other Agreements</u>. If there is a default or other failure to perform in any agreement to which Borrower and/or its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of Two Hundred Fifty Thousand Dollars (\$250,000) or that could reasonably be expected to have a Material Adverse Effect;
- 8.8 <u>Subordinated Debt</u>. If Borrower and/or its Subsidiaries makes any payment on account of Subordinated Debt, except to the extent the payment is allowed under any subordination agreement entered into with Bank;
- 8.9 <u>Judgments</u>; <u>Settlements</u>. If one or more (a) judgments, orders, decrees or arbitration awards requiring the Borrower and/or its Subsidiaries that are not covered by insurance and which require payment in an aggregate amount of Two Hundred Fifty Thousand Dollars (\$250,000) or greater shall be rendered against Borrower and/or its Subsidiaries and the same shall not have been vacated or stayed within ten (10) days thereafter (provided that no Credit Extensions will be made prior to such matter being vacated or stayed); or (b) settlements is agreed upon by Borrower and/or its Subsidiaries for the payment by Borrower and/or its Subsidiaries of an aggregate amount of Two Hundred Fifty Thousand Dollars (\$250,000) or greater or that could reasonably be expected to have a Material Adverse Effect.

- 8.10 <u>Misrepresentations</u>. If any material misrepresentation or material misstatement exists now or hereafter in any warranty or representation set forth herein or in any certificate delivered to Bank by any Responsible Officer pursuant to this Agreement or to induce Bank to enter into this Agreement or any other Loan Document.
- 8.11 <u>Guaranty</u>. Except by its terms, if any guaranty of all or a portion of the Obligations (a "Guaranty") ceases for any reason to be in full force and effect, or any guarantor fails to perform any obligation under any Guaranty or a security agreement securing any Guaranty (collectively, the "Guaranty Documents"), or any event of default occurs under any Guaranty Document or any guarantor revokes or purports to revoke a Guaranty, or any material misrepresentation or material misstatement exists now or hereafter in any warranty or representation set forth in any Guaranty Document or in any certificate delivered to Bank in connection with any Guaranty Document, or if any of the circumstances described in Sections 8.3 through 8.9 occur with respect to any guarantor.

#### 9. BANK'S RIGHTS AND REMEDIES.

- 9.1 <u>Rights and Remedies</u>. Upon the occurrence and during the continuance of an Event of Default, Bank may, at its election, without notice of its election and without demand, do any one or more of the following, all of which are authorized by Borrower:
- (a) Declare all Obligations, whether evidenced by this Agreement, by any of the other Loan Documents, or otherwise, immediately due and payable (provided that upon the occurrence of an Event of Default described in Section 8.6 (Insolvency), all Obligations shall become immediately due and payable without any action by Bank);
- (b) Demand that Borrower (i) deposit cash with Bank in an amount equal to the amount of any Letters of Credit remaining undrawn, as collateral security for the repayment of any future drawings under such Letters of Credit, and (ii) pay in advance all Letter of Credit fees scheduled to be paid or payable over the remaining term of the Letters of Credit, and Borrower shall promptly deposit and pay such amounts;
- (c) Cease advancing money or extending credit to or for the benefit of Borrower under this Agreement or under any other agreement between Borrower and Bank;
- (d) Settle or adjust disputes and claims directly with account debtors for amounts, upon terms and in whatever order that Bank reasonably considers advisable;
- (e) Make such payments and do such acts as Bank considers necessary or reasonable to protect its security interest in the Collateral. Borrower agrees to assemble the Collateral if Bank so requires, and to make the Collateral available to Bank as Bank may designate. Borrower authorizes Bank to enter the premises where the Collateral is located, to take and maintain possession of the Collateral, or any part of it, and to pay, purchase, contest, or compromise any encumbrance, charge, or lien which in Bank's determination appears to be prior or superior to its security interest and to pay all expenses incurred in connection therewith. With respect to any of Borrower's owned premises, Borrower hereby grants Bank a license to enter into possession of such premises and to occupy the same, without charge, in order to exercise any of Bank's rights or remedies provided herein, at law, in equity, or otherwise;
- (f) Set off and apply to the Obligations any and all (i) balances and deposits of Borrower held by Bank, and (ii) indebtedness at any time owing to or for the credit or the account of Borrower held by Bank;

- (g) Ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell (in the manner provided for herein) the Collateral. Bank is hereby granted a license or other right, solely pursuant to the provisions of this Section 9.1, to use, without charge, Borrower's labels, patents, copyrights, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any property of a similar nature, as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Bank's exercise of its rights under this Section 9.1, Borrower's rights under all licenses and all franchise agreements shall inure to Bank's benefit;
- (h) Sell the Collateral at either a public or private sale, or both, by way of one or more contracts or transactions, for cash or on terms, in such manner and at such places (including Borrower's premises) as Bank determines is commercially reasonable, and apply any proceeds to the Obligations in whatever manner or order Bank deems appropriate. Bank may sell the Collateral without giving any warranties as to the Collateral. Bank may specifically disclaim any warranties of title or the like. This procedure will not be considered adversely to affect the commercial reasonableness of any sale of the Collateral. If Bank sells any of the Collateral upon credit, Borrower will be credited only with payments actually made by the purchaser, received by Bank, and applied to the indebtedness of the purchaser. If the purchaser fails to pay for the Collateral, Bank may resell the Collateral and Borrower shall be credited with the proceeds of the sale;
  - (i) Bank may credit bid and purchase at any public sale;
- (j) Apply for the appointment of a receiver, trustee, liquidator or conservator of the Collateral, without notice and without regard to the adequacy of the security for the Obligations and without regard to the solvency of Borrower, any guarantor or any other Person liable for any of the Obligations; and
  - (k) Any deficiency that exists after disposition of the Collateral as provided above will be paid immediately by Borrower.

Bank may comply with any applicable state or federal law requirements in connection with a disposition of the Collateral and compliance will not be considered adversely to affect the commercial reasonableness of any sale of the Collateral.

9.2 Power of Attorney. Effective only upon the occurrence and during the continuance of an Event of Default, Borrower hereby irrevocably appoints Bank (and any of Bank's designated officers, agents or employees) as Borrower's true and lawful attorney, with full power of substitution, to: (a) send requests for verification of Accounts or notify account debtors of Bank's security interest and Liens in the Accounts, Inventory and other Collateral; (b) endorse Borrower's name on any checks or other forms of payment or security that may come into Bank's possession; (c) sign Borrower's name on any invoice or bill of lading relating to any Account, drafts against account debtors, schedules and assignments of Accounts, verifications of Accounts, and notices to account debtors; (d) dispose of any Collateral; (e) make, settle, and adjust all claims under and decisions with respect to Borrower's policies of insurance; (f) settle and adjust disputes and claims respecting the accounts directly with account debtors, for amounts and upon terms which Bank determines to be reasonable; (g) transfer all or any part of the Collateral into the name of Bank or a third party to the extent permitted under the Code; (h) file, in its sole discretion, one or more financing or continuation statements and amendments thereto, relative to any of the Collateral without the signature of Borrower where permitted by law; (i) execute and do all such assurances, acts and things which Borrower is required, but fails to do under the covenants and provisions of the Loan Documents; (j) to take any and all such actions as Bank may reasonably determine to be necessary or advisable for the purpose of maintaining, preserving or protecting the Collateral or any of the rights, remedies, powers or privileges of Bank under this Agreement or the other Loan Documents; and (k) sign Borrower's name on any documents or Security Instruments necessary to perfect or continue the perfection of, or maintain the priority of, Bank's security interest in the Collateral; provided Bank may exercise such power of attorney to sign the name of Borrower on any of the documents, and take any of the actions, described in clauses (h) through (k) above, regardless of whether an Event of Default has occurred or is continuing. The appointment of Bank as Borrower's attorney in fact, and each and every one of Bank's rights and powers, being coupled with an interest, is irrevocable until all of the Obligations (other than inchoate indemnity obligations as to which no claim has been asserted or is known to exist) have been fully repaid and performed and all of Bank's obligations to provide Credit Extensions or other financial accommodations to Borrower under this Agreement or any of the other Loan Documents shall have terminated.

- 9.3 <u>Accounts Collection</u>. At any time after the occurrence and during the continuation of an Event of Default, Bank may notify any Person owing funds to Borrower of Bank's security interest in such funds and verify the amount of such Account. Borrower shall collect all amounts owing to Borrower for Bank, receive in trust all payments as Bank's trustee, and immediately deliver such payments to Bank in their original form as received from the account debtor, with proper endorsements for deposit.
- 9.4 <u>Bank Expenses</u>. If Borrower fails to pay any amounts or furnish any required proof of payment due to third persons or entities, as required under the terms of this Agreement, then Bank may do any or all of the following after reasonable notice to Borrower: (a) make payment of the same or any part thereof; (b) set up such reserves under any revolving line of credit provided by Bank as Bank deems necessary to protect Bank from the exposure created by such failure; or (c) obtain and maintain insurance policies of the type discussed in Section 6.5 of this Agreement, and take any action with respect to such policies as Bank deems prudent. Any amounts so paid or deposited by Bank shall constitute Bank Expenses, shall be immediately due and payable, and shall bear interest at the then applicable rate hereinabove provided, and shall be secured by the Collateral. Any payments made by Bank shall not constitute an agreement by Bank to make similar payments in the future or a waiver by Bank of any Event of Default under this Agreement.
- 9.5 <u>Bank's Liability for Collateral</u>. Bank has no obligation to clean up or otherwise prepare the Collateral for sale. All risk of loss, damage or destruction of the Collateral shall be borne by Borrower.
- 9.6 No Obligation to Pursue Others. Bank has no obligation to attempt to satisfy the Obligations by collecting them from any other Person liable for them and Bank may release, modify or waive any collateral provided by any other Person to secure any of the Obligations, all without affecting Bank's rights against Borrower waives any right it may have to require Bank to pursue any other Person for any of the Obligations.
- 9.7 <u>Remedies Cumulative</u>. Bank's rights and remedies under this Agreement, the Loan Documents, and all other agreements shall be cumulative. Bank shall have all other rights and remedies not inconsistent herewith as provided under the Code, by law, or in equity. No exercise by Bank of one right or remedy shall be deemed an election, and no waiver by Bank of any Event of Default on Borrower's part shall be deemed a continuing waiver. No delay by Bank shall constitute a waiver, election, or acquiescence by it. No waiver by Bank shall be effective unless made in a written document signed on behalf of Bank and then shall be effective only in the specific instance and for the specific purpose for which it was given. Borrower expressly agrees that this Section 9.7 may not be waived or modified by Bank by course of performance, conduct, estoppel or otherwise.
- 9.8 <u>Demand; Protest</u>. Except as otherwise provided in this Agreement, Borrower waives demand, protest, notice of protest, notice of default or dishonor, notice of payment and nonpayment and any other notices relating to the Obligations.

# 10. NOTICES.

Unless otherwise provided in this Agreement, all notices or demands by any party relating to this Agreement or any other agreement entered into in connection herewith shall be in writing and (except for financial statements and other informational documents which may be sent by first-class mail, postage prepaid) shall be personally delivered or sent by a recognized overnight delivery service, certified mail, postage prepaid, return receipt requested, or by telefacsimile to Borrower or to Bank, as the case may be, at its addresses set forth below:

If to Borrower:

SERES HEALTH, INC. 161 First Street Cambridge, MA 02142 Attn: Chief Excutive Officer FAX: (617) 868-1115 with copies to:

Latham & Watkins LLP

John Hancock Tower, 20th Floor

200 Clarendon Street Boston, MA 02116 Attn: Peter Handrinos FAX: (617) 948-6001

Latham & Watkins LLP

505 Montgomery Street, 20th Floor

San Francisco, CA 94111 Attn: Haim Zaltzman FAX: (415) 395-8095

If to Bank: Comerica Bank

M/C 7578

39200 Six Mile Rd. Livonia, MI 48152

Attn: National Documentation Services

with a copy to: Comerica Bank

100 Federal Street, 28th Floor

Boston, MA 02110

Attn: Paula Howell & Jason Pan

FAX: (617) 757-6351

Notwithstanding the foregoing, however, the failure by the Bank to deliver a copy of a notice or demand to Borrower's counsel shall not affect the validity or efficacy of such notice or demand if otherwise sent to Borrower in accordance with this Section 10. The parties hereto may change the address at which they are to receive notices hereunder, by notice in writing in the foregoing manner given to the other.

### 11. CHOICE OF LAW AND VENUE; JURY TRIAL WAIVER.

This Agreement shall be governed by, and construed in accordance with, the internal laws of the State of California, without regard to principles of conflicts of law. Each of Borrower and Bank hereby submits to the exclusive jurisdiction of the State and Federal courts located in the Count of Santa Clara, State of California. THE UNDERSIGNED ACKNOWLEDGE THAT THE RIGHT TO TRIAL BY JURY IS A CONSTITUTIONAL ONE, BUT THAT IT MAY BE WAIVED UNDER CERTAIN CIRCUMSTANCES. TO THE EXTENT PERMITTED BY LAW, EACH PARTY, AFTER CONSULTING (OR HAVING HAD THE OPPORTUNITY TO CONSULT) WITH COUNSEL OF ITS, HIS OR HER CHOICE, KNOWINGLY AND VOLUNTARILY, AND FOR THE MUTUAL BENEFIT OF ALL PARTIES, WAIVES ANY RIGHT TO TRIAL BY JURY IN THE EVENT OF LITIGATION ARISING OUT OF OR RELATED TO THIS AGREEMENT OR ANY OTHER DOCUMENT, INSTRUMENT OR AGREEMENT BETWEEN THE UNDERSIGNED PARTIES.

