UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-37465

Seres Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**27-4326290**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
200 Sidney Street – 4th Floor Cambridge, Massachusetts	**02139**
(Address of Principal Executive Offices)	**(Zip Code)**

(617) 945-9626

(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.001 per share	MCRB	The Nasdaq Global Select Market

Securities Registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. **Yes** ☐ **No** ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. **Yes** ☐ **No** ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. **Yes** ☒ **No** ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). **Yes** ☒ **No** ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of the "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). **Yes** ☐ **No** ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant based on the closing price of the registrant's common stock as reported on the Nasdaq Global Select Market on June 30, 2022, was $239,918,450. Solely for purposes of this disclosure, shares of common stock held by executive officers, directors and certain stockholders of the registrant as of such date have been excluded because such holders may be deemed to be affiliates.

As of March 3, 2023 there were 126,076,391 shares of the registrant's common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to its 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2022 are incorporated herein by reference in Part III.

TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including without limitation 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, including the anticipated PDUFA target action date and potential FDA approval of SER-109, manufacturing activities and related timing, commercialization efforts and related timing, our ability to continue as a going concern, 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 Annual Report on Form 10-K 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 report and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the risks, uncertainties and assumptions described under the sections in this report titled "Summary Risk Factors," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual Report on Form 10-K.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

TRADEMARKS, SERVICE MARKS AND TRADENAMES

We have proprietary rights to trademarks used in this Annual Report on Form 10-K, which are important to our business and many of which are registered under applicable intellectual property laws. Solely for convenience, the trademarks, service marks, logos and trade names referred to in this Annual Report on Form 10-K 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 to these trademarks, service marks and trade names. This Annual Report on Form 10-K 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 Annual Report on Form 10-K 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.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 1A. "Risk Factors" in this Annual Report on Form 10-K. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include the following:

- 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.
- We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern.
- We will need additional funding in order to complete development of our product candidates and commercialize our products, if approved. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

- Other than SER-109, we are early in our development efforts and may not be successful in our efforts to use our reverse translational microbiome therapeutics platform to build a pipeline of product candidates and develop marketable drugs.
- Our product candidates are based on microbiome therapeutics, which is an unproven approach to therapeutic intervention.
- Clinical drug development involves a risky, lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Delays or difficulties in the enrollment of patients in clinical trials, could result in our receipt of necessary regulatory approvals being delayed or prevented.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or our collaborators 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. Additionally, failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.
- Our collaboration and license agreements with Société des Produits Nestlé S.A., successor in interest to Nestec Ltd., and NHSc Rx License GmbH, successor in interest to NHSc Pharma Partners (collectively, and together with their affiliates and subsidiaries, Nestlé) are important to our business. If we or Nestlé fail to adequately perform under these agreements, or if we or Nestlé terminate the agreements, the development and commercialization of our CDI and IBD product candidates, including SER-109, SER-287 and SER-301, could be delayed or terminated and our business would be adversely affected.
- We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.
- We rely on third parties for certain aspects of the manufacture of our product candidates for preclinical 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.
- Even if any of our product candidates receive 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.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- If we are unable to adequately protect our proprietary technology or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- We may expand our operational capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- We will continue to incur costs as a result of being a public company, and our management will continue to devote substantial time to compliance initiatives and corporate governance practices.

PART I

Item 1. Business

Overview

We are a microbiome therapeutics company developing a novel class of biological drugs, which are designed to treat disease by modulating the microbiome to restore health by repairing the function of a disrupted microbiome to a non-disease state. We have an advanced drug pipeline with clinical assets that are formulated for oral delivery and a differentiated microbiome therapeutics drug discovery and development platform including good manufacturing practices, or GMP, manufacturing capabilities for this novel drug modality.

Our highest priority is preparing for potential commercialization of SER-109, an investigational oral microbiome therapeutic in development for recurrent *Clostridioides difficile* infection, or CDI. In October 2022, the U.S. Food and Drug Administration, or FDA, accepted for review our biologics license application, or BLA, for SER-109. The BLA has been granted Priority Review designation with a Prescription Drug User Fee Act, or PDUFA, target action date of April 26, 2023. If approved by the FDA, we plan to launch SER-109 with our collaborator, Nestlé Health Science, soon after approval.

We are also designing microbiome therapeutics to decolonize pathogens and modulate host function to reduce and prevent infections. We believe that the scientific and clinical data from our SER-109 program validate this novel approach, which we refer to as Infection Protection. We believe the Infection Protection approach may be replicable across different bacterial pathogens to develop microbiome therapeutics with the potential to protect a range of medically compromised patients from infections. We are evaluating SER-155 in a Phase 1b study in patients receiving allogeneic hematopoietic stem cell transplantation, or allo-HSCT, to reduce incidences of gastrointestinal infections, bloodstream infections and graft-versus-host disease, or GvHD. In December 2022, the study's Data and Safety Monitoring Board reviewed available clinical data for cohort 1 and cleared advancement to cohort 2. In February 2023, we announced the initiation of enrollment in cohort 2. We plan to announce initial safety and pharmacological data, including drug bacterial species engraftment from cohort 1, in May 2023. We are also progressing additional preclinical stage programs to evaluate how microbiome therapeutics may reduce incidence of infections in indications such as cancer neutropenia, chronic liver disease, solid organ transplant, and antimicrobial resistant infections more broadly in settings of high-risk such as intensive care units, or ICUs.

We continue our research activities in ulcerative colitis, or UC, including evaluating the potential to utilize biomarker-based patient selection and stratification for future studies. In addition, we continue to leverage microbiome pharmacokinetic and pharmacodynamic data from across our clinical and preclinical portfolios, using our reverse translational microbiome therapeutic development platform to conduct research on various indications, including inflammatory and immune diseases, cancer, and metabolic diseases.

We have built and deploy a reverse translational platform for the discovery and development of microbiome therapeutics. This platform incorporates high-resolution analysis of human clinical data to identify microbiome biomarkers associated with disease and non-disease states; preclinical screening using human cell-based assays and in vitro/ex vivo and in vivo disease models customized for microbiome therapeutics; and microbiological capabilities and a strain library that spans broad biological and functional breadth to both identify specific microbes and microbial metabolites that are associated with disease and to design consortia of bacteria with specific pharmacological properties.

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 Pioneering. Through Flagship Pioneering's 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 Eric Shaff, our President and Chief Executive Officer, our experienced management team possesses core capabilities and know-how in microbiome therapeutics, drug development, commercialization, chemistry, manufacturing and controls, or CMC, public company management and finance.

Our Strategy

Our goal is to remain the leading biopharmaceutical company developing and commercializing microbiome therapeutics to address significant unmet medical needs. We intend to focus in the near term on gaining FDA approval for SER-109 for recurrent CDI and continuing development of our highest priority clinical programs. Additionally, we continue to advance our differentiated microbiome drug discovery, development and manufacturing platforms and capabilities.