### 12. REFERENCE PROVISION.

12.1 In the event the Jury Trial Waiver set forth above is not enforceable, the parties elect to proceed under this Judicial Reference Provision.

12.2 With the exception of the items specified in Section 12.3, below, any controversy, dispute or claim (each, a "Claim") between the parties arising out of or relating to this Agreement or any other document, instrument or agreement between the undersigned parties (collectively in this Section, the "Comerica Documents"), will be resolved by a reference proceeding in California in accordance with the provisions of Sections 638 et seq. of the California Code of Civil Procedure ("CCP"), or their successor sections, which shall constitute the exclusive remedy for the resolution of any Claim, including whether the Claim is subject to the reference proceeding. Except as otherwise provided in the Comerica Documents, venue for the reference proceeding will be in the Superior Court in the County where the real property involved in the action, if any, is located or in a County where venue is otherwise appropriate under applicable law (the "Court").

12.3 The matters that shall not be subject to a reference are the following: (i) foreclosure of any security interests in real or personal property, (ii) exercise of self-help remedies (including, without limitation, set-off), (iii) appointment of a receiver and (iv) temporary, provisional or ancillary remedies (including, without limitation, writs of attachment, writs of possession, temporary restraining orders or preliminary injunctions). This Agreement does not limit the right of any party to exercise or oppose any of the rights and remedies described in clauses (i) and (ii) or to seek or oppose from a court of competent jurisdiction any of the items described in clauses (iii) and (iv). The exercise of, or opposition to, any of those items does not waive the right of any party to a reference pursuant to this Agreement.

12.4 The referee shall be a retired Judge or Justice selected by mutual written agreement of the parties. If the parties do not agree within ten (10) days of a written request to do so by any party, then, upon request of any party, the referee shall be selected by the Presiding Judge of the Court (or his or her representative). A request for appointment of a referee may be heard on an ex parte or expedited basis, and the parties agree that irreparable harm would result if ex parte relief is not granted.

12.5 The parties agree that time is of the essence in conducting the reference proceedings. Accordingly, the referee shall be requested, subject to change in the time periods specified herein for good cause shown, to (i) set the matter for a status and trial-setting conference within fifteen (15) days after the date of selection of the referee, (ii) if practicable, try all issues of law or fact within one hundred twenty (120) days after the date of the conference and (iii) report a statement of decision within twenty (20) days after the matter has been submitted for decision.

12.6 The referee will have power to expand or limit the amount and duration of discovery. The referee may set or extend discovery deadlines or cutoffs for good cause, including a party's failure to provide requested discovery for any reason whatsoever. Unless otherwise ordered based upon good cause shown, no party shall be entitled to "priority" in conducting discovery, depositions may be taken by either party upon seven (7) days written notice, and all other discovery shall be responded to within fifteen (15) days after service. All disputes relating to discovery which cannot be resolved by the parties shall be submitted to the referee whose decision shall be final and binding.

12.7 Except as expressly set forth in this Agreement, the referee shall determine the manner in which the reference proceeding is conducted including the time and place of hearings, the order of presentation of evidence, and all other questions that arise with respect to the course of the reference proceeding. All proceedings and hearings conducted before the referee, except for trial, shall be conducted without a court reporter, except that when any party so requests, a court reporter will be used at any hearing conducted before the referee, and the referee will be provided a courtesy copy of the transcript. The party making such a request shall have the obligation to arrange for and pay the court reporter. Subject to the referee's power to award costs to the prevailing party, the parties will equally share the cost of the referee and the court reporter at trial.

12.8 The referee shall be required to determine all issues in accordance with existing case law and the statutory laws of the State of California. The rules of evidence applicable to proceedings at law in the State of California will be applicable to the reference proceeding. The referee shall be empowered to enter equitable as well as legal relief, enter equitable orders that will be binding on the parties and rule on any motion which would be authorized in a court proceeding, including without limitation motions for summary judgment or summary adjudication. The referee shall issue a decision at the close of the reference proceeding which disposes of all claims of the parties that are the subject of the reference. Pursuant to CCP § 644, such decision shall be entered by the Court as a judgment or an order in the same manner as if the action had been tried by the Court and any such decision will be final, binding and conclusive. The parties reserve the right to appeal from the final judgment or order or from any appealable decision or order entered by the referee. The parties reserve the right to findings of fact, conclusions of laws, a written statement of decision, and the right to move for a new trial or a different judgment, which new trial, if granted, is also to be a reference proceeding under this provision.

12.9 If the enabling legislation which provides for appointment of a referee is repealed (and no successor statute is enacted), any dispute between the parties that would otherwise be determined by reference procedure will be resolved and determined by arbitration. The arbitration will be conducted by a retired judge or Justice, in accordance with the California Arbitration Act §1280 through §1294.2 of the CCP as amended from time to time. The limitations with respect to discovery set forth above shall apply to any such arbitration proceeding.

12.10 THE PARTIES RECOGNIZE AND AGREE THAT ALL CONTROVERSIES, DISPUTES AND CLAIMS RESOLVED UNDER THIS REFERENCE PROVISION WILL BE DECIDED BY A REFEREE AND NOT BY A JURY. AFTER CONSULTING (OR HAVING HAD THE OPPORTUNITY TO CONSULT) WITH COUNSEL OF ITS, HIS OR HER OWN CHOICE, EACH PARTY KNOWINGLY AND VOLUNTARILY, AND FOR THE MUTUAL BENEFIT OF ALL PARTIES, AGREES THAT THIS REFERENCE PROVISION WILL APPLY TO ANY CONTROVERSY, DISPUTE OR CLAIM BETWEEN OR AMONG THEM ARISING OUT OF OR IN ANY WAY RELATED TO, THIS AGREEMENT OR THE OTHER COMERICA DOCUMENTS.

#### 13. GENERAL PROVISIONS.

- 13.1 <u>Successors and Assigns</u>. This Agreement shall bind and inure to the benefit of the respective successors and permitted assigns of each of the parties and shall bind all Persons who become bound as a debtor to this Agreement; <u>provided</u>, <u>however</u>, that neither this Agreement nor any rights hereunder may be assigned by Borrower without Bank's prior written consent, which consent may be granted or withheld in Bank's sole discretion. Bank shall have the right without the consent of or notice to Borrower to sell, transfer, negotiate, or grant participation in all or any part of, or any interest in, Bank's obligations, rights and benefits hereunder.
- 13.2 <u>Indemnification</u>. Borrower shall defend, indemnify and hold harmless Bank and its officers, employees, and agents against: (a) all obligations, demands, claims, and liabilities claimed or asserted by any other party in connection with the Collateral or the transactions contemplated by this Agreement and/or the other Loan Documents; and (b) all losses or Bank Expenses in any way suffered, incurred, or paid by Bank, its officers, employees and agents as a result of or in any way arising out of, following, or consequential to transactions between Bank and Borrower whether under this Agreement, or otherwise (including without limitation reasonable attorneys' fees and expenses), except for losses caused by Bank's gross negligence or willful misconduct.
  - 13.3 <u>Time of Essence</u>. Time is of the essence for the performance of all obligations set forth in this Agreement.
- 13.4 <u>Severability of Provisions</u>. Each provision of this Agreement shall be severable from every other provision of this Agreement for the purpose of determining the legal enforceability of any specific provision.
- 13.5 <u>Correction of Loan Documents</u>. Bank may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties.
- 13.6 <u>Amendments in Writing, Integration</u>. This Agreement cannot be amended or terminated orally. All amendments to or terminations of this Agreement or the other Loan Documents must be in writing signed by the parties. All prior agreements, understandings, representations, warranties, and negotiations between the parties hereto with respect to the subject matter of this Agreement and the other Loan Documents, if any, are merged into this Agreement and the Loan Documents.
- 13.7 <u>Counterparts</u>. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, shall be deemed to be an original, and all of which, when taken together, shall constitute but one and the same Agreement.
- 13.8 <u>Survival</u>. All covenants, representations and warranties made in this Agreement shall continue in full force and effect so long as any Obligations (other than inchoate indemnity obligations as to which no claim has been asserted or is known to exist) remain outstanding or Bank has any obligation to make any Credit

Extension to Borrower. The obligations of Borrower to indemnify Bank with respect to the expenses, damages, losses, costs and liabilities described in Section 13.2 shall survive, notwithstanding termination of this Agreement, until all applicable statute of limitations periods with respect to actions that may be brought against Bank have run.

13.9 Confidentiality. In handling any confidential information, Bank and all employees and agents of Bank shall exercise the same degree of care that Bank exercises with respect to its own proprietary information of the same types to maintain the confidentiality of any non-public information thereby received or received pursuant to this Agreement except that disclosure of such information may be made (i) to the subsidiaries or Affiliates of Bank in connection with their present or prospective business relations with Borrower, (ii) to prospective transferees, participants, or purchasers of any interest in the Obligations that are subject to confidentiality provisions substantially similar to the provisions of this Section 13.9 or that have agreed with Bank to comply with this Section 13.9, (iii) as required by law, regulations, rule or order, subpoena, judicial order or similar order, (iv) as may be required in connection with the examination, audit or similar investigation of Bank, (v) to Bank's accountants, auditors and regulators, (vi) as Bank may determine in connection with the enforcement of any remedies under any of the Loan Documents, and (vii) to third-party service providers of Bank so long as such service providers have executed a confidentiality agreement with Bank with terms no less restrictive than those contained herein. Confidential information hereunder shall not include information that either: (a) is in the public domain or in the knowledge or possession of Bank when disclosed to Bank, or becomes part of the public domain after disclosure to Bank through no fault of Bank; or (b) is disclosed to Bank by a third party, provided Bank does not have actual knowledge that such third party is prohibited from disclosing such information.

13.10 <u>Termination</u>. Upon written request of Borrower to Bank, this Agreement shall terminate on the indefeasible payment in full in cash of the Obligations (other than inchoate indemnity obligations as to which no claim has been asserted or is known to exist), the deposit of cash collateral with respect to all contingent Obligations (excluding inchoate indemnification obligations as to which no claim has been asserted) in amounts and on terms and conditions and with parties satisfactory to Bank, and the full and final termination of all of Bank's obligations and commitments to make Credit Extensions. Promptly after any such termination and written request of Borrower to Bank, Bank shall at Borrower's sole cost and expense, execute and deliver to Borrower a payoff letter on Bank's standard form and release the security interest in the Collateral granted under this Agreement.

[Remainder of Page Left Blank]

SERES HEALTH, INC.
By: /s/ David Berry
Name: David Berry
Title: President
COMERICA BANK

/s/ Jason Pan

Vice President

Name: Jason Pan

By:

Title:

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first above written.

#### EXHIBIT A

#### **DEFINITIONS**

"Accounts" means all presently existing and hereafter arising accounts, contract rights, payment intangibles and all other forms of obligations owing to Borrower arising out of the sale or lease of goods (including, without limitation, the licensing of software and other technology), the licensing, sale or other transfer of any intellectual property of Borrower or any of its Subsidiaries, or the rendering of services by Borrower, whether or not earned by performance, and including, without limitation, all accounts, contract rights and payment intangibles of Borrower under or in respect of term license agreements, subscription license agreements and maintenance contracts, and also including all accounts, payment intangibles and other forms of obligations owing to Borrower under any and all credit insurance, guaranties, and other security therefor, as well as all merchandise returned to or reclaimed by Borrower and Borrower's Books relating to any of the foregoing.

"Affiliate" means, with respect to any Person, any Person that owns or controls directly or indirectly such Person, any Person that controls or is controlled by or is under common control with such Person, and each of such Person's senior executive officers, directors, and partners.

"Bank Expenses" means all costs or expenses of Bank, or any other holder or owner of the Loan Documents (including, without limit, court costs, legal expenses and reasonable attorneys' fees and expenses, whether generated in-house or by outside counsel, whether or not suit is instituted, and, if suit is instituted, whether at trial court level, appellate court level, in a bankruptcy, probate or administrative proceeding or otherwise) incurred in connection with the preparation, negotiation, execution, delivery, amendment, administration, performance and enforcement of the Loan Documents, or incurred in collecting, attempting to collect under the Loan Documents or the Obligations, or incurred in defending the Loan Documents, or incurred in any other matter or proceeding relating to the Loan Documents or the Obligations; and reasonable Collateral audit fees, in each case whether incurred before, during and after an Insolvency Proceeding.

"Borrower State" means Delaware, the state under whose laws Borrower is organized.

"Borrower's Books" means all of Borrower's books and records including: ledgers; records concerning Borrower's assets or liabilities, the Collateral, business operations or financial condition; and all computer programs, or tape files, and the equipment, containing such information.

"Business Day" means any day that is not a Saturday, Sunday, or other day on which banks in the State of California are authorized or required to close.

"Cash" means unrestricted cash and cash equivalents.

"Change in Control" means the occurrence of any one or more of the foregoing:

(a) prior to the Parent Holding Company Acquisition: (i) any transaction or series of related transactions in which any "person" or "group" (within the meaning of Section 13(d) and 14(d)(2) of the Securities Exchange Act of 1934), other than Flagship, becomes the "beneficial owner" (as defined in Rule 13d-3 under the Securities Exchange Act of 1934), directly or indirectly, of a sufficient number of shares of all classes of Equity Interests then outstanding of Borrower ordinarily entitled to vote in the election of directors, empowering such "person" or "group" to elect a majority of the Board of Directors of Borrower, who did not have such power before such transaction, or (ii) Borrower's existing venture capital investors ceasing to own and control at least twenty percent (20%) of the voting power of all classes of Borrower's Equity Interests entitled to vote for the election of directors (other than as a result of the Initial Public Offering); or

(b) following the Parent Holding Company Acquisition: (i) any transaction or series of related transactions in which any "person" or "group" (within the meaning of Section 13(d) and 14(d)(2) of the Securities Exchange Act of 1934), other than Flagship, becomes the "beneficial owner" (as defined in Rule 13d-3 under the Securities Exchange Act of 1934), directly or indirectly, of a sufficient number of shares of all classes of Equity Interests then

outstanding of Parent Holding Company ordinarily entitled to vote in the election of directors, managers or similar governing authority, empowering such "person" or "group" to elect a majority of the Board of Directors (or similar governing authority) of Parent Holding Company, who did not have such power before such transaction, or (ii) Flagship ceasing to own and control at least twenty percent (20%) of the voting power of all classes of Parent Holding Company's Equity Interests entitled to vote for the election of directors or similar governing body or authority (other than as a result of the Initial Public Offering), or (iii) Parent Holding Company ceasing to own and control one hundred percent (100%) of the voting power of all classes of Borrower's Equity Interests entitled to vote for the election of directors.

Notwithstanding the foregoing, subject to compliance with Section 6.11 and the requirements of Section 1.5 of the Warrant, the Parent Holding Company Acquisition shall not be deemed to be a Change in Control.

"Chief Executive Office State" means Massachusetts, where Borrower's chief executive office is located.

"Closing Date" means the date of this Agreement.

"Code" means the California Uniform Commercial Code as amended or supplemented from time to time.

"Collateral" means the property described on Exhibit B attached hereto and all Negotiable Collateral to the extent not described on Exhibit B.

"Collateral Access Agreement" means an agreement in form and substance satisfactory to Bank in its reasonable discretion, pursuant to which a mortgagee or lessor of real property on which Collateral is stored or otherwise located, or a warehouseman, processor, contract manufacturer, equipment holder, co-location facility or other bailee of Inventory, Equipment or other property owned by Borrower, that acknowledges the Liens of Bank and waives any Liens held by such Person on such Inventory, Equipment or other property and, includes such other agreements with respect to the Collateral, including agreements relating to access to the Collateral, as Bank may require in its sole discretion, as the same may be amended, restated or otherwise modified from time to time.

"Collateral State" means the state or states where the Collateral is located, which is Massachusetts.

"Contingent Obligation" means, as applied to any Person, any direct or indirect liability, contingent or otherwise, of that Person with respect to (i) any indebtedness, lease, dividend, letter of credit or other obligation of another, including, without limitation, any such obligation directly or indirectly guaranteed, endorsed, co-made or discounted or sold with recourse by that Person, or in respect of which that Person is otherwise directly or indirectly liable; (ii) any obligations with respect to undrawn letters of credit, corporate credit cards or merchant services issued for the account of that Person; and (iii) all obligations arising under any interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, or other agreement or arrangement designed to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; provided, however, that the term "Contingent Obligation" shall not include endorsements for collection or deposit in the ordinary course of business. The amount of any Contingent Obligation shall be deemed to be an amount equal to the stated or determined amount of the primary obligation in respect of which such Contingent Obligation is made or, if not stated or determinable, the maximum reasonably anticipated liability in respect thereof as determined by such Person in good faith; provided, however, that such amount shall not in any event exceed the maximum amount of the obligations under the guarantee or other support arrangement.

"Copyrights" means any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret, now or hereafter existing, created, acquired or held.

"Credit Extension" means each Growth Capital Advance or any other extension of credit by Bank to or for the benefit of Borrower hereunder.

"Environmental Laws" means all laws, rules, regulations, orders and the like issued by any federal state, local foreign or other governmental or quasigovernmental authority or any agency pertaining to the environment or to any hazardous materials or wastes, toxic substances, flammable, explosive or radioactive materials, asbestos or other similar materials. "Equipment" means all present and future machinery, equipment, tenant improvements, furniture, fixtures, vehicles, tools, parts and attachments in which Borrower has any interest.

"Equity Interests" means, with respect to any Person, any of the shares of capital stock of (or other ownership, membership or profit interests in) such Person, any of the warrants, options or other rights for the purchase or acquisition from such Person of shares of capital stock of (or other ownership, membership or profit interests in) such Person, any of the securities convertible into or exchangeable for shares of capital stock of (or other ownership, membership or profit interests in) such Person or warrants, rights or options for the purchase or acquisition from such Person of such shares (or such other interests), and any of the other ownership, membership or profit interests in such Person (including partnership, member or trust interests therein), whether voting or nonvoting, and whether or not such shares, warrants, options, rights or other interests are outstanding on any date of determination.

"ERISA" means the Employee Retirement Income Security Act of 1974, as amended, and the regulations thereunder.

"Event of Default" has the meaning assigned in Article 8.

"Excluded Foreign Subsidiary" means any Foreign Subsidiary that is a controlled foreign corporation (as defined in the IRC) in respect of which either (a) the pledge of all of the voting Equity Interests of such Foreign Subsidiary as Collateral or (b) the guaranteeing by such Foreign Subsidiary of the Obligations, would result in material adverse tax consequences to Borrower.

"Flagship" means, collectively, FLAGSHIP VENTURES FUND IV, L.P, a Delaware limited partnership, and its affiliated investment funds.

"Foreign Subsidiary" means, in relation to any Person, any Subsidiary of that Person that is organized under the laws of a jurisdiction other than the United States of America or any of the States (or the District of Columbia) thereof.

"Final Payment" is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) due on the earliest to occur of (a) the Growth Capital Maturity Date, or (b) the acceleration of any Growth Capital Advances, or (c) the prepayment of any Growth Capital Advance pursuant to Section 2.1(c)(iv) or (v), equal to Sixty Thousand Dollars (\$60,000).

"GAAP" means generally accepted accounting principles, consistently applied, as in effect from time to time in the United States of America.

"Governmental Authority" means the Government of Canada, the United States of America, any State thereof or the District of Columbia, any other nation or any political subdivision thereof, whether provincial, state, territorial or local, and any agency, authority, instrumentality, regulatory body, court, central bank, fiscal or monetary authority or other authority regulating financial institutions, and any other entity exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to government, including the Bank Committee on Banking Regulation and Supervisory Practices of the Bank of International Settlements.

"Growth Capital Advance(s)" means a cash advance or cash advances under the Growth Capital Line.

"Growth Capital Availability End Date" means August 31, 2014.

"Growth Capital Line" means a Credit Extension of up to Three Million Dollars (\$3,000,000).

"Growth Capital Maturity Date" means February 1, 2017.

"Initial Public Offering" means the closing of the initial firm commitment underwritten offering of Borrower's common stock pursuant to a registration statement under the Securities Act of 1933 filed with, and declared effective by, the Securities and Exchange Commission.

"Indebtedness" means (a) all indebtedness for borrowed money or the deferred purchase price of property or services, including without limitation reimbursement and other obligations with respect to surety bonds and letters of credit, (b) all obligations evidenced by notes, bonds, debentures or similar instruments, (c) all capital lease obligations, and (d) all Contingent Obligations.

"Insolvency Proceeding" means any proceeding or case commenced by or against any Person or entity under any provision of the United States Bankruptcy Code, as amended, or under any other bankruptcy or insolvency law, including assignments for the benefit of creditors, formal or informal moratoria, compositions, extension generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

"Intellectual Property" means all of Borrower's Copyrights, Patents, Trademarks, servicemarks and applications therefor, now owned or hereafter acquired, and any claims for damages by way of any past, present and future infringement of any of the foregoing.

"Inventory" means all present and future inventory in which Borrower has any interest, including any returns upon any accounts or other proceeds, including insurance proceeds, resulting from the sale or disposition of any of the foregoing and any documents of title representing any of the above, and Borrower's Books relating to any of the foregoing.

"Investment" means any beneficial ownership of (including stock, partnership or limited liability company interest or other securities) any Person, or any loan, advance or capital contribution to any Person.

"IRC" means the Internal Revenue Code of 1986, as amended, and the regulations thereunder.

"Letter of Credit" means a commercial or standby letter of credit or similar undertaking issued by Bank at Borrower's request.

"Lien" means any mortgage, lien, deed of trust, charge, pledge, security interest or other encumbrance.

"Loan Documents" means, collectively, this Agreement, any note or notes executed by Borrower, and any other document, instrument or agreement entered into in connection with this Agreement, all as amended or extended from time to time. For the sake of clarity, Loan Documents shall include all present or future agreements by Borrower with or for the benefit of Bank in connection with bank products, credit services, and/or financial accommodations previously, now, or hereafter provided to Borrower by Bank including, without limitation, any letters of credit, cash management services (including, without limitation, merchant services, direct deposit of payroll, business credit cards, and check cashing services), interest rate swap arrangements, and foreign exchange services as any such products or services may be identified in Bank's various agreements related thereto, all as amended, restated, or otherwise modified.

"Material Adverse Effect" means (i) a material adverse change in Borrower's business or financial condition, or (ii) a material impairment in the prospect of repayment of all or any portion of the Obligations or in otherwise performing Borrower's obligations under the Loan Documents, (iii) a material impairment in the perfection, value or priority of Bank's security interests in the Collateral or any security provided by any guarantor.

"Negotiable Collateral" means all of Borrower's present and future letters of credit of which it is a beneficiary, drafts, instruments (including promissory notes), securities, documents of title, and chattel paper, and Borrower's Books relating to any of the foregoing.

"Obligations" means all debt, principal, interest, Bank Expenses, the Final Payment and other amounts owed to Bank by Borrower pursuant to this Agreement or any other agreement, whether absolute or contingent, due or to become due, now existing or hereafter arising, including any interest that accrues after the commencement of an Insolvency Proceeding and including any debt, liability, or obligation owing from Borrower to others that Bank may have obtained by assignment or otherwise but excluding any obligations under the Warrant.

"Parent Holding Company" means a limited liability company duly formed and organized and validly existing under the laws of a state of the United States for the sole purpose of acquiring and holding the Equity Interests of Borrower that (a) holds no assets other than assets incidental to the ownership of such Equity Interests of Borrower, and (b) conducts no other business or financial operations.

"Parent Holding Company Acquisition" means the acquisition by a Parent Holding Company of all of the Equity Interests of Borrower, such that Borrower becomes a wholly-owned Subsidiary of such Parent Holding Company, and the voting and non-voting Equity Interests of the Parent Holding Company following such transaction are held by Borrower's former stockholders in substantially the same percentages of ownership as such stockholders held Borrower's Equity Interests immediately prior to such transaction.

"Patents" means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

"Periodic Payments" means all installments or similar recurring payments that Borrower may now or hereafter become obligated to pay to Bank pursuant to the terms and provisions of any instrument, or agreement now or hereafter in existence between Borrower and Bank.

#### "Permitted Indebtedness" means:

- (a) Indebtedness of Borrower in favor of Bank arising under this Agreement or any other Loan Document;
- (b) Indebtedness existing on the Closing Date and disclosed in the Schedule;
- (c) Indebtedness of Borrower not to exceed Two Hundred Fifty Thousand Dollars (\$250,000) in the aggregate outstanding at any time secured by a lien described in clause (c) of the defined term "Permitted Liens," provided such Indebtedness does not exceed the lesser of the cost or fair market value of the equipment financed with such Indebtedness;
- (d) Subordinated Debt;
- (e) Indebtedness to trade creditors incurred in the ordinary course of business, including Indebtedness incurred in the ordinary course of business with corporate credit cards with Bank; and
- (f) extensions, refinancings and renewals of any items of Permitted Indebtedness described in clauses (a) through (c) above, provided that the principal amount is not increased or the terms modified to impose more burdensome terms upon Borrower or its Subsidiary, as the case may be;
- (g) Indebtedness that also constitutes an intercompany loan under clause (e) of the definition of Permitted Investment;
- (h) reimbursement obligations not to exceed Fifty Thousand Dollars (\$50,000) in the aggregate at any time, in connection with letters of credit that are secured by cash or cash equivalents and issued on behalf of a Borrower or a Subsidiary thereof with respect to leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business); and
- (i) other Indebtedness in an amount not to exceed One Hundred Thousand Dollars (\$100,000) at any time outstanding.