Advancing our Programs

- ***Supporting the BLA submission for our lead product candidate, SER-109, for patients with recurrent CDI, and advancing preparations for potential commercialization.*** In October 2022, our BLA for SER-109 was accepted for Priority Review by the FDA. A PDUFA target action date has been set for April 26, 2023. We continue to execute pre-commercialization activities with our commercialization collaborator, Nestlé Health Science, including appropriate market education and data dissemination to the medical community. In addition, activities are ongoing to engage payers.

We launched a disease education campaign in the fourth quarter of 2021 with an increasingly robust media plan as we approach potential commercial launch. In the second quarter of 2022, we deployed an experienced Nestlé payer team to conduct preapproval information exchange activities. To date, this team has engaged payers covering more than 150 million lives. In order to complement the current gastroenterology sales force of Nestlé Health Science, in the fourth quarter of 2022, a hospital selling team of twenty employees were hired to profile the top volume hospitals across the U.S. during the remainder of our prelaunch phase. In addition, we have SER-109 drug supply ready in anticipation of product approval and continue to make progress expanding commercial-scale production of SER-109 to prepare for anticipated future market demand. Our Long-Term Manufacturing Agreement with BacThera AG, or Bacthera, a global leader in biopharmaceutical product manufacturing, is designed to increase longer-term SER-109 product supply and adds to existing manufacturing capabilities.

- ***Maximizing the opportunity in Infection Protection.*** We believe that the scientific and clinical data from our SER-109 program validate our Infection Protection approach of using microbiome therapeutics to decolonize pathogens and modulate host function to reduce and prevent infections. Infection Protection may be replicable across different bacterial pathogens to develop microbiome therapeutics with the potential to protect a range of medically compromised patients from infections. We are evaluating SER-155 in a Phase 1b study in patients receiving allo-HSCT to reduce incidences of gastrointestinal infections, bloodstream infections and GvHD. We are also progressing additional preclinical stage programs to evaluate how microbiome therapeutics may reduce incidence of infection in indications such as cancer neutropenia, chronic liver disease, solid organ transplant, and antimicrobial resistant infections more broadly in settings of high-risk such as ICUs.
- ***Continuing research to inform further development in UC and immune modulation.*** We previously announced clinical, microbiome and metabolomic data from our SER-287 Phase 2b study and the first cohort of our SER-301 Phase 1b study. Available data for these investigational microbiome therapeutics suggest that there may be an opportunity to utilize biomarker-based patient selection and stratification for future studies. Research activities remain ongoing to inform potential further development activities that include patient population and disease severity selection and dose optimization in these populations.

Advancing Our Capabilities

- ***Leveraging our leading reverse translational microbiome therapeutics platform to develop additional innovative and novel microbiome therapeutics across a range of serious medical conditions with high unmet need including infectious and inflammatory disease and disease associated with modulation of host immunity.*** We believe that the combination of experience, proprietary data and proprietary know-how related to the microbiome, the functional properties of microbial species and strains, microbe-host interactions, the cultivation of microbial strains, and microbiome-specific functional screens and analytics 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 design treatments for acute and complex chronic diseases. We intend to leverage this advantage to develop additional innovative microbiome therapeutics.
- ***Developing manufacturing capabilities sufficient to support commercialization of any approved microbiome therapeutic candidates.*** Microbiome therapeutic manufacturing requires capabilities that are distinct from other biologic drugs. We have made 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 microbiome therapeutic candidates. 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.

Our Microbiome Therapeutics Platform

We have developed the leading reverse translational microbiome therapeutics platform which we believe enables us to apply our capabilities to efficiently identify, manufacture and develop novel microbiome therapeutics for serious human diseases. We use a reverse translational discovery platform that incorporates analysis of microbiome biomarkers from human clinical data and preclinical assessments using human cell-based assays and *in vitro/ex vivo* and *in vivo* disease models. Specifically, we start with data sets from both healthy subjects and subjects with disease to delineate at high-resolution the composition of the microbiome and physiological state of subjects and to identify specific microbiome and host signatures that associate with disease or the onset of disease. These in-human insights on how different microbe species and strains and microbe-associated metabolites are associated with disease along with how these microbes and metabolites directly or indirectly modulate disease-relevant functional pathways in the host are leveraged in preclinical drug design and development.

Our discovery process begins with human data derived from clinical trials and cohort studies, which we use as a basis for target identification and the design of our microbiome therapeutic candidates. We compare healthy, normal colonic microbiomes to those in an unhealthy disrupted or disease state, revealing the ecological, compositional and functional differences between various states of disease and during the transition from health to disease or vice versa. Specifically, we utilize clinical data sets combined with

advanced data sciences and microbiome analytics to identify microbiome signatures of disease at the resolution of specific species and strains, metabolites, and even genes that are associated with disease states. These microbiome biomarkers are associated with host signatures and biomarkers of disease to identify drug targets for our microbiome therapeutics. Our clinical data from the SER-109, SER-262, SER-401, SER-287 and SER-301 programs, and microbiome data generated with external collaborators, serve to instruct us on how the introduction of certain keystone microbes have the potential to restructure the microbiome and modulate the metabolic state of the gut to shift it to a non-disease state.

We have developed a proprietary functionally characterized strain library and a suite of assays and screens, bioinformatics and computational tools, and databases, which facilitate our insights into the human microbiome. We have established proprietary, curated, reference databases and algorithms that: (i) integrate high-resolution genomic, metagenomic, metabolomic, and transcriptomic data sets, and data from *in vitro* and human cell-based assays, and *in vitro/ex vivo* and *in vivo* disease models, and (ii) enable us to track changes in the microbiome at the level of microbial species and individual strains and associate these changes with changes in the metabolic state of the gut and host physiology. Our analytics can integrate gene profiling and metabolomics data (the small molecules made by the microbiome) with genomic data (the collection of microbes defined by sequencing) to delineate microbiome biomarkers (the specific species or strains and functional pathways) that contribute to the state of disease or health. Further, we have established *de novo* analytics for pharmacokinetic and pharmacodynamic assessments of microbiome therapeutics. Additionally, leveraging all of these data we have curated and continue to build a database that links and associates: (i) functional properties of microbial species/strains, (ii) functional pathways in hosts that can be modulated by the microbiome, (iii) the association of functional pathways to disease, and (iv) the association of existing non-microbiome drugs to the functional pathways. This continually growing database can be mined to inform drug design and disease area and patient population prioritization.

Our proprietary strain library of bacterial isolates from healthy donors and patients enables us to translate microbiome biomarker insights into defined consortia of bacteria. The strain library contains bacterial species isolated from individuals that are either healthy or that have a disease. Seres has developed extensive isolation and cultivation know-how. The strain library contains a majority of the Human Microbiome Project's "most wanted" and many novel species we do not believe are described in other databases or the scientific literature. The functional properties of strains are characterized using proprietary *in vitro* and *ex vivo* human cell-based assays as well as full-genome sequences and genome functional annotation. Functional characterization of target strains includes properties such as how the bacteria interact with human colonic epithelial cells and human immune cells. We also seek to understand how these microbes improve the health of barrier cells in the gut and how they may impact immune responses.