#### "Permitted Investment" means:

- (a) Investments existing on the Closing Date disclosed in the Schedule;
- (b) (i) Marketable direct obligations issued or unconditionally guaranteed by the United States of America or any agency or any State thereof maturing within one (1) year from the date of acquisition thereof, (ii) commercial paper maturing no more than one (1) year from the date of creation thereof and currently having rating of at least A-2 or P-2 from either Standard & Poor's Rating Services or Moody's Investors Service, Inc., (iii) Bank's certificates of deposit maturing no more than one (1) year from the date of investment therein, and (iv) Bank's money market accounts;
- (c) Repurchases of stock from former employees or directors of Borrower under the terms of customary board-approved stock repurchase agreements to the extent permitted under Section 7.6;
- (d) Investments accepted in connection with Permitted Transfers;
- (e) Investments of wholly-owned Subsidiaries of Borrower in or to other wholly-owned Subsidiaries of Borrower or Borrower and Investments by Borrower in its wholly-owned Subsidiaries not to exceed Five Hundred Thousand Dollars (\$500,000) in the aggregate in any fiscal year;
- (f) Investments not to exceed One Hundred Twenty-Five Thousand Dollars (\$125,000) in the aggregate in any fiscal year consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plan agreements approved by Borrower's Board of Directors:
- (g) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of Borrower's business;
- (h) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business, provided that this subparagraph (h) shall not apply to Investments of Borrower in any Subsidiary;
- (i) Joint ventures, strategic alliances or research and development collaborations with non-Affiliated third parties consistent with the ordinary course of business in Borrower's industry, provided that any cash Investments by Borrower do not exceed Three Hundred Fifty Thousand Dollars (\$350,000) in the aggregate in any fiscal year; and
- (j) Additional Investments, other than Investments in Subsidiaries, that do not exceed \$200,000 in the aggregate during the term of this Agreement.

#### "Permitted Liens" means the following:

- (a) Any Liens existing on the Closing Date and disclosed in the Schedule (excluding Liens to be satisfied with the proceeds of the Credit Extensions) or arising under this Agreement or the other Loan Documents;
- (b) Liens for taxes, fees, assessments or other governmental charges or levies, either not delinquent or being contested in good faith by appropriate proceedings and for which Borrower maintains adequate reserves, provided the same have no priority over any of Bank's security interests;
- (c) Liens securing Permitted Indebtedness not to exceed Two Hundred Fifty Thousand Dollars (\$250,000) in aggregate principal amount outstanding at any time (i) upon or in any Equipment (other than Equipment financed by Bank) acquired or held by Borrower or any of its Subsidiaries to secure the purchase price of such Equipment or indebtedness incurred solely for the purpose of financing the acquisition or lease of

- such Equipment, or (ii) existing on such Equipment at the time of its acquisition, provided that the Lien is confined solely to the property so acquired and improvements thereon, and the proceeds of such Equipment;
- (d) Liens incurred in connection with the extension, renewal or refinancing of the indebtedness secured by Liens of the type described in clauses (a) through (c) above, provided that any extension, renewal or replacement Lien shall be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness being extended, renewed or refinanced does not increase;
- (e) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Sections 8.4 (Attachment) or 8.8 (Judgments; Settlements);
- (f) Liens in favor of other financial institutions arising in connection with Borrower's deposit accounts held at such institutions to secured standard fees for deposit services charged by, but not financing made available by such institutions, provided that Bank has a perfected, first-priority security interest in the amounts held in such deposit accounts and Borrower is in compliance with the requirements of Section 6.6 with respect to such accounts;
- (g) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed Fifty Thousand Dollars (\$50,000) and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;
- (h) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);
- (i) Licenses for the use of the property of Borrower or its Subsidiaries permitted under clause (b) of the definition of Permitted Transfer;
- (j) Liens securing reimbursement obligations not to exceed Fifty Thousand Dollars (\$50,000) in the aggregate at any time, in connection with letters of credit issued with respect to leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business); and
- (k) Liens in favor of Bank securing Indebtedness for corporate credit cards issued by Bank.

"Permitted Transfer" means the conveyance, sale, lease, transfer or disposition by Borrower or any Subsidiary of:

- (a) Inventory in the ordinary course of business;
- (i) Non-exclusive licenses for the use of the Intellectual Property of Borrower or its Subsidiaries in the ordinary course of business, and (ii) licenses of Intellectual Property of Borrower or its Subsidiaries granted in the ordinary course of business that could not result in a legal transfer of title of the licensed property that (A) may be exclusive in respects other than territory and that may be exclusive as to territory only as to discreet geographical areas outside of the United States or (B) if not limited in geographical scope, whereby Borrower only exclusively licenses its platform Intellectual Property for use in connection with the licensee's products; provided that with respect to each licenses described in clause (i) or (ii) above, such license not interfere in any material respect with the business of Borrower and its Subsidiaries taken as a whole;
- (c) Worn-out or obsolete Equipment not financed by Bank;

- (d) transfers of cash that constitute Permitted Investments; payments of money by Borrower for its ordinary course business operating expenses (such as the payment, in each case in the ordinary course of Borrower's business, of payroll, rent, debt service, accounts payable, payments to vendors or other third parties for goods provided or services rendered to or on behalf of Borrower; and payments of money by any Subsidiary of Borrower for such Subsidiary's own ordinary course business operating expenses (such as the payment, in each case in the ordinary course of such Subsidiary's business, of payroll, rent, debt service, accounts payable, payments to vendors or other third parties for goods provided or services rendered to or on behalf of such Subsidiary); or
- (e) Other assets of Borrower or its Subsidiaries (other than Intellectual Property) that do not in the aggregate exceed One Hundred Thousand Dollars (\$100,000) during any fiscal year.
- "Person" means any individual, sole proprietorship, partnership, limited liability company, joint venture, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or governmental agency.
- "Pricing Addendum" means that certain Prime Referenced Rate Addendum to Loan and Security Agreement, dated as of the Closing Date, by and between Borrower and Bank, as the same may be amended, modified, supplemented, extended of restated from time to time.
- "Prohibited Territory" means any person or country listed by the Office of Foreign Assets Control of the United States Department of Treasury as to which transactions between a United States Person and that territory are prohibited.
- "Responsible Officer" means each of the Chief Executive Officer, the Chief Operating Officer, the Chief Financial Officer and the Controller of Borrower.
- "Restricted Agreement" is any material license or other material agreement (other than over-the-counter software that is commercially available to the public) to which Borrower is a party or under which Borrower is bound (including licenses and agreements under which Borrower is the licensee): (a) that prohibits or otherwise restricts Borrower from assigning to Bank, or granting to Bank a Lien in, Borrower's interest in such license or agreement, the rights arising thereunder or any other property, or (b) for which a default under or termination of such license or contract could interfere with the Bank's right to use, license, sell or collect any Collateral or otherwise exercise its rights and remedies with respect to the Collateral under the Loan Documents or applicable law.
- "Schedule" means the schedule of exceptions attached hereto and approved by Bank, if any.
- "Security Instrument" means any security agreement, assignment, pledge agreement, financing or other similar statement or notice, continuation statement, other agreement or instrument, or any amendment or supplement to any thereof, creating, governing or providing for, evidencing or perfecting or maintaining the priority of any security interest or Lien.
- "Shares" means one hundred percent (100%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower in any Subsidiary of Borrower.
- "SOS Reports" means the official reports from the Secretaries of State of each Collateral State, Chief Executive Office State and the Borrower State and other applicable federal, state or local government offices identifying all current security interests filed in the Collateral and Liens of record as of the date of such report.
- "Subordinated Debt" means Indebtedness incurred by Borrower that is subordinated in writing to the Obligations owing by Borrower to Bank on terms reasonably satisfactory to Bank (and identified as being such by Borrower and Bank), including without limiting the generality of the foregoing, subordination of such Indebtedness in right of payment to the prior indefeasible payment in full, in cash, of the Obligations, the subordination of the priority of any Lien at any time securing such Indebtedness to Bank's Lien, and prohibitions on the exercise of any rights or remedies of the holder of such Indebtedness against Borrower or any of Borrower's property pursuant to a written subordination agreement executed and delivered by Bank.

"Subsidiary" means, with respect to any Person, any corporation, partnership or, limited liability company or joint venture in which (i) any general partnership interest or (ii) more than fifty percent (50%) of the stock, limited liability company interest, joint venture interest or other Equity Interest of which by the terms thereof has the ordinary voting power to elect the Board of Directors, managers, trustees or similar governing body of the entity, at the time as of which any determination is being made, is owned or controlled by such Person, either directly or through an Affiliate. Unless otherwise stated, references herein to a "Subsidiary" are to Subsidiaries of Borrower.

"Trademarks" means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

"Warrant" means that certain Warrant to Purchase Stock issued on the Closing Date by Borrower to Bank.

DEBTOR: SERES HEALTH, INC.

SECURED PARTY: COMERICA BANK

#### EXHIBIT B

#### COLLATERAL DESCRIPTION ATTACHMENT TO LOAN AND SECURITY AGREEMENT

All personal property of SERES HEALTH, INC., a Delaware corporation (herein referred to as "Borrower" or "Debtor") whether presently existing or hereafter created or acquired, and wherever located, including, but not limited to:

- (a) all accounts (including health-care-insurance receivables), chattel paper (including tangible and electronic chattel paper), deposit accounts, documents (including negotiable documents), equipment (including all accessions and additions thereto), financial assets, general intangibles (including payment intangibles and software), goods (including fixtures), instruments (including promissory notes), inventory (including all goods held for sale or lease or to be furnished under a contract of service, and including returns and repossessions), investment property (including securities and securities entitlements), letter of credit rights, money, and all of Debtor's books and records with respect to any of the foregoing, and the computers and equipment containing said books and records; and
- (b) any and all cash proceeds and/or noncash proceeds of any of the foregoing, including, without limitation, insurance proceeds, and all supporting obligations and the security therefor or for any right to payment.

Notwithstanding the foregoing, the Collateral shall not include (i) property that is nonassignable by its terms without the consent of the licensor thereof or another party (but only to the extent such prohibition on transfer is enforceable under applicable law, including, without limitation, Sections 9406 and 9408 of the Code), (ii) property where the granting of a security interest therein is contrary to applicable law, provided that upon the cessation of any such restriction or prohibition, such property shall automatically become part of the Collateral, (iii) more than sixty five percent (65%) of the voting power of all classes of capital stock of an Excluded Foreign Subsidiary, or (iv) any copyrights, patents, trademarks, servicemarks and applications therefor, now owned or hereafter acquired, or any claims for damages by way of any past, present and future infringement of any of the foregoing (collectively, the "Intellectual Property"); provided, however, that the Collateral shall include all accounts, all general intangibles that consist of rights to payment, and all proceeds from the sale, licensing or disposition of all or any part of, or rights in, any property, including the Intellectual Property (the "Rights to Payment"). Notwithstanding the foregoing, if a judicial authority (including a U.S. Bankruptcy Court) holds that a security interest in the underlying Intellectual Property is necessary to have a security interest in the Rights to Payment, then the Collateral shall automatically, and effective as of September , 2013, include the Intellectual Property to the extent necessary to permit perfection of Bank's security interest in the Rights to Payment.

All terms above have the meanings given to them in the California Uniform Commercial Code, as amended or supplemented from time to time.

# EXHIBIT C

# TECHNOLOGY & LIFE SCIENCES DIVISION LOAN ANALYSIS LOAN ADVANCE/PAYDOWN REQUEST FORM

#### **EXHIBIT D**

#### **COMPLIANCE CERTIFICATE**

Please send all Required Reporting to:

Comerica Bank Technology & Life Sciences Division Loan Analysis Department 250 Lytton Avenue, 3rd Floor, Mail Code 4240 Palo Alto, CA 94301

Phone: (650) 462-6060 Fax: (650) 462-6061

#### FROM: SERES HEALTH, INC.

The undersigned authorized Officer of SERES HEALTH, INC. ("Borrower"), hereby certifies that in accordance with the terms and conditions of the Loan and Security Agreement between Borrower and Bank (the "Agreement"), (i) Borrower is in complete compliance for the period ending \_\_\_\_\_ with all required covenants, including without limitation the ongoing registration of intellectual property rights in accordance with Section 6.8, except as noted below and (ii) except as noted below with respect to the representation and warranty in the last sentence of Section 5.7, all representations and warranties of Borrower stated in the Agreement are true and correct in all material respects on and as of the date hereof as though made at and as of each such date (provided, however, that that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof and those representations and warranties expressly referring to another date shall be true, correct and complete in all material respects as of such date). Attached herewith are the required documents supporting the above certification. The Officer further certifies that these are prepared in accordance with Generally Accepted Accounting Principles (GAAP) and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes.

Please indicate compliance status by circling Yes/No under "Complies" or "Applicable" column.

REPORTING COVENANTS	REQUIRED	COMP	LIES
Company Prepared Monthly F/S		(FS)	
	Monthly, within 30 days		NO
Compliance Certificate		(ES)	
	Monthly, within 30 days		NO
CPA Audited, Unqualified F/S		(ES)	
	Annually, within 180 days of FYE*		NO
Annual Business Plan (incl. operating budget)		(ES)	
	Annually, within 45 days of FYE		NO
Audit		(ES)	
	Semi-annual		NO
If Public:			
10-Q	Quarterly, within 5 days of SEC filing (50 days)	YES	NO
10-K	Annually, within 5 days of SEC filing (95 days)	YES	NO
Total amount of Borrower's cash and investments		(ES)	
	Amount: \$2,689,705.00		NO
Total amount of Borrower's cash and investments			
maintain with Bank	Amount: \$	YES	NO

commencing with FY ending December 31, 2013.

	DESCRIPTION	APPLI	CABLE
Legal Action > \$250,000			68
	Notify promptly upon notice	YES	
Inventory Disputes > \$250,000			NO
	Notify promptly upon notice	YES	
Cross default with other agreements > \$250,000			NO
	Notify promptly upon notice	YES	
Judgment > \$250,000			NO
	Notify promptly upon notice	YES	

FINANCIAL COVENANTS TO BE TESTED MONTHLY, UNLESS OTHERWISE NOTED:	REQUIRED	ACTUAL	COMPLIES
N/A			
OTHER COVENANTS	REQUIRED	ACTUAL	COMPLIES
Permitted Indebtedness for equipment leases			(ES)
	<\$250,000	0	NO
Permitted Investments for stock repurchase			<b>YES</b>
	<\$100,000	0	NO
Permitted Investments for Subsidiaries			(ES)
	<\$500,000	0	NO
Permitted Investments for employee loans			(ES)
	<\$125,000	0	NO
Permitted Investments for joint ventures			(ES)
	<\$350,000	0	NO
Permitted Liens for equipment leases			(ES)
	<\$250,000	0	NO
Permitted Transfers			(ES)
	<\$100,000	0	NO

Please enter below comments regarding violations:

Very truly yours,

President

Title:

Please enter below exceptions to representation and warranty in last sentence of Section 5.7:

The Officer further acknowledges that at any time Borrower is not in compliance with all the terms set forth in the Agreement, including, without limitation, the financial covenants, no credit extensions will be made.

/s/ David Berry Authorized Signer David Berry

#### **SCHEDULE OF EXCEPTIONS**

#### TO LOAN AND SECURITY AGREEMENT

# Permitted Indebtedness (Exhibit A)

Silicon Valley Bank Credit Card in the amount of \$4,000 as of June 30, 2013

#### Permitted Investments (Exhibit A)

None

# Permitted Liens (Exhibit A)

None

# Prior Names (Section 5.5)

Newco LS21,Inc.

# <u>Inventory or Equipment Locations</u> (Section 5.5)

Northeastern University, Mugar Hall, 360 Huntington Ave., Boston, MA 02115

# Litigation (Section 5.6)

None.

# Restricted Agreements (Section 5.12)

None.

# Deposit and Securities Accounts (Section 6.6)

Checking account number 3300776807 at Silicon Valley Bank

Money Market account 3300891963 at Silicon Valley Bank

#### Corporation Resolutions and Incumbency Certification Authority to Procure Loans

I certify that I am the duly elected and qualified Secretary of SERES HEALTH, INC., a Delaware corporation (the "Corporation"); that the Corporation's exact legal name is set forth above; that the Corporation is a corporation duly organized, existing and in good standing under the laws of the State of Delaware; that the following is a true and correct copy of resolutions duly adopted by the Board of Directors of the Corporation in accordance with its bylaws and applicable statutes.

#### **Copy of Resolutions:**

#### Be it Resolved, That:

- 1. Any one (1) of the following <u>President or CFO</u> (insert titles only) of the Corporation are/is authorized, for, on behalf of, and in the name of the Corporation to:
  - (a) Negotiate and procure loans, letters of credit and other credit or financial accommodations from Comerica Bank ("Bank"), a Texas banking association, from time to time, including without limitation that certain Loan and Security Agreement dated as of September , 2013, as may be subsequently amended, modified, supplemented, extended or restated from time to time.
  - (b) Discount with the Bank, commercial or other business paper belonging to the Corporation made or drawn by or upon third parties, without limit as to amount;
  - (c) Purchase, sell, exchange, assign, endorse for transfer and/or deliver certificates and/or instruments representing stocks, bonds, evidences of Indebtedness or other securities owned by the Corporation, whether or not registered in the name of the Corporation;
  - (d) Give security for any liabilities of the Corporation to the Bank by grant, security interest, assignment, lien, deed of trust or mortgage upon any real or personal property, tangible or intangible of the Corporation;
  - (e) Issue a warrant or warrants to purchase the Corporation's capital stock; and
  - (f) Execute and deliver in form and content as may be required by the Bank any and all notes, evidences of Indebtedness, applications for letters of credit, guaranties, subordination agreements, loan and security agreements, financing statements, assignments, liens, deeds of trust, mortgages, trust receipts and other agreements, instruments or documents to carry out the purposes of these Resolutions, ,and any and all amendments or modifications thereto, any or all of which may relate to all or to substantially all of the Corporation's property and assets.
- 2. Said Bank be and it is authorized and directed to pay the proceeds of any such loans or discounts as directed by the persons so authorized to sign, whether so payable to the order of any of said persons in their individual capacities or not, and whether such proceeds are deposited to the individual credit of any of said persons or not;
- 3. Any and all agreements, instruments and documents previously executed and acts and things previously done to carry out the purposes of these Resolutions are ratified, confirmed and approved as the act or acts of the Corporation.
- 4. These Resolutions shall continue in force, and the Bank may consider the holders of said offices and their signatures to be and continue to be as set forth in a certified copy of these Resolutions delivered to the Bank, until notice to the contrary in writing is duly served on the Bank (such notice to have no effect on any action previously taken by the Bank in reliance on these Resolutions).
- 5. Any person, corporation or other legal entity dealing with the Bank may rely upon a certificate signed by an officer of the Bank to effect that these Resolutions and any agreement, instrument or document executed pursuant to them are still in full force and effect and binding upon the Corporation.
- 6. The Bank may consider the holders of the offices of the Corporation and their signatures, respectively, to be and continue to be as set forth in the Certificate of the Secretary of the Corporation until notice to the contrary in writing is duly served on the Bank.

I further certify that the above Resolutions are in full force and effect as of the date of this Certificate; that these Resolutions and any borrowings or financial accommodations under these Resolutions have been properly noted in the corporate books and records, and have not been rescinded, annulled, revoked or modified; that neither the foregoing Resolutions nor any actions to be taken pursuant to them are or will be in contravention of any provision of the certificate of incorporation or bylaws of the Corporation or of any agreement, indenture or other instrument to which it is bound; and that neither the certificate of incorporation nor bylaws of the Corporation nor any agreement, indenture or other instrument to which the Corporation is a party or by which it is bound require the vote or consent of shareholders of the Corporation to authorize any act, matter or thing described in the foregoing Resolutions.

I further certify that the following named persons have been duly elected to the offices set opposite their respective names, that they continue to hold these offices at the present time, and that the signatures which appear below are the genuine, original signatures of each respectively:

# (PLEASE SUPPLY GENUINE SIGNATURES OF AUTHORIZED SIGNERS BELOW)

NAME (Type or Print)	TITLE	SIGNATURE		
David Berry	President	/s/ David Berry		
Gregg Beloff	Chief Financial Officer	/s/ Gregg Beloff		
I further certify that attached as Exhibit A hereto is a true, correct and complete copy of the Corporation's Certificate of Incorporation (including amendments), as filed with the Delaware Secretary of State. Such Certificate of Incorporation has not been amended, annulled, rescinded, revoked or supplemented, and remains in full force and effect as of the date hereof.  I further certify that attached as Exhibit B hereto is a true, correct and complete copy of Borrower's By-Laws (including amendments). Such By-Laws have not been amended, annulled, rescinded, revoked or supplemented, and remain in full force and effect as of the date hereof.				
In Witness Whereof, I have affixed my name as Secretary and September , 2013.	have caused the corporate seal (	where available) of said Corporation to be affixed on		
		/s/ David Berry		
		Name: David Berry		
		Title: President		
	***			
The Above Statements are Correct. /s/ Gregg Beloff				

Failure to complete the above when the Secretary is authorized to sign alone shall constitute a certification by the Secretary that the Secretary is the sole Shareholder, Director and Officer of the Corporation.

Name: Gregg Beloff

Title: Chief Financial Officer

# COMERICA BANK Member FDIC

# ITEMIZATION OF AMOUNT FINANCED DISBURSEMENT INSTRUCTIONS (Growth Capital Advances)

Name(s	): SERES HEALTH, INC.	. Date: September , 2013	3
\$		credited to deposit account No when Growth Capital Advances are requested or disbursed to Borrow cashiers check or wire transfer	er by
Amoun	ts paid to others on your be	ehalf:	
\$5	,000	to Comerica Bank for Facility Fee	
\$		to Bank counsel fees and expenses	
\$		to	
\$		to	
\$		TOTAL (AMOUNT FINANCED)	
Upon c	onsummation of this transa	action, this document will also serve as the authorization for Comerica Bank to disburse the loan proceeds as stated a	above.
/s/ Davi	id Berry		
Name:	David Berry		
Title:	President		



#### Agreement to Furnish Insurance to Loan and Security Agreement

(Herein called "Bank")

Borrower(s): SERES HEALTH, INC.

I understand that the Loan and Security Agreement or Deed of Trust which I executed in connection with this transaction requires me to provide a physical damage insurance policy including a Lenders Loss Payable Endorsement in favor of the Bank as shown below, within ten (10) days from the date of this agreement.

The following minimum insurance must be provided according to the terms of the security documents.

<b>VEHICL</b> Comp	OBILES, TRUCKS, RECREATIONAL ES prehensive & Collision er's Loss Payable Endorsement	$\boxtimes$	MACHINERY & EQUIPMENT:  MISCELLANEOUS PERSONAL PROPERTY  Fire & Extended Coverage  Lender's Loss Payable Endorsement  □ Breach of Warranty Endorsement
Lende	isk Hull Insurance er's Loss Payable Endorsement Breach of Warranty Endorsement		AIRCRAFT  All Risk Ground & Flight Insurance Lender's Loss Payable Endorsement  □ Breach of Warranty Endorsement
Fire, 'Lendo	E <b>HOMES</b> Theft & Combined Additional Coverage er's Loss Payable Endorsement Earthquake		REAL PROPERTY  Fire & Extended Coverage Lender's Loss Payable Endorsement  All Risk Coverage  Special Form Risk Coverage  Earthquake
☑ INVENT	URY		$\square$ Other

☑ **Other** Borrower, at its expense, shall keep the Collateral insured against loss or damage by fire, theft, explosion, sprinklers, and all other hazards and risks, and in such amounts, as ordinarily insured against by other owners in similar businesses conducted in the locations where Borrower's business is conducted on the date hereof. Borrower shall also maintain liability and other insurance in amounts and of a type that are customary to businesses similar to Borrower's.

I may obtain the required insurance from any company that is acceptable to the Bank, and will deliver proof of such coverage with an effective date of September , 2013 or earlier.

I understand and agree that if I fail to deliver proof of insurance to the Bank at the address below, or upon the lapse or cancellation of such insurance, the Bank may procure Lender's Single Interest Insurance or other similar coverage on the property. If the Bank procures insurance to protect its interest in the property described in the security documents, the cost for the insurance will be added to my indebtedness as provided in the security documents. Lender's Single Interest Insurance shall cover only the Bank's interest as a secured party, and shall become effective at the earlier of the funding date of this transaction or the date my insurance was canceled or expired. I UNDERSTAND THAT LENDER'S SINGLE INTEREST INSURANCE WILL PROVIDE ME WITH ONLY LIMITED PROTECTION AGAINST PHYSICAL DAMAGE TO THE COLLATERAL, UP TO THE BALANCE OF THE LOAN, HOWEVER, MY EQUITY IN THE PROPERTY WILL NOT BE INSURED. FURTHER, THE INSURANCE WILL NOT PROVIDE MINIMUM PUBLIC LIABILITY OR PROPERTY DAMAGE INDEMNIFICATION AND DOES NOT MEET THE REQUIREMENTS OF THE FINANCIAL RESPONSIBILITY LAW.

CALIFORNIA CIVIL CODE SECTION 2955.5. HAZARD INSURANCE DISCLOSURE: No lender shall require a borrower, as a condition of receiving or maintaining a loan secured by real property, to provide hazard insurance coverage against risks to the improvements on that real property in an amount exceeding the replacement value of the improvements on the property.

Bank Address for Insurance Document	s:
Comerica Bank – Collateral Operations,	
Mail Code 6514	
1508 W. Mockingbird Lane	
Dallas, Texas 75235	

agent or company) any information necessary to obtain the insurance coverage required.

OWNER(S) OF COLLATERAL:

DATED: September , 2013

SERES HEALTH, INC.

/s/ David Berry

Name: David Berry
Title: President

INSURANCE VERIFICATION
Date \_\_\_\_\_\_ Phone \_\_\_\_\_
Agents Name \_\_\_\_\_ Person Talked To \_\_\_\_\_\_

Agents Address
Insurance Company
Policy Number(s)

I acknowledge having read the provisions of this agreement, and agree to its terms. I authorize the Bank to provide to any person (including any insurance

To: \_\_\_\_

Comments:

Effective Dates: From

Deductible \$



# AUTOMATIC LOAN PAYMENT AUTHORIZATION

					Date: <u>Septembe</u>	r , 2013
Obl <sup>:</sup>	igor Na	ame: SERI	ES HEALTH, INC.			
	igor Nı			Lender's Cost Center #:		
Add	dress:	161 First Street, Cam	bridge, MA 02142			
belo mod	ow and dification	all renewals, extensions	, modifications and/or sub	stitutions thereof. This authoriz	ted below for the payments due on the loation will remain in effect unless the undible for all amounts outstanding to Bank	ersigned requests a
×			zation for <u>all</u> payments on principal, interest, fees, cos		gs, as and when such payments come due	(which payments
				only the specific borrowing ide at, fees, costs, and expenses).	ntified below, as and when such payment	es come due (which
Spe	cific O	bligation Number:				
	Auto	omatic Payment Authori	zation for less than all pay	ments on only the specific borr	owing identified below, as and when such	payments come due.
Spe	cific O	bligation Number:				
		Principal and Interest	payments only			
		Principal payments on	ly			
		Interest payments only	I			
		SPECIAL INSTRUCT	ΓΙΟNS/IRREGULAR PAY	MENT INSTRUCTIONS		
whe	en there	are available funds) un	less that day is a Saturday,		on the dates such payments become due ich case such payments will be charged o	
Acc	ount to	be Charged:				
Trai Nun		f lead days to issue billir	ng .lls pursuant to account reso	olution)		
					BORROWER:	
					SERES HEALTH, INC.	
					By: /s/ David Berry	
					Name: David Berry	
					Title: President	

#### **USA PATRIOT ACT**

### NOTICE OF CUSTOMER IDENTIFICATION

#### IMPORTANT INFORMATION ABOUT PROCEDURES FOR OPENING A NEW ACCOUNT

To help the government fight the funding of terrorism and money laundering activities, Federal law requires all financial institutions to obtain, verify, and record information that identifies each person who opens an account.