We select bacteria from our library with specific predicted properties using novel algorithms for *in silico* functional design and optimization and grow the compositions in the lab to be tested both *in vitro/ex vivo models* as delineated above and in *in vivo* animal models. Our animal models include conventional mice, germ-free mice, and "humanized avatar" mice that possess only bacteria derived from humans; these models were developed to minimize confounding variables presented by model organism microbes. Data from our *in vitro/ex vivo* and *in vivo* screens are analyzed and used to optimize compositional designs; introducing new bacterial strains and optimizing existing strains until we identify a lead composition suitable for clinical testing.

Finally, we manufacture the bacterial composition under current Good Manufacturing Practices, or cGMP, or similar foreign requirements, which are required by FDA and European regulators. We believe our unique manufacturing capacities position us to exploit the insights of our proprietary human data and the novel biology of species and strains that have not previously been used for therapeutics. We have optimized fermentation conditions to generate spores and enhance bacterial yields in anaerobic fermentation and have in-house capabilities to formulate both spores and live non-spore bacteria. Our manufacturing facility in Cambridge, Massachusetts was designed to be fit-for-purpose and is highly differentiated compared to the offerings of commercial contract research organizations. We have secured additional capacity, designed to our specifications, via contract manufacturing organizations, or CMOs, to ensure adequate supply for potential commercial products. We continue working to address quality control requirements for our microbiome therapeutic candidates using proprietary microbiological and sequence-based testing schemes, including high-throughput quantitative analytics to assess the identity, potency, and purity of the final product. We intend to continue to work with regulators to meet the requirements for product approval.

Taken together, we believe our platform, spanning drug discovery, preclinical translation, and novel manufacturing and quality control approaches, has enabled a field leading pipeline across a range of therapeutics areas.

Disease Overview and Our Product Pipeline

We believe our microbiome therapeutic candidates represent a novel approach with potential application across a broad range of human diseases. Our lead product candidate, SER-109, is designed to reduce further recurrence of CDI, a debilitating infection of the colon, in patients who have received antibiotic therapy for recurrent CDI by restructuring the gastrointestinal microbiome and modulating the metabolic landscape to address CDI. If approved by the FDA, we believe SER-109 will be a first-in-field oral microbiome drug. Building upon SER-109, we are developing novel microbiome therapeutics, such as SER-155, to specifically target infections and antimicrobial resistance. SER-155, a microbiome therapeutic candidate consisting of a consortium of cultivated bacteria, is designed to reduce incidences of gastrointestinal infections, bloodstream infections and GvHD in patients receiving allo-HSCT. We are progressing additional preclinical stage programs to evaluate how microbiome therapeutics may reduce incidence of infection in indications such as cancer neutropenia, chronic liver disease, solid organ transplant, and antimicrobial resistant infections

more broadly in settings of high-risk such as ICUs. We are also continuing research activities in UC, including evaluating the potential to utilize biomarker-based patient selection and stratification for future studies. In addition, we continue to leverage microbiome pharmacokinetic and pharmacodynamic data from across our clinical and preclinical portfolios, using our reverse translational microbiome therapeutic development platform to conduct research on various indications, including inflammatory and immune diseases, cancer, and metabolic diseases.

CDI Overview and SER-109

Clostridioides difficile Infection

C. difficile is a Gram-positive, toxin-producing, spore forming bacterium that may cause debilitating diarrhea in infected individuals, but can also lead to more severe outcomes, such as inflammation of the colon, or colitis, toxic megacolon and death. *C. difficile* bacteria express toxins that disrupt the structural architecture of cells causing leakage of fluids through the gastrointestinal, or GI, epithelium. The cells disrupted by these toxins eventually undergo apoptosis and die, disrupting the epithelial barrier and exposing the immune system to inflammatory stimuli, severe and persistent diarrhea and, in the most serious cases, death.

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 colonization resistance to CDI by disrupting the microbiome. Since *C. difficile* spores are able to survive for long periods of time outside the body, and because healthcare settings are often sites of significant antibiotic use, CDI is a leading cause of healthcare-associated infections in the United States. CDI is also a cause of morbidity and mortality among hospitalized cancer patients and bone marrow transplant patients as their immune systems are suppressed by cytotoxic drugs, which inhibit or prevent the functioning of cells, and they may be heavily treated with antibiotics to prevent or treat infections. More recently, the rise of community-acquired CDI has been recognized as a growing problem.

The Centers for Disease Control and Prevention, 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 most common cause of hospital acquired infection in the United States, having overtaken MRSA. CDI is responsible for the deaths of over 20,000 Americans each year. During 2023, it is estimated that there will be approximately 459,000 cases of primary CDI and 156,000 incidences of recurrent CDI within the United States. CDI is also 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, the average recurrent CDI treatment cost in the U.S. is estimated to be $34 thousand per patient, comprising mostly (88%) hospital-related costs (*Rodrigues Infect Control Hosp Epidemiol 2017*). The national incidence of CDI remains high despite declining from 476,000 in 2011 to 462,000 in 2017 (Guh, *New England Journal of Medicine 2020*). 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. Due to suboptimal approaches to treatment, patients with primary CDI have an approximate 20% - 25% change of recurrent infection increasing to greater than 40% after the first recurrence (*Gerding, CID 2018; Lashner ACG 2020; Dubberke CID 2018*).

Current and developing treatment alternatives and their limitations

Antibiotics. According to the Infectious Disease Society of America, or IDSA, guidelines, the current standard of care for primary CDI is to treat with antibiotics, such as fidaxomicin or vancomycin. Fidaxomicin is recommended to treat primary CDI, it does not have a label claim to reduce or prevent CDI recurrence. No antibiotic therapeutics are currently approved for treatment of recurrent CDI.

Recurrent CDI, defined as the presence of diarrhea and a positive *C. difficile* stool assay within two to eight weeks following the initial episode, is not well addressed by any of the available antibiotics. The risk of recurrent CDI increases to greater than 40% after the first recurrence. In extreme cases, patients may be treated continuously for years with vancomycin.

Antibiotics have two major limitations: they have no effect on the spores that germinate in a disrupted microbiome and their use appears to exacerbate microbiome disruption, resulting in increased risk of future CDI. Research in animal models has shown that antibiotic use not only eliminates many healthy bacteria in the GI 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 microbiome disruption 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 recurrent CDI. 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 hundreds of unknown strains of bacteria, fungi, viruses and potentially parasites from donor to subject, and is difficult to perform on a mass scale. In November 2019 the FDA held a public hearing to obtain input on the use of FMT to treat Clostridioides difficile infection not responsive to standard therapies. Presentations were made by the academic community and development companies regarding the current and future use of FMT. In January, 2020, we submitted comments to the docket for the meeting that recommended: 1) increased scrutiny and regulation of unapproved, commercially available FMT that does not comply with IND requirements; 2) implementation of guidance for establishing safety of source materials for all microbiome products; and 3) safety and

efficacy of all microbiome products to reduce recurrent CDI must be based on adequate and well controlled clinical trials including accurate assurance of diagnosis of the disease state – specifically toxin testing.