WHAT THIS MEANS FOR YOU: when you open an account, we will ask your name, address, date of birth, and other information that will allow us to identify you. We may also ask to see your driver's license or other identifying documents.

# COMERICA BANK CLIENT AUTHORIZATION

Fax

# **General Authorization**

/s/ David Berry

E-Mail

September , 2013

I hereby authorize Comerica Bank to use my company name, logo, and information relating to our banking relationship in its marketing and advertising campaigns which is intended for Comerica Bank's customers, prospects and shareholders.

Comerica Bank will forward any advertising or article including client for prior review and approval.

, o, _ a a _ a ,
Printed name: David Berry
Title: President
SERES HEALTH, INC.
Company
161 First Street
Mailing Address
Cambridge, MA 02142
City, State, Zip Code
617-868-1888
Phone Number
617-868-1115
Fax Number
dberry@FlagshipVentures.com

DEBTOR: SERES HEALTH, INC.

SECURED PARTY: COMERICA BANK

#### **EXHIBIT A to UCC Financing Statement**

#### COLLATERAL DESCRIPTION ATTACHMENT TO UCC NATIONAL FINANCING FORM

All personal property of SERES HEALTH, INC., a Delaware corporation (herein referred to as "Borrower" or "Debtor") whether presently existing or hereafter created or acquired, and wherever located, including, but not limited to:

- (a) all accounts (including health-care-insurance receivables), chattel paper (including tangible and electronic chattel paper), deposit accounts, documents (including negotiable documents), equipment (including all accessions and additions thereto), financial assets, general intangibles (including payment intangibles and software), goods (including fixtures), instruments (including promissory notes), inventory (including all goods held for sale or lease or to be furnished under a contract of service, and including returns and repossessions), investment property (including securities and securities entitlements), letter of credit rights, money, and all of Debtor's books and records with respect to any of the foregoing, and the computers and equipment containing said books and records; and
- (b) any and all cash proceeds and/or noncash proceeds of any of the foregoing, including, without limitation, insurance proceeds, and all supporting obligations and the security therefor or for any right to payment.

Notwithstanding the foregoing, the Collateral shall not include (i) property that is nonassignable by its terms without the consent of the licensor thereof or another party (but only to the extent such prohibition on transfer is enforceable under applicable law, including, without limitation, Sections 9406 and 9408 of the Code), (ii) property where the granting of a security interest therein is contrary to applicable law, provided that upon the cessation of any such restriction or prohibition, such property shall automatically become part of the Collateral, (iii) more than sixty five percent (65%) of the voting power of all classes of capital stock of a controlled foreign corporation (as defined in the Internal Revenue Code of 1986, as amended, and the regulations thereunder) entitled to vote where the pledge of a greater percentage would result in material adverse tax consequences to Borrower, or (iv) Debtor's copyrights, patents, trademarks, servicemarks and applications therefor, now owned or hereafter acquired, or any claims for damages by way of any past, present and future infringement of any of the foregoing (collectively, the "Intellectual Property"); provided, however, that the Collateral shall include all accounts, all general intangibles that consist of rights to payment, and all proceeds from the sale, licensing or disposition of all or any part of, or rights in, any property, including the Intellectual Property (the "Rights to Payment"). Notwithstanding the foregoing, if a judicial authority (including a U.S. Bankruptcy Court) holds that a security interest in the underlying Intellectual Property is necessary to have a security interest in the Rights to Payment, then the Collateral shall automatically, and effective as of September , 2013, include the Intellectual Property to the extent necessary to permit perfection of Secured Party's security interest in the Rights to Payment.

All terms above have the meanings given to them in the California Uniform Commercial Code, as amended or supplemented from time to time.

# PRIME REFERENCED RATE ADDENDUM TO LOAN AND SECURITY AGREEMENT

This Prime Referenced Rate Addendum to Loan and Security Agreement (this "Addendum") is entered into as of September , 2013, by and between COMERICA BANK ("Bank") and SERES HEALTH, INC., a Delaware corporation ("Borrower"). This Addendum supplements the terms of the Loan and Security Agreement dated as of the date hereof by and between Borrower and Bank (as the same may be amended, modified, supplemented, extended or restated from time to time, collectively, the "Agreement").

- 1. <u>Definitions</u>. As used in this Addendum, the following terms shall have the following meanings. Initially capitalized terms used and not defined in this Addendum shall have the meanings ascribed thereto in the Agreement.
  - a. "Applicable Margin" means three percent (3.00%) per annum.
- b. "Business Day" means any day, other than a Saturday, Sunday or any other day designated as a holiday under Federal or applicable State statute or regulation, on which Bank is open for all or substantially all of its domestic and international business (including dealings in foreign exchange) in San Jose, California, and, in respect of notices and determinations relating to the Daily Adjusting LIBOR Rate, also a day on which dealings in dollar deposits are also carried on the London interbank market and on which banks are open for business in London, England.
- c. "Change in Law" means the occurrence, after the date hereof, of any of the following: (i) the adoption or introduction of, or any change in any applicable law, treaty, rule or regulation (whether domestic or foreign) now or hereafter in effect and whether or not applicable to Bank on such date, or (ii) any change in interpretation, administration or implementation thereof of any such law, treaty, rule or regulation by any Governmental Authority, or (iii) the issuance, making or implementation by any Governmental Authority of any interpretation, administration, request, regulation, guideline, or directive (whether or not having the force of law), including any risk-based capital guidelines. For purposes of this definition, (x) a change in law, treaty, rule, regulation, interpretation or implementation shall include, without limitation, any change made or which becomes effective on the basis of a law, treaty, rule, regulation, interpretation administration or implementation then in force, the effective date of which change is delayed by the terms of such law, treaty, rule, regulation, interpretation, administration or implementation, and (y) the Dodd-Frank Wall Street Reform and Consumer Protection Act (Pub. L. 111-203, H.R. 4173) and all requests, rules, regulations, guidelines, interpretations or directives promulgated thereunder or issued in connection therewith shall be deemed to be a "Change in Law", regardless of the date enacted, adopted, issued or promulgated, whether before or after the date hereof, and (z) all requests, rules, guidelines or directives promulgated by the Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States regulatory authorities, in each case pursuant to Basel III, shall each be deemed to be a "Change in Law", regardless of the date enacted, adopted, issued or implemented.
  - d. "Daily Adjusting LIBOR Rate" means, for any day, a per annum interest rate which is equal to the quotient of the following:
    - (1) for any day, the per annum rate of interest determined on the basis of the rate for deposits in United States Dollars for a period equal to one (1) month appearing on Page BBAM of the Bloomberg Financial Markets Information Service as of 8:00 a.m. (California time) (or as soon thereafter as practical) on such day, or if such day is not a Business Day, on the immediately preceding Business Day. In the event that such rate does not appear on Page BBAM of the Bloomberg Financial Markets Information Service (or otherwise on such Service) on any day, the "Daily Adjusting LIBOR Rate" for such day shall be determined by reference to such other publicly available service for displaying eurodollar rates as may be reasonably selected by Bank, or in the absence of such other service, the "Daily Adjusting LIBOR Rate" for such day shall, instead, be determined based upon the average of the rates at which Bank is offered dollar deposits at or about 8:00 a.m. (California time) (or as soon thereafter as practical), on such day, or if such day is not a Business Day, on the immediately preceding Business Day, in the interbank eurodollar market in an amount comparable to the outstanding principal amount of the Obligations and for a period equal to one (1) month;

divided by

- (2) 1.00 minus the maximum rate (expressed as a decimal) on such day at which Bank is required to maintain reserves on "Euro-currency Liabilities" as defined in and pursuant to Regulation D of the Board of Governors of the Federal Reserve System or, if such regulation or definition is modified, and as long as Bank is required to maintain reserves against a category of liabilities which includes eurodollar deposits or includes a category of assets which includes eurodollar loans, the rate at which such reserves are required to be maintained on such category.
- e. "Governmental Authority" means the government of the United States of America or any other nation, or of any political subdivision thereof, whether state or local, and any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to government (including, without limitation, any supranational bodies such as the European Union or the European Central Bank).
- f. "LIBOR Lending Office" means Bank's office located in the Cayman Islands, British West Indies, or such other branch of Bank, domestic or foreign, as it may hereafter designate as its LIBOR Lending Office by notice to Borrower.
- g. "Prime Rate" means the per annum interest rate established by Bank as its prime rate for its borrowers, as such rate may vary from time to time, which rate is not necessarily the lowest rate on loans made by Bank at any such time.
- h. "Prime Referenced Rate" means, for any day, a per annum interest rate which is equal to the Prime Rate in effect on such day, but in no event and at no time shall the Prime Referenced Rate be less than the sum of the Daily Adjusting LIBOR Rate for such day plus two and one-half percent (2.50%) per annum. If, at any time, Bank determines that it is unable to determine or ascertain the Daily Adjusting LIBOR Rate for any day, the Prime Referenced Rate for each such day shall be the Prime Rate in effect at such time, but not less than two and one-half percent (2.50%) per annum.
- 2. <u>Interest Rate</u>. Subject to the terms and conditions of this Addendum, the Obligations under the Agreement shall bear interest at the Prime Referenced Rate plus the Applicable Margin.
- 3. <u>Payment of Interest</u>. Accrued and unpaid interest on the unpaid balance of the Obligations outstanding under the Agreement shall be payable monthly, in arrears, on the first day of each month, until maturity (whether as stated herein, by acceleration, or otherwise). In the event that any payment under this Addendum becomes due and payable on any day which is not a Business Day, the due date thereof shall be extended to the next succeeding Business Day, and, to the extent applicable, interest shall continue to accrue and be payable thereon during such extension at the rates set forth in this Addendum. Interest accruing hereunder shall be computed on the basis of a year of 360 days, and shall be assessed for the actual number of days elapsed, and in such computation, effect shall be given to any change in the applicable interest rate as a result of any change in the Prime Referenced Rate on the date of each such change.
- 4. <u>Bank's Records</u>. The amount and date of each advance under the Agreement, its applicable interest rate, and the amount and date of any repayment shall be noted on Bank's records, which records shall be conclusive evidence thereof, absent manifest error; <u>provided</u>, <u>however</u>, any failure by Bank to make any such notation, or any error in any such notation, shall not relieve Borrower of its obligations to repay Bank all amounts payable by Borrower to Bank under or pursuant to this Addendum and the Agreement, when due in accordance with the terms hereof.

- 5. <u>Default Interest Rate</u>. From and after the occurrence of any Event of Default, and for so long as any such Event of Default remains unremedied or uncured thereafter, the Obligations outstanding under the Agreement shall bear interest at a per annum rate of five percent (5%) above the otherwise applicable interest rate hereunder, which interest shall be payable upon demand. In addition to the foregoing, a late payment charge equal to five percent (5%) of each late payment hereunder may be charged on any payment not received by Bank within ten (10) calendar days after the payment due date therefor, but acceptance of payment of any such charge shall not constitute a waiver of any Event of Default under the Agreement. In no event shall the interest payable under this Addendum and the Agreement at any time exceed the maximum rate permitted by law.
- 6. <u>Prepayment</u>. Borrower may prepay all or part of the outstanding balance of any Obligations at any time without premium or penalty. Any prepayment hereunder shall also be accompanied by the payment of all accrued and unpaid interest on the amount so prepaid. Borrower hereby acknowledges and agrees that the foregoing shall not, in any way whatsoever, limit, restrict, or otherwise affect Bank's right to make demand for payment of all or any part of the Obligations under the Agreement due on a demand basis in Bank's sole and absolute discretion.