Fecal microbiota therapy. In November 2022, the FDA approved Rebyota, the first fecal microbiota product approved by the FDA, for the prevention of recurrence of CDI in individuals 18 years of age and older following antibiotic treatment for recurrent CDI. Rebyota is administered rectally and is prepared from stool sourced from qualified donors. The stool is tested for a panel of transmissible pathogens. We believe our CMC process is differentiated by additional processes to inactivate and clear potential adventitious agents to help ensure product safety.

Antibodies. Bezlotoxumab a fully human monoclonal antibody directed against *C. difficile* toxin B was approved in the United States in October 2016 and in Europe in 2017 for the treatment of CDI. According to Phase 3 studies, the antibody demonstrated 10% absolute risk reduction in preventing recurrence of CDI. Antibodies bind toxins to alleviate the symptoms of CDI, but they do not address the underlying disruption of the microbiome, which we believe is the cause of recurrent CDI. Bezlotoxumab requires intravenous infusion.

SER-109

SER-109 is an oral microbiome therapeutic candidate consisting of a consortium of purified Firmicutes spores. The SER-109 manufacturing purification process is designed to remove unwanted microbes in an effort to reduce the risk of pathogen transmission beyond donor screening alone. SER-109 is designed to reduce recurrent CDI in patients with a history of CDI by modulating the microbiome to a state that resists *C. difficile* germination and growth. SER-109, if approved, is intended to treat individuals with recurrent CDI, a patient population that is estimated to include approximately 156,000 cases in the United States during 2023.

Phase 1b/2 clinical study

The Phase 1b/2 clinical study was an open-label, single arm, descending-dose study that enrolled 30 patients with recurrent CDI. All enrolled patients received standard-of-care antibiotic treatment, followed by oral administration of SER-109. Of the 30 study patients, 26 (87%) achieved the primary endpoint of absence of CDI (defined in this study as more than three unformed bowel movements in a 24-hour period with laboratory confirmation of a positive *C. difficile* stool test) up to eight weeks following dosing. Three of the four patients who did not meet the primary endpoint were determined by their primary investigator to be recovering from CDI, and all symptoms resolved without further therapeutic intervention or antibiotics. In total, 29 of 30 patients (97%) achieved the clinical cure rate, which we defined as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing. SER-109 was well tolerated in the study, with the most common adverse events being mild to moderate gastrointestinal symptoms. No drug related serious adverse events were observed.

Phase 2 clinical study

The Phase 2 clinical study was a randomized, double-blinded, placebo-controlled, parallel-group two arm trial that enrolled a total of 89 patients with a history of multiply-recurrent CDI, defined as 3 or more CDI episodes within 9 months. SER-109 was administered orally following the completion of antibiotic treatment for CDI. The predefined study primary efficacy endpoint was the relative risk of CDI recurrence up to 8 weeks after treatment with SER-109 compared to treatment with placebo. CDI recurrence was defined as diarrhea for 2 or more consecutive days, a positive CDI test, and the requirement for antibiotic treatment. Based on 8-week data, CDI recurrence occurred in 44% of subjects (26 of 59) who received SER-109, compared to 53% of subjects (16 of 30) who received placebo. The relative risk of CDI recurrence for the placebo population compared to the SER-109 population was not statistically significant. The most commonly reported AEs in both the SER-109 and placebo arms were in the GI category, and were diarrhea, abdominal pain, flatulence, and nausea. No drug-related SAEs were observed.

Analysis of Phase 1b/2 and Phase 2 clinical study results

In our Phase 2 clinical study, the study's primary endpoint of reducing the relative risk of CDI recurrence at up to 8 weeks after treatment was not achieved. In order to understand the difference in outcome between Phase 1b/2 and Phase 2 clinical studies, we conducted an analysis of the available clinical, microbiome and CMC data. We identified key factors that potentially explain the Phase 2 clinical study results, including issues related to both the accurate diagnosis of *C. difficile* recurrent infection, and potential suboptimal dosing of subjects in the trial.

The key factors include:

- The diagnostic test for entry may not have differentiated subjects with active CDI disease from those with other disease but who had *C. difficile* carriage (e.g., irritable bowel syndrome);
- The diagnostic test for CDI recurrence during the study (the primary endpoint) overestimated recurrences, as PCR was the most common test performed;
- The safety profile of SER-109, which may include diarrhea in the first week following dosing, led to SER-109 subjects presenting for evaluation of recurrence at a time when they were likely to be colonized with *C. difficile* leading to mistaken diagnosis of recurrent CDI; and

- The dose and dosing regimen used in the study may not have been optimal in the Phase 2 clinical study based upon an assessment of the microbiome response using whole metagenomics shotgun sequencing.

From our reanalysis of the phase 1b/2 and 2 trials, we learned that there is a dose-dependent response governing early SER-109 pharmacokinetics, with increased engraftment associated with successful CDI resolution through 8 weeks. In the Phase 2 trial, SER-109 was dosed at 1×10^8 spores based on equivalent clinical outcomes and week 8 engraftment measures observed between the phase 1 dosing cohorts. However, our integrated analysis of both trials revealed that (1) engraftment kinetics at week 1 were of greater importance for reducing rCDI than later time points, (2) week 1 engraftment was highly variable in Phase 2 subjects, and (3) rapid engraftment was dependent on dose, which was clearly suboptimal in the Phase 2 trial (McGovern, 2020; Young, 2020). We hypothesized that rapid engraftment of a microbiome therapeutic may be critical to efficacy since CDI recurrence usually occurs within 1–3 weeks of antibiotic discontinuation, the "window of vulnerability"; consistent with this hypothesis, in the Phase 2 trial, greater engraftment of SER-109 species at week 1 was correlated with reduced CDI rates. This correlation was not previously appreciated due to the use of lower resolution 16S rRNA gene amplicon–based methods used in the Phase 1b/2 study for determining drug engraftment (Khanna, 2016).

Phase 3 clinical study design

In the Phase 3 ECOSPOR III clinical study of SER-109, patients with multiply recurrent CDI were randomized 1:1 between SER-109 and placebo. Diagnosis of CDI for both study entry and for endpoint analysis utilized a *C. difficile* cytotoxin assay, compared to the Phase 2 clinical study, where most patients were diagnosed by PCR. Patients in the SER-109 arm received a total SER-109 dose, administered over three days, approximately 10-fold higher than the dose used in the Phase 2 clinical study to drive rapid engraftment of SER-109 bacteria in treated patients. The study evaluated patients for 24 weeks and the primary endpoint was to compare the *C. difficile* recurrence rate in subjects who receive SER-109 verses placebo at up to eight weeks after dosing. CDI recurrence is defined as diarrhea (>3 unformed bowel movements/day for 2 or more consecutive days), a positive CDI toxin test, and the decision by the primary investigator that antibiotic treatment is warranted. The study was conducted at approximately 100 sites in the United States and Canada.

Phase 3 clinical study results

The study enrolled 182 patients with multiply recurrent CDI. ECOSPOR III data demonstrated that the study achieved its primary endpoint where SER-109 was superior to placebo in reducing CDI recurrence at eight weeks, reflecting a recurrence-free rate of approximately 88% at eight weeks post-treatment. SER-109 resulted in a 27% absolute reduction of recurrence of CDI compared to placebo at eight weeks post-treatment, which is a relative risk reduction of 68%. The number-needed-to treat was 3.6. The rate of recurrence at 12 weeks in the SER-109 arm was 18.0%, compared to a rate of 46.2% in the placebo arm, representing an absolute risk reduction of 28% (relative risk 0.40; 95% CI 0.24-0.65; $p < 0.001$ and $p < 0.002$ for the test sequence), and thereby consistent with the results seen at eight weeks. Results across stratifications of age and antibiotics remained similar. The study's efficacy results related to the primary endpoint from all analyses exceeded the statistical threshold previously provided in consultation with the FDA that could allow this single clinical study to fulfill efficacy requirements for a BLA. The efficacy results remained durable through 24 weeks of follow-up, as SER-109 was observed to significantly reduced recurrence rates compared to placebo over 24 weeks, 21.3% vs. 47.3%, respectively. These data were published in the *New England Journal of Medicine* in January 2022 and in the *Journal of the American Medical Association* in October 2022.

We believe the SER-109 safety results across completed studies have been favorable, with a well-tolerated adverse event profile. Overall incidence of patients who experienced treatment-emergent adverse events, or TEAEs, was 92.2% for SER-109 and 91.3% for placebo. SER-109 had no serious treatment-related adverse events. The most commonly observed TEAEs were gastrointestinal disorders, the majority of which were mild to moderate in nature.

The study also examined the pharmacokinetics (i.e., drug bacterial species engraftment) and pharmacodynamics (i.e., metabolic changes) following SER-109 dosing. The data demonstrate that SER-109 administration resulted in the rapid and durable engraftment of SER-109-derived bacterial species into the gastrointestinal tract as soon as one week following dosing, and that this engraftment was maintained at subsequent timepoints evaluated, including at the eight-week timepoint corresponding to the study's primary endpoint and the 24-week safety follow-up timepoint. The presence of SER-109 bacterial species was significantly greater ($p<0.001$) in SER-109 treated patients than in placebo patients at all timepoints evaluated. Significant differences were maintained in predefined subpopulation analyses of age and antibiotic use. Seres utilized advanced microbiome biomarker analytics and proprietary genomic reference datasets to identify, at a resolution of bacterial species, the gastrointestinal microbiome signatures associated with SER-109 engraftment.

SER-109 administration also resulted in modulation of the gastrointestinal metabolic landscape. Notably, data demonstrated a significant decrease in primary bile acids ($p=0.038$) and an increase in secondary bile acids ($p<0.001$) by one-week post-dosing; significant differences were maintained through week eight for secondary bile acids. Notably, SER-109 subjects had less variance across subjects in bile acid response than placebo subjects. Observations for both primary and secondary bile acids were maintained in predefined subpopulation analyses of age and antibiotic use. All microbiome analyses were conducted according to the treatment subjects actually received. Published research as well as preclinical studies have demonstrated that primary bile acids support

germination of *C. difficile* spores that are the source of disease recurrence. In contrast, secondary bile acids have been reported to inhibit germination and the growth of *C. difficile* (Theriot and Young, Annu. Rev. Microbiol. 2015).

In November 2021, we initiated a SER-109 expanded access program across the United States. The program is designed to enable eligible adults with recurrent CDI to obtain access to SER-109 prior to a potential FDA product approval.

In June 2022, we announced confirmatory results from the ECOSPOR IV open-label study. The overall safety results observed in ECOSPOR IV through 24 weeks showed that SER-109 was well tolerated, consistent with the safety results observed in the prior completed Phase 3 study, ECOSPOR III. In ECOSPOR IV, subjects treated with SER-109 had a recurrence rate of 8.7% at eight weeks, which represented a 91.3% recurrence-free rate, consistent with the 88% rate observed in the ECOSPOR III study. Subjects with a first recurrence of CDI (29% of subjects in the ECOSPOR IV study) had a CDI recurrence rate of 6.5%, and subjects with ≥ two prior CDI episodes (ECOSPOR III inclusion criteria) had a CDI recurrence rate of 9.7% at eight weeks. At 24 weeks, 13.7% of all subjects treated with SER-109 had a recurrence of CDI. In addition to data from the ECOSPOR III study, the ECOSPOR IV data was included as part of our BLA submission to the FDA.

In October 2022, the FDA accepted for review our BLA for SER-109. The BLA has been granted Priority Review designation with a PDUFA target action date of April 26, 2023. If approved by the FDA, we plan to launch SER-109 with our collaborator, Nestlé Health Science, soon after approval.

In addition, we plan on initiating a Phase 3 trial in the European Union, or EU, in order to expand access to the EU market upon potential approval.

Sales and Marketing

In July 2021, we entered into an agreement with NHSc Pharma Partners, succeeded by NHSc Rx License GmbH, or, together with Société des Produits Nestlé S.A, Nestlé, to jointly commercialize SER-109 in the United States and Canada. Under the terms of the agreement, Nestlé will assume the role of lead commercialization party. We received license payments of $175 million up front, and will receive an additional $125 million upon FDA approval of SER-109. The agreement also includes sales target milestones which, if achieved, could total up to $225 million. We will be responsible for development and pre-commercialization costs in the United States. Upon commercialization, we will be entitled to share equally in its commercial profits and losses.

This agreement represents a second strategic collaboration between the companies. Nestlé already has commercial rights to our investigational treatments for CDI and IBD outside of the United States and Canada, and with the July 2021 expansion, Nestlé became our global collaborator in SER-109.

If SER-109 is approved in the United States and Canada, we believe it can be commercialized with a focused specialty sales force that will target gastrointestinal and infectious disease physicians, which are the two primary groups of physicians who treat recurrent CDI patients. We have initiated commercial readiness activities that include: *C. difficile* market assessments, publication and presentation planning, stakeholder and advocacy relationship mapping, brand name selection, and initiation of payer and reimbursement strategic planning. We launched a disease education campaign in the fourth quarter of 2021 with an increasingly robust media plan as we approach potential commercial launch. In the second quarter of 2022, we deployed an experienced Nestlé payer team to conduct preapproval information exchange activities. To date, this team has engaged payers covering more than 150 million lives. In order to complement the current gastroenterology sales force of our commercialization collaborator, Nestlé Health Science, in the fourth quarter of 2022, a hospital selling team of twenty employees were hired to profile the top volume hospitals across the United States during the remainder of our prelaunch phase.

Infection Protection and SER-155

We believe that the scientific and clinical data from our SER-109 program validate our novel approach of using microbiome therapeutics to decolonize pathogens, resulting in reduced rate of infections in medically compromised patients. Data from the SER-109 Phase 3 trial published in the *New England Journal of Medicine* and *Journal of the American Medical Association* show that microbiome therapeutics can restructure the gut microbiome and shift the gut metabolic landscape. Additional data show that SER-109 rapidly reduces the abundance of bacteria associated with common antibiotic resistance genes, or ARGs, and reduces ARG abundance in the gut. Collectively, these data demonstrate the potential for microbiome therapeutics to restore colonization resistance and ultimately to reduce infections and antimicrobial resistance. This Infection Protection approach may be replicable in protecting a range of medically compromised patients from infections seeded by the gut microbiome. It may also enable us to reduce antimicrobial resistant infections, which the World Health Organization declared as a top ten global public health threat facing humanity.

We are evaluating SER-155 in a Phase 1b study in allo-HSCT recipients to reduce incidences of gastrointestinal infections, bloodstream infections and GvHD. We are also progressing additional preclinical stage programs to evaluate how microbiome therapeutics may reduce incidence of infection in indications such as cancer neutropenia, chronic liver disease, solid organ transplant, and antimicrobial resistant infections more broadly in settings of high-risk such as ICUs.

SER-155, an oral microbiome therapeutic candidate consisting of a consortium of cultivated bacteria, is designed to decrease infection and translocation of antibiotic resistant bacteria in the gastrointestinal tract and modulate host immune responses to decrease GvHD. The rationale for this program is based in part on published clinical evidence from our collaborators at Memorial Sloan

Kettering Cancer Center showing that allo-HSCT patients with decreased diversity of commensal microbes are significantly more likely to die due to infection and/or lethal GvHD. SER-155 was designed using our reverse translational microbiome therapeutics development platform to reduce incidences of gastrointestinal infections, bloodstream infections and GvHD in patients receiving allo-HSCT. The SER-155 Phase 1b study is designed to include approximately 70 patients in both an open-label and a randomized, double-blind, placebo-controlled cohort that will evaluate safety and tolerability before and after HSCT. Additionally, the engraftment of SER-155 bacteria (a measure of pharmacokinetics) and the efficacy of SER-155 in preventing infections and GvHD will be evaluated. In December 2022, the study's Data and Safety Monitoring Board reviewed available clinical data for cohort 1 and cleared advancement to cohort 2. In February 2023, we announced the initiation of enrollment in cohort 2. We plan to announce initial safety and pharmacological data, including drug bacterial species engraftment from cohort 1, in May 2023. The study is being conducted at a number of leading cancer centers across the U.S.

Irritable Bowel Disease, Ulcerative Colitis, SER-287 and SER-301

UC, a form of irritable bowel disease, or IBD, is a relapsing-remitting chronic inflammatory disorder affecting the mucosal surface of the colon, leading to episodes of bloody diarrhea, urgency and mucosal inflammation (Danese and Fiocchi, 2011), which generally begins in young adulthood and endures for life. The incidence of UC is rising worldwide, and the prevalence of the disease is highest in the United States, Canada, and Europe. In the United States alone, the prevalence of UC in adults is estimated to be 263 per 100,000, while in the pediatric population (age <20 years), prevalence of the disease is estimated to be 33.9 per 100,000. (Kappelman et al., 2013). The severity, extent, and duration of disease are also risk factors for developing colon cancer, which occurs at a rate as high as 0.5-1.0% per year, an important complication given the young age at which the disease strikes. Patients with UC also experience increased risk of CDI and primary sclerosing cholangitis, compared to the general population.

Currently, patients with UC require life-long therapy. Current medical therapies for the treatment of UC suppress the immune system rather than reduce the triggers of immune activation. We believe there remains an unmet need for safer agents with novel non-immunosuppressive mechanisms of action. Moreover, alternative therapy is needed for patients with UC who experience frequent flares or are intolerant to the aminosalicylate class of medication or where there are safety concerns relating to the use of immunomodulator or steroid therapy.

We continue our research activities in IBD, including evaluating the potential to utilize biomarker-based patient selection and stratification in future clinical studies in UC. UC patient populations are generally heterogeneous in their disease manifestation and we believe biomarker-based strategies may enable targeting more homogeneous patient populations in future studies.

In July 2021, we announced topline results from the SER-287 Phase 2b study evaluating SER-287 in patients with mild-to-moderate UC, which did not meet its primary endpoint of improving clinical remission rates compared to placebo. Following the data readout, in December 2021, we completed preliminary microbiome drug pharmacology analyses that demonstrated the engraftment of SER-287 bacterial species, however, unlike the Phase 1b study, anticipated changes in disease-relevant metabolites post-administration with SER-287 in the Phase 2b study were not observed to the same extent across the patients treated in the Phase 1b study.

In addition, we have completed preliminary analysis of data from the first cohort of the SER-301 Phase 1b study evaluating SER-301 in patients with mild-to-moderate UC, which included 15 subjects. Evaluation of the first cohort data by an independent Data Safety Monitoring Board indicated that it would be safe to proceed to the placebo-controlled second cohort. While efficacy was not a defined endpoint in the first cohort, evaluation of clinical outcome data collected as part of the study indicated that no subjects in the first cohort achieved clinical remission as defined by the FDA using the Three-Component Modified Mayo Score after 10 weeks of treatment, though there were improvements in one or more individual components (endoscopic, stool frequency and rectal bleeding subscores) in some patients. SER-301 was optimized relative to SER-287 to incorporate bacterial strains that engrafted across the majority of patients in our previous trials, and strains that were associated with positive clinical outcomes and the modulation of key microbial-associated metabolites. In the Phase 1b study, strains in SER-301 were observed to engraft in subjects across the trial period, and based on the assessment of metabolomic data, SER-301 demonstrated pharmacological properties consistent with its design and further led to baseline-dependent modulation of the metabolic landscape in the gastrointestinal tract of patients treated. In April 2022, we announced our decision not to proceed with the planned SER-301 Phase 1b second study cohort. In aggregate, our clinical and preclinical data suggest that there are IBD patient populations that may be more amenable to microbiome therapeutic intervention, and we continue to conduct analyses of data from our UC clinical stage programs and conduct preclinical studies to inform next steps for further development in UC and IBD more broadly.