#### 7. Regulatory Developments or Other Circumstances Relating to the Daily Adjusting LIBOR Rate.

a. If any Change in Law shall: (a) subject Bank to any tax, duty or other charge with respect to this Addendum or any Obligations under the Agreement, or shall change the basis of taxation of payments to Bank of the principal of or interest under this Addendum or any other amounts due under this Addendum in respect thereof (except for changes in the rate of tax on the overall net income of Bank or its LIBOR Lending Office imposed by the jurisdiction in which Bank's principal executive office or LIBOR Lending Office is located); or (b) impose, modify or deem applicable any reserve (including, without limitation, any imposed by the Board of Governors of the Federal Reserve System), special deposit or similar requirement against assets of, deposits with or for the account of, or credit extended by Bank, or shall impose on Bank or the foreign exchange and interbank markets any other condition affecting this Addendum or the Obligations; and the result of any of the foregoing is to increase the cost to Bank of maintaining any part of the Obligations or to reduce the amount of any sum received or receivable by Bank under this Addendum by an amount deemed by Bank to be material, then Borrower shall pay to Bank, within fifteen (15) days of Borrower's receipt of written notice from Bank demanding such compensation, such additional amount or amounts as will compensate Bank for such increased cost or reduction. A certificate of Bank, prepared in good faith and in reasonable detail by Bank and submitted by Bank to Borrower, setting forth the basis for determining such additional amount or amounts necessary to compensate Bank shall be conclusive and binding for all purposes, absent manifest error.

b. In the event that any Change in Law affects or would affect the amount of capital required or expected to be maintained by Bank (or any corporation controlling Bank), and Bank determines that the amount of such capital is increased by or based upon the existence of any obligations of Bank hereunder or the maintaining of any Obligations, and such increase has the effect of reducing the rate of return on Bank's (or such controlling corporation's) capital as a consequence of such obligations or the maintaining of such Obligations to a level below that which Bank (or such controlling corporation) could have achieved but for such circumstances (taking into consideration its policies with respect to capital adequacy), then Borrower shall pay to Bank, within fifteen (15) days of Borrower's receipt of written notice from Bank demanding such compensation, additional amounts as are sufficient to compensate Bank (or such controlling corporation) for any increase in the amount of capital and reduced rate of return which Bank reasonably determines to be allocable to the existence of any obligations of Bank hereunder or to maintaining any Obligations. A certificate of Bank as to the amount of such compensation, prepared in good faith and in reasonable detail by Bank and submitted by Bank to Borrower, shall be conclusive and binding for all purposes absent manifest error.

- 8. Legal Effect. Except as specifically modified hereby, all of the terms and conditions of the Agreement remain in full force and effect.
- 9. <u>Conflicts</u>. As to the matters specifically the subject of this Addendum, in the event of any conflict between this Addendum and the Agreement, the terms of this Addendum shall control.

(remainder of page left blank)

IN WITNESS WHEREOF, the parties have agreed to the foregoing as of the date first set forth above.			
COME	RICA BANK	SERES	HEALTH, INC.
By:	/s/ Jason Pan	By:	/s/ David Berry
Name:	Jason Pan	Name:	David Berry
Title:	Vice President	Title:	President

# FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

This First Amendment to Loan and Security Agreement (this "Amendment") is entered into as of December 22, 2014, by and between COMERICA BANK ("Bank") and SERES HEALTH, INC., a Delaware corporation ("Borrower").

#### **RECITALS**

- A. Borrower and Bank are parties to that certain Loan and Security Agreement dated as of September 9, 2013, as amended, modified, supplemented, extended or restated from time to time (collectively, the "Agreement").
- B. Borrower has requested that Bank amend certain provisions of the Agreement, and, while Bank is under no obligation to do so, Bank is willing to amend the Agreement in accordance with and subject to the terms and conditions of this Amendment.

NOW, THEREFORE, for good and valuable consideration, the receipt of which is hereby acknowledged, the parties agree as follows:

- 1. Amendments to the Agreement.
  - 1.1 Section 5.10 of the Agreement is hereby amended and restated in its entirety to read as follows:
  - 5.10 <u>Subsidiaries</u>. Borrower does not own any stock, partnership interest or other equity securities of any Person, except for Permitted Investments. As of the First Amendment Closing Date, Borrower has no Subsidiaries other than Seres Securities. Series Securities is an MSC Subsidiary and qualifies as an Excluded MSC Subsidiary.
  - 1.2 Section 6.6 of the Agreement is hereby amended and restated in its entirety to read as follows:
  - 6.6 <u>Accounts</u>. Borrower shall, and shall cause all of its Subsidiaries (other than MSC Subsidiaries) to maintain all its and their depository, operating, cash management accounts with Bank and all of its and their primary investment and securities accounts with Bank. Seres Securities may maintain assets in deposit or securities accounts outside of Bank; <u>provided however</u>, no transfers or withdrawals from such accounts shall be permitted except to a deposit account of Borrower maintained with Bank.
  - 1.3 Section 6.10 of the Agreement is hereby amended and restated in its entirety to read as follows:
  - 6.10 <u>Creation/Acquisition of Subsidiaries</u>. Without limiting the generality of any other provision hereof, in the event Borrower or any Subsidiary creates or acquires any Subsidiary, Borrower and such Subsidiary shall (a) promptly notify Bank in writing of the creation or acquisition of such new Subsidiary, (b) take all such action as may be reasonably required by Bank to cause each such Subsidiary (other than an Excluded Subsidiary) to guarantee the Obligations of Borrower under the Loan Documents and, in each case, grant a continuing pledge and security interest in and to the property and assets of such Subsidiary (substantially as described on <u>Exhibit B</u> hereto), and (c) Borrower (or any intermediate Subsidiary holding the Equity Interests in such Subsidiary) shall grant and pledge to Bank a perfected security interest in the Equity Interests of such Subsidiary (unless it is an Excluded MSC Subsidiary and such grant or pledge would result in material adverse tax consequences to Bank); provided that Bank shall not have a security interest in more than sixty five percent (65%) of the voting Equity Interests of any Excluded Foreign Subsidiary.

1.4 The Agreement is hereby amended by adding a new Section 7.12 to read as follows:

7.12 MSC Subsidiaries. Cause or permit (i) any MSC Subsidiary to incur or be liable for any Indebtedness other than expenses incurred in the ordinary course of its business that are incidental to the maintenance of its existence and ownership of its assets, (ii) any Lien to exist with respect to any assets of any MSC Subsidiary, and (iii) any MSC Subsidiary to transfer or withdraw funds, securities or other assets from its deposit, investment or securities accounts other than transfers to deposit accounts of Borrower maintained with Bank. Borrower shall provide to Bank prompt written notice of each transfer of funds to any MSC Subsidiary.

1.5 Exhibit A to the Agreement is hereby amended by adding or amending and restating the following defined terms to read as follows:

"Excluded MSC Subsidiary" means an MSC Subsidiary as to which all of the following apply (i) it is qualified as a Massachusetts securities corporation, (ii) the guaranteeing of the Obligations by such MSC Subsidiary and the granting of a Lien on any of its assets to secure the Obligations, would result in material adverse tax consequences to Borrower, (iii) all of its assets are maintained in deposit accounts maintained that have been disclosed in writing to Bank, (iv) such MSC Subsidiary has no operations or business activities other than the maintenance, investment and management of funds transferred from Borrower from the proceeds of the sale and issuance of Borrower's Equity Interests and Subordinated Debt, (v) its Equity Interests are pledged to Bank as security for the Obligations and all original share certificates have been promptly delivered to Bank as Collateral together with undated stock powers duly executed in blank (unless the pledge of such Equity Interests would result in material adverse tax consequences to Borrower), (vi) such MSC Subsidiary has no outstanding Indebtedness other than expenses incurred in the ordinary course of its business that are incidental to the maintenance of its existence and ownership of its assets, and (vii) no Liens exist with respect to any of its assets or properties.

"Excluded Subsidiary" means (a) each Excluded Foreign Subsidiary, and (b) each Excluded MSC Subsidiary.

"First Amendment Closing Date" means December , 2014.

"MSC Subsidiary" means a Subsidiary of Borrower that is a corporation that qualifies as a Massachusetts securities corporation by meeting the requirements of Chapter 63, Section 38B of the Massachusetts General Laws.

"Seres Securities" means Seres Therapeutics Securities Corporation, a Massachusetts corporation.

- 1.6 Exhibit A to the Agreement is further amended by amending and restating paragraph (e) of the definition of "Permitted Investments" in its entirety to read as follows:
  - (e) (i) Investments of wholly-owned Subsidiaries of Borrower in or to other wholly-owned Subsidiaries of Borrower or Borrower; (ii) Investments by Borrower in its wholly-owned Subsidiaries (other than MSC Subsidiaries) not to exceed Five Hundred Thousand Dollars (\$500,000) in the aggregate in any fiscal year; (iii) Investments by Borrower in MSC Subsidiaries to the extent of the cash proceeds of the sale and issuance of Borrower's Equity Interests and Subordinated Debt, so long as no Event of Default has occurred and is continuing at the time of such Investment; and (iv) Investments by Borrower in an MSC Subsidiary (which, at the time of the Investment, has no assets) in amounts and to the extent reasonably necessary to cover such MSC Subsidiary's taxes, bank fees and other ordinary course of business operating expenses, if any, so long as no Event of Default has occurred and is continuing at the time of such transfer;

- 1.7 Exhibit B to the Agreement is hereby amended in its entirety and replaced with Exhibit B attached hereto.
- 2. <u>Consent</u>. Bank hereby consents to the formation by Borrower of Series Securities as a wholly-owned MSC Subsidiary. Bank's consent: (a) in no way shall be deemed to be a waiver by Bank of, or an agreement by Bank to waive, any covenant, liability or obligation of Borrower or any other Person or to waive any right, power, or remedy of Bank, except as expressly set forth herein; (b) shall not limit or impair Bank's right to demand strict performance of Borrower's liabilities and obligations to Bank and the Obligations under the Agreement and the other Loan Documents at all times following the date hereof; (c) in no way shall obligate Bank to make any future waivers, consents or modifications to the Agreement or any other Loan Document; and (d) is not a continuing waiver with respect to any failure to perform any Obligation. Borrower acknowledges and agrees that Bank is relying upon Borrower's representations, warranties and agreements, as set forth herein and in the Loan Documents in granting the foregoing waiver and consent.
- 3. <u>No Waivers</u>. No course of dealing on the part of Bank or its officers, nor any failure or delay in the exercise of any right by Bank, shall operate as a waiver thereof, and any single or partial exercise of any such right shall not preclude any later exercise of any such right. Bank's failure at any time to require strict performance by Borrower of any provision shall not affect any right of Bank thereafter to demand strict compliance and performance. Any suspension or waiver of a right must be in writing signed by an officer of Bank.
- 4. Miscellaneous. Unless otherwise defined, all initially capitalized terms in this Amendment shall be as defined in the Agreement. The Agreement, as amended hereby, shall be and remain in full force and effect in accordance with its terms and hereby is ratified and confirmed in all respects. Except as expressly set forth herein, the execution, delivery, and performance of this Amendment shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of Bank under the Agreement, as in effect prior to the date hereof. Borrower ratifies and reaffirms the continuing effectiveness of all promissory notes, guaranties, security agreements, mortgages, deeds of trust, environmental agreements, and all other instruments, documents and agreements entered into in connection with the Agreement. Borrower hereby further affirms its absolute and unconditional promise to pay to Bank the Growth Capital Advances, other Credit Extensions all other amounts due under the Letters of Credit and the other Loan Documents (including, without limitation, the Obligations), at the times and in the amounts provided for therein. Borrower confirms and agrees that the obligations of Borrower to Bank under the Agreement as supplemented hereby are secured by and entitled to the benefits of the Loan Documents. The parties agree that this Amendment shall be deemed to be one of the Loan Documents under the Agreement. Nothing in this Amendment shall constitute a satisfaction of any of Borrower's Obligations.
  - 5. Representations and Warranties. In order to induce Bank to enter into this Amendment, Borrower hereby represents and warrants to Bank as follows:
- 5.1 The representations and warranties contained in the Agreement and the other Loan Documents were true and correct in all material respects when made and continue to be true and correct in all material respects as of the date of this Amendment (provided, however, that those representations and warranties expressly referring to another date shall be true, correct and complete in all material respects as of such date).
- 5.2 Both before and immediately after giving effect to this Amendment and the other transactions contemplated hereby, no Event of Default, or other event or circumstance that with the giving of notice or the passage of time could become an Event of Default, has occurred and is continuing.
- 5.3 The execution, delivery, and performance by Borrower of this Amendment and the other documents, instruments and agreements delivered or to be delivered to Bank in connection herewith (i) are within the corporate powers of Borrower and have been duly authorized by all necessary corporate action on the part of Borrower, (ii) do not require any governmental or third party consents, except those which have been duly obtained and are in full force and effect, (iii) do not and will not conflict with any requirement of law, Borrower's articles or certificate of incorporation, bylaws, partnership agreement, operating agreement, minutes or resolutions, (iv) after giving effect to this Amendment, do not result in any breach of or constitute a default under any agreement or instrument to which Borrower or any of its Subsidiaries is a party or by which Borrower or any of its Subsidiaries or their respective properties are bound, and (v) do not result in or require the creation or imposition of any mortgage, deed of trust, pledge, lien, security interest or other charge or encumbrance of any nature upon any of the assets or properties of Borrower, other than those in favor of Bank.

- 5.4 This Amendment and the other instruments and agreements delivered or to be delivered to Bank in connection herewith have been duly executed and delivered by Borrower and constitute the legal, valid, and binding obligation of Borrower, enforceable against Borrower in accordance with their respective terms, except to the extent that (i) enforcement may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws of general application affecting the rights and remedies of creditors, (ii) enforcement may be subject to general principles of equity, and (iii) the availability of the remedies of specific performance and injunctive relief may be subject to the discretion of the court before which any proceedings for such remedies may be brought.
- 5.5 Borrower has no right of offset, defense, counterclaim, dispute or disagreement of any kind or nature whatsoever with respect to any of its liabilities, obligations or indebtedness arising under or in connection with any Loan Document.
- 6. <u>Conditions Precedent</u>. As a condition to the effectiveness of this Amendment, Bank shall have received, in form and substance satisfactory to Bank, the following:
  - 6.1 this Amendment, duly executed by Borrower;
  - 6.2 a certificate of the Secretary of Borrower with respect to resolutions and incumbency;
  - 6.3 all Bank Expenses incurred through the date of this Amendment, which may be debited from any of Borrower's accounts; and
- 6.4 such other documents, instruments and certificates and completion of such other matters, as Bank may reasonably deem necessary or appropriate.
- 7. <u>Counterparts</u>. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

[Remainder of Page Left Blank]

SER	ES HEALTH, INC.
By: Title	/s/ Eric Shaff : CFO
COM	MERICA BANK
By: Title	/s/ Jason Pan : Vice President

IN WITNESS WHEREOF, the undersigned have executed this Amendment as of the first date above written.