Manufacturing

Donor-derived product candidates

SER-109 is a purified consortium of Firmicutes spores produced through a process of separation and purification from a natural human stool source, obtained from qualified, highly screened donors. The donor raw material is collected in a controlled setting, under a protocol that is designed to ensure that donors meet appropriate qualification criteria.

Donors are required to be in good health, and to possess a medical history that minimizes the risk of exposure to and transmission of an infectious disease. Donors are tested for infectious agents and screened for GI and other relevant health factors. Donors are monitored for health status changes on an ongoing basis throughout the donation period. At periodic intervals, 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 a periodic or exit screening, donations are released for use in manufacturing.

We initially process the donor material in our in-house Cambridge manufacturing facility, and then transfer the process intermediate to our partner CMO, GenIbet BioPharmaceuticals, SA, or GenIbet (acquired by Recipharm in February 2022), to further isolate and concentrate SER-109 for finishing to the oral capsule dosage form. The manufacturing process includes processes to inactivate and clear potential adventitious agents, to help ensure product safety. The purified drug substance is tested for identity, potency and purity, and subsequently formulated into drug product where it is again tested for identity, potency, purity, and pharmaceutical properties. The final drug product oral dosage form is four capsules daily for 3-days. Steps are specifically built into the process to remove and kill non-spore microbes. We have conducted validation studies demonstrating the ability of the process to inactivate and clear any potential extraneous pathogens of concern, and we believe we have sufficient data from these studies to support product registration. If approved, we anticipate that we will be able to produce a sufficient commercial supply of SER-109 to meet estimated demand in the United States using donations from a modest number of donors.

Commercial product supply for the initial phase of U.S. commercial launch is being produced at our Cambridge manufacturing facility and further processed at GenIbet. In November 2021, we entered into a collaboration with Bacthera to manufacture SER-109 to expand upon our existing capabilities for commercial product supply to meet anticipated demand in later years. Under the terms of the agreement, Bacthera is constructing a dedicated full-scale production suite for us at Bacthera's Microbiome Center of Excellence in Visp, Switzerland, and is intended to provide manufacturing services for SER-109.

Cultivated product candidates

The production of live bacterial products is highly specialized. Owing to their hardiness and environmental persistence, production of aerobic and anaerobic vegetative bacteria, as well as spore-forming organisms, poses unique considerations for product, personnel, and facility design, operation, quality assurance and quality control. Manufacturing activities with spores are subject to specialized regulations. We expect that a typical commercial fermentation will yield on the order of hundreds or thousands of doses per liter depending on the product and its composition. Additionally, because a given total dose contains multiple strains, the per-strain requirements for production may be even lower. As a result, we believe the relatively high productivity of our manufacturing processes relative to the dose level will enable production scales for both clinical and commercial supply to be modest by traditional industry standards for biologics and vaccine manufacturing.

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

- *Fermentation.* We are using microscale screening to optimize culture of the bacterial strains of interest in our current and foreseeable fermentation-based product candidates. These screens are designed to identify the fermentation platform that is best-suited for optimization and scale-up of the strains. Small-scale fermentation systems (0.1 L to 50 L) enable the optimization of a wide variety of culture conditions and have been demonstrated to be scalable to larger fermentation processes and enable technology transfer to clinical and final manufacturing sites. We employ platform fermentation processes as starting points for cGMP production processes and develop strain specific processes as required. To develop master cell banks, working cell banks, and bulk drug substance for commercial product, we are using bacterial strains that each originate from a unique research cell bank precursor, so we expect the research cell banks and final drug product should be genetically and physiologically similar.
- *Purification.* Similar to fermentation, we believe small-scale purification operations are available for assessing large-scale cGMP manufacturing of live cells, and to quickly assess downstream process yield, quality and robustness. Our products in development are predominantly oral dosage forms containing live bacteria, hence purification is typically less complex than for parenteral biologics such as monoclonal antibodies that must separate highly similar components from the culturing process. Separation of viable microbes from soluble fermentation broth components is typically much simpler by comparison.
- *Formulation.* Our microbiome therapeutic candidates are combinations of bacteria and can be administered by a number of methods and by different routes. Where possible, our product formulation development is focused on oral delivery for patient convenience. The primary goal in developing a formulation is to deliver bacteria to the intended location in a condition where they are able to replicate and modulate the microbiome. Formulation development generally uses approved excipients and preservatives with pharmaceutical industry precedent, and will include screening of liquid, solid, and suspension formulations to maximize the opportunity for extended stability with minimal cold-chain requirements. Dosage forms for oral products may be liquid- or powder-filled capsules, tablets, sachets, or liquid containers.

- *Analytical.* We are addressing quality control requirements for our microbiome therapeutic candidates using proprietary microbiological, chemical, biochemical, and molecular sequence-based testing schemes. We have available and are further developing quality control, environmental monitoring 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 products to be manufactured. Throughout the bioprocess and formulation development platform we use and will expand on quantitative analytics to assess the identity, potency and purity of the final product.

We currently have a 10,000 square foot cGMP manufacturing facility at our headquarters where we conduct cGMP manufacture of therapeutic candidates to support drug substance and drug product for early phase and small-scale clinical supplies and with the ability to perform both drug substance and drug product manufacturing for early and late-phase clinical development and at larger scales of operation. We may establish further manufacturing facilities that will serve late-phase clinical and commercial supply for our product candidates. We may do this by expanding our current facilities, or by purchasing or building additional facilities. We also use contract manufacturing and testing organizations to supplement our internal capacity.

Material Agreements

Collaboration and Manufacturing Agreements

Collaboration and License Agreement with Société des Produits Nestlé S.A. (Nestlé)

In January 2016, we entered into the Collaboration and License Agreement, or the 2016 License Agreement, with Nestec, Ltd., as succeeded by Société des Produits Nestlé S.A., or, together with NHSc Pharma Partners, succeeded by NHSc Rx License GmbH, their affiliates, and their subsidiaries, Nestlé, for the development and commercialization of certain of our product candidates in development for the treatment and management of CDI and IBD, including UC and Crohn's disease. The 2016 License Agreement will support the development of our portfolio of products for CDI and IBD in markets outside of the United States and Canada, or the 2016 Licensed Territory.

License Agreement with NHSc Rx License GmbH (Nestlé)

In July 2021, we entered into a License Agreement, or the 2021 License Agreement, with NHSc Pharma Partners, succeeded by NHSc Rx License GmbH, or, together with Société des Produits Nestlé S.A., their affiliates and their subsidiaries, Nestlé. Pursuant to the 2021 License Agreement, we granted to Nestlé, under certain of our patent rights and know how, a co-exclusive, sublicensable (under certain circumstances) license to develop, commercialize and conduct medical affairs activities for (i) therapeutic products based on our microbiome technology (including our SER-109 product candidate) that are developed by us or on our behalf for the treatment of CDI and recurrent CDI, as well as any other indications pursued for the products upon mutual agreement of the parties, or the 2021 Field in the United States and Canada, or the 2021 Licensed Territory, and (ii) our SER-109 product candidate and any improvements and modifications thereto developed pursuant to the terms of the 2021 License Agreement, or the 2021 Collaboration Products, for any indications in the 2021 Licensed Territory. We are responsible for completing development of SER-109 in the 2021 Field in the United States until first regulatory approval for SER-109 is obtained.

Long Term Manufacturing Agreement with Bacthera

In November 2021, we entered into a Long Term Manufacturing Agreement with BacThera AG, or Bacthera, a joint venture between Chr. Hansen and a Lonza Group affiliate, which was amended on December 14, 2022, or the Bacthera Agreement. The Bacthera Agreement governs the general terms under which Bacthera, or one of its affiliates, will (i) construct a dedicated full-scale production suite for us at Bacthera's Microbiome Center of Excellence in Visp, Switzerland, which is currently under construction; and (ii) provide manufacturing services to us for our SER-109 product and other products, as agreed to by both parties.

GenIbet Supply Agreement

In September 2015, we entered into a Supply Agreement, or the Supply Agreement, with GenIbet BioPharmaceuticals, SA (acquired by Recipharm in February 2022) to provide certain manufacturing and supply services to us for our product candidates for purposes of conducting clinical trials and supporting commercial supply. In March 2022, the term of the Supply Agreement was extended through June 30, 2023.

Indebtedness

Loan and Security Agreement with Hercules

In October 2019, we entered into a loan and security agreement with Hercules Capital, Inc., or Hercules, pursuant to which a term loan in an aggregate principal amount of up to $50.0 million, or the Original Credit Facility, was available to us in three tranches, subject to certain terms and conditions. We received the first tranche of $25.0 million upon signing the agreement on October 29, 2019, but did not borrow either of the second two tranches, which were available at different times upon Hercules' approval until June 30, 2021.

In April 2020, we entered into an amendment to the loan and security agreement with Hercules, or the First Amendment, permitting us to enter into a promissory note under the Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Stability Act.

In February 2022, we entered into a Second Amendment to the Original Credit Facility (as amended by the First Amendment), or the New Credit Facility, pursuant to which, term loans in an aggregate principal amount of up to $100.0 million have become available to us in five tranches subject to certain terms and conditions: (i) the first tranche in an aggregate principal amount of $25.0 million that was outstanding as of the February 24, 2022 effective date, or the Effective Date, (ii) the second tranche in an aggregate principal amount of $12.5 million that has been advanced to us and was outstanding as of the Effective Date, (iii) the third tranche in an aggregate principal amount of $12.5 million that has been advanced to us and was outstanding as of the Effective Date, (iv) the fourth tranche in an aggregate principal amount of $25.0 million that is available upon satisfaction of certain conditions, including the approval by the FDA of a biologics license application in respect of SER-109, or the Regulatory Approval Milestone, by no later than December 15, 2023, and (v) the fifth tranche in an aggregate principal amount of up to $25.0 million that is available through the amortization date upon satisfaction of certain conditions, including the lenders' investment committee approval.

For a further description of our material agreements, see "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources" in Part II, Item 7 of this Annual Report on Form 10-K.

Intellectual Property

We strive to protect the proprietary technology that 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 utilize regulatory exclusivity as well as trade secrets to protect aspects of our business.

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

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

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

Our patent portfolio includes issued U.S. patents and patent applications in various stages of prosecution, including ex-U.S. international counterparts. We believe that issued claims will provide protection for our microbiome therapeutic candidates.

Patent Term

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

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

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

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. We typically utilize trade secrets to protect aspects of our business. We protect trade secrets and know-how by establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and collaborators. These agreements provide that all confidential information developed or made known during the course of an individual or entities' relationship with us must be kept confidential during and after the relationship. These agreements also provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties.

Competition

The development and commercialization of new drug and biologic products is highly competitive and is characterized by rapid and substantial technological development and product innovations. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. We are aware of a number of large pharmaceutical and biotechnology companies, as well as smaller, early-stage companies, that are pursuing the development of products, including microbiome therapeutics, and disease indications we are targeting. 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, preclinical 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, clinical, manufacturing 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 the 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 preclinical, clinical and commercial approval requirements of the governing regulatory authorities of the countries in which we wish to conduct studies or seek approval for our product candidates. The process of obtaining regulatory approvals and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, the FDA regulates drug and biologic products under the Federal Food, Drug and Cosmetic Act, its implementing regulations and other laws, including, in the case of biologics, the Public Health Service Act. Our product candidates

are subject to regulation by the FDA as biologics. Biologics require the submission of a BLA and approval by the FDA before being marketed in the United States.

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

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before clinical trials in the United States may begin;
- approval by an institutional review board, or IRB, or ethics committee at each clinical site before a trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the product candidate for each proposed indication, conducted in accordance with the FDA's good clinical practice, or GCP, regulations;
- preparation and submission to the FDA of a BLA after completion of all pivotal trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- 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 to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the BLA prior to any commercial marketing, sale or shipment of the product.

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

Preclinical and Clinical Trials

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical 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 preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational new drug to humans. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing clinical trials to commence on the terms originally specified in the IND. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development, and the FDA must grant permission, either explicitly or implicitly by not objecting, before each clinical trial can begin.

Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. 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. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or in vitro testing suggesting a significant risk to humans exposed to the drug, and any clinically important increased rate of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

An independent institutional review board, or IRB, for each investigator site proposing to participate in a clinical trial must also review and approve the clinical trial before it can begin at that site, and the IRB must monitor the clinical trial until it is completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. 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. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

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

- *Phase 1* — The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are typically 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* — The investigational product is typically administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.
- *Phase 3* — The investigational product is administered 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.

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 preclinical 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 BLA must include all relevant data available from preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by independent investigators. The submission of a BLA requires payment of a substantial user fee unless a waiver is granted or exemption applies.

Each BLA submitted to the FDA is reviewed for administrative completeness and reviewability within 60 days of the FDA's receipt of the application. If the BLA is found to be complete, the FDA will file the BLA, triggering a full review of the application. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission. In this event, the BLA must be resubmitted with the additional information.

Once a BLA has been accepted for review, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for Priority Review, six months after the FDA accepts the application for filing, 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 also 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 it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA may inspect one or more clinical sites to assure that such trials were conducted in compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the

application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information, and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy implemented to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. 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 of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA maintains several programs intended to facilitate and expedite development and review of new biologics designed 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 expedite the development and review of qualifying product candidates.

A biologic is eligible for Fast Track designation if it is intended to treat a serious or life- threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in addition to the potential for rolling review, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. Product candidates receiving Fast Track status may also be eligible for Priority Review, if the relevant criteria are met.

In addition, a biologic product candidate 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 product candidate 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 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 candidate submitted to the FDA for approval, including a product candidate 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 BLA is eligible