DEBTOR: SERES HEALTH, INC.

SECURED PARTY:

#### **COMERICA BANK**

#### **EXHIBIT B**

#### COLLATERAL DESCRIPTION ATTACHMENT TO LOAN AND SECURITY AGREEMENT

All personal property of SERES HEALTH, INC., a Delaware corporation (herein referred to as "Borrower" or "Debtor") whether presently existing or hereafter created or acquired, and wherever located, including, but not limited to:

- (a) all accounts (including health-care-insurance receivables), chattel paper (including tangible and electronic chattel paper), deposit accounts, documents (including negotiable documents), equipment (including all accessions and additions thereto), financial assets, general intangibles (including payment intangibles and software), goods (including fixtures), instruments (including promissory notes), inventory (including all goods held for sale or lease or to be furnished under a contract of service, and including returns and repossessions), investment property (including securities and securities entitlements), letter of credit rights, money, and all of Debtor's books and records with respect to any of the foregoing, and the computers and equipment containing said books and records; and
- (b) any and all cash proceeds and/or noncash proceeds of any of the foregoing, including, without limitation, insurance proceeds, and all supporting obligations and the security therefor or for any right to payment.

Notwithstanding the foregoing, the Collateral shall not include (i) property that is nonassignable by its terms without the consent of the licensor thereof or another party (but only to the extent such prohibition on transfer is enforceable under applicable law, including, without limitation, Sections 9406 and 9408 of the Code), (ii) property where the granting of a security interest therein is contrary to applicable law, provided that upon the cessation of any such restriction or prohibition, such property shall automatically become part of the Collateral, (iii) more than sixty five percent (65%) of the voting power of all classes of capital stock of an Excluded Foreign Subsidiary, (iv) the capital stock issued by any MSC Subsidiary to the extent the pledge of such shares to Bank would result in material adverse tax consequences to Borrower, or (v) any copyrights, patents, trademarks, servicemarks and applications therefor, now owned or hereafter acquired, or any claims for damages by way of any past, present and future infringement of any of the foregoing (collectively, the "Intellectual Property"); provided, however, that the Collateral shall include all accounts, all general intangibles that consist of rights to payment, and all proceeds from the sale, licensing or disposition of all or any part of, or rights in, any property, including the Intellectual Property (the "Rights to Payment"). Notwithstanding the foregoing, if a judicial authority (including a U.S. Bankruptcy Court) holds that a security interest in the underlying Intellectual Property is necessary to have a security interest in the Rights to Payment, then the Collateral shall automatically, and effective as of September 9, 2013, include the Intellectual Property to the extent necessary to permit perfection of Bank's security interest in the Rights to Payment.

All terms above have the meanings given to them in the California Uniform Commercial Code, as amended or supplemented from time to time.

# SUBSIDIARIES OF SERES HEALTH, INC.

<u>Legal Name of Subsidiary</u> Seres Therapeutics Securities Corporation

Jurisdiction of Organization

Massachusetts

# LATHAM & WATKINS LLP

January 27, 2015

#### VIA EDGAR AND HAND DELIVERY

Mr. Jeffrey P. Riedler Assistant Director U.S. Securities and Exchange Commission Division of Corporation Finance 100 F Street, N.E. Mail Stop 3720 Washington, D.C. 20549 John Hancock Tower, 27th Floor 200 Clarendon Street Boston, Massachusetts 02116 Tel: +1.617.948.6000 Fax: +1.617.948.6001 www.lw.com

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Houston

Shanohai

Silicon Valley

Re: Seres Health, Inc. Registration Statement on Form S-1 (CIK No. 0001609809)

#### Dear Mr. Riedler:

On behalf of Seres Health, Inc., a Delaware corporation (the "Company"), we are transmitting this letter in response to comments received from the staff (the "Staff") of the Securities and Exchange Commission (the "Commission") by letter dated January 8, 2015 with respect to the Company's Registration Statement on Form S-1 (the "Registration Statement"). This letter is being submitted together with Amendment No. 1 ("Amendment No. 1") to the Registration Statement, which has been revised to address various of the Staff's comments. The bold and numbered paragraphs below correspond to the numbered paragraphs in the Staff's letter and are followed by the Company's responses. For the Staff's convenience, we are also sending, by courier, copies of this letter and marked copies of Amendment No. 1 that reflect changes made to the Registration Statement.

#### **Prospectus Summary, page 1**

1. We note your disclosure that you plan to begin enrollment of your Phase 3 trials for SER-109 by the end of the first quarter of 2015. We also note your disclosure at page 99 that prior to commencing your Phase 3 clinical trial of SER-109, you will need to complete validation studies demonstrating the ability of the process to inactivate and clear the potential pathogens of concern. Please revise your disclosure here and throughout the prospectus to reflect the timing of the required validation studies and how they impact the commencement of Phase 3 trials for SER-109.

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 3, 84, 92, 97, and 100 of Amendment No. 1.

#### LATHAM&WATKINSup

2. We note your disclosure that you are a first-in-field microbiome therapeutics platform company. Please reconcile your statement that you are "first-in-field" with your risk factor discussion on page 25 which discusses several competitors in the microbiome therapeutics field. Please make any corresponding changes to the prospectus, as necessary to clarify you reference.

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 1, 64, 82 and F-7 of Amendment No. 1.

Please describe the meaning and significance of the term "bedside-to-bench-to-bedside approach" at your first reference.

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 2 and 83 of Amendment No. 1.

4. Please describe the meaning and significance of the term "cytotoxic drugs."

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 2 and 93 of Amendment No. 1.

#### **Risk Factors**

#### Even if this offering is successful we will need additional funding..., page 13

5. Please expand your disclosure in this risk factor to quantify the amount of your existing cash and cash equivalents.

Response: In response to the Staff's comment, the Company has revised the disclosure on page 13 of Amendment No. 1.

### If we are unable to adequately protect our proprietary technology..., page 34

6. Please describe the meaning and significance of the term "PCT," at your first reference in this risk factor.

Response: In response to the Staff's comment, the Company has revised the disclosure on page 35 of Amendment No. 1.

#### **Industry sand Other Data, page 53**

7. We note your statements that you have not independently verified market and industry data from third-party sources or internal company research or market definitions by any independent source. Please revise your disclosure to remove these statements as it is improper to disclaim liability for information presented in the prospectus.

#### LATHAM&WATKINSup

Response: In response to the Staff's comment, the Company has revised the disclosure on page 53 of Amendment No. 1.

#### Use of Proceeds, page 54

- 8. Pursuant to the requirements of Item 504 of Regulation S-K, where you have identified the specific purposes for which you intend to use the offering proceeds, you must disclose the approximate amount of proceeds intended to be used for each such purpose. Accordingly, please revise your disclosure to estimate the amount of proceeds that will be used for each of the following:
  - to advance the clinical development of SER-109 for the prevention of further recurrences of CDI in patients suffering from recurrent CDI through a Phase 3 clinical trial;
  - to continue pre-clinical studies and, subsequently, Phase 1 clinical development of SER-262 to prevent an initial recurrence of CDI following antibiotic treatment of primary CDI;
  - to conduct pre-clinical and clinical research of microbiome therapeutics in non-*C. difficile* infections, metabolic and inflammatory diseases, including our product candidates SER-301 and SER-155; and
  - to fund manufacturing activity, including scale up of the manufacturing process for SER-109 and development of our manufacturing facilities,

We note your statement that you 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 you will actually spend on the uses set forth, however, that does not relieve you of your obligation to provide investors with an approximation of the manner in which you will allocate funds from the offering.

Response: In response to the Staff's comment, the Company has revised the disclosure on page 54 of Amendment No. 1.

9. Please expand your disclosure to include how far in the clinical development process you expect the proceeds from this offering will enable you to reach for each of the product candidates.

Response: In response to the Staff's comment, the Company has revised the disclosure on page 54 of Amendment No. 1.

10. Please expand your disclosure to indicate whether the amount of proceeds allocated for the funding of manufacturing activity with respect to SER-109 will be sufficient to accomplish your plans. If not, please revise your disclosure accordingly.

#### LATHAM&WATKINS LLP

Response: In response to the Staff's comment, the Company has revised the disclosure on page 54 of Amendment No. 1.

# Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Significant Judgments and Estimates Stock-Based Compensation, page 68

11. We may have additional comments on your accounting for equity issuances including stock compensation and beneficial conversion features.

Once you have an estimated offering price, please provide us an analysis explaining the reasons for the differences between recent valuations of your common stock leading up to the IPO and the estimated offering price.

Response: The Company acknowledges the Staff's comment and will provide the Staff with the analysis requested once the Company has an estimated offering price.

#### Business, page 82

#### <u>Understanding the Microbiome and its impact on disease, page 87</u>

2. Please describe the meaning and significance of the term "commensal bacteria."

Response: In response to the Staff's comment, the Company has revised the disclosure on page 87 of Amendment No. 1.

#### Our Microbiome Therapeutics Platform, page 88

13. We note that the graphics on page 88 include images, charts, and graphs with very small text. Please revise the graphics to provide a readable presentation for a potential investor. In addition, please define the term "POC."

Response: In response to the Staff's comment, the Company has revised the graphic on page 88 of Amendment No. 1.

#### Ecobiotic Candidate Design, page 89

14. Please define the terms "phenotype" and "Phylogentic R-Group" as they are used in your chart at page 89.

Response: In response to the Staff's comment, the Company has revised the graphic on page 89 of Amendment No. 1.

#### LATHAM&WATKINSup

15. Please increase the size of the labels and text of the charts on page 101 to provide a readable presentation for a potential investor.

Response: In response to the Staff's comment, the Company has revised the graphic on page 101 of Amendment No. 1.

#### Directors, page 120

16. Please revise your disclosure with respect to David A. Berry, M.D., Ph.D., to include his tenure as Interim President and Chief Executive Officer, as disclosed in "Office of the Chief Executive Officer," on page 130.

Response: In response to the Staff's comment, the Company has revised the disclosure on page 121 of Amendment No. 1.

#### **Intellectual Property, page 104**

17. Please revise your disclosure to indicate whether the patent application families described on pages 105 and 106 of the prospectus are expected to provide patent protection for each of your primary product candidates. Please also identify the specific product candidates covered under each patent application family.

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 105 and 106 of Amendment No. 1.

#### **Executive and Director Compensation, page 126**

18. Please update your executive and director compensation disclosure to reflect compensation information as of the registrant's last completed fiscal year ended December 31, 2014. You should also continue to include 2013 executive compensation information in your Summary Compensation Table. Please refer to Instruction 1 to Item 402(n) of Regulation S-K.

<u>Response</u>: In response to the Staff's comment, the Company has revised the disclosures in the Executive and Director Compensation section of Amendment No. 1.

19. We note your disclosure with respect to the 2015 Employee Stock Purchase Plan. Please expand your disclosure to include the material terms of the 2015 Employee Stock Purchase Plan and file a copy as an exhibit.

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 134 to 135 of Amendment No. 1. The Company acknowledges the Staff's request to file the plan as an exhibit and confirms that it will do so once the plan is final.

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#### **Employment Agreements, page 129**

20. Please provide a summary of the Offer Letter with respect to Eric Shaff, Chief Financial Officer and Executive Vice President.

Response: In response to the Staff's comment, the Company has added the disclosure on page 129 to 130 of Amendment No. 1.

#### European Economic Area, page 160

21. Please define the term "FSMA" in the last paragraph on page 160.

Response: In response to the Staff's comment, the Company has revised the disclosure on page 160 of Amendment No. 1.

#### General

22. Please submit all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.

<u>Response</u>: In response to the Staff's comment, the Company has filed additional documents as exhibits with Amendment No. 1. The Company will file the remaining exhibits as soon as practicable.

23. Please confirm that the graphics included in your registration statement are the only graphics you will use in your prospectus. If those are not the only graphics, please provide any additional graphics prior to their use for our review.

Response: In response to the Staff's comment, the Company confirms that the graphics included in Amendment No. 1 are the only graphics that will be included in the prospectus.

24. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Response: The Company acknowledges the Staff's comment and respectfully advises the Staff that at this time neither it, nor anyone on its behalf, has presented written

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communications to potential investors. The Company advises the Staff that, to the extent such written communications are made or used, the Company will provide the Staff with copies under separate supplemental cover.

If you have any questions regarding the foregoing responses or the enclosed Amendment, please do not hesitate to contact me by telephone at (617) 948-6060.

Very truly yours,

/s/ Peter N. Handrinos

Peter N. Handrinos of LATHAM & WATKINS LLP

c: Roger J. Pomerantz, M.D., Seres Health, Inc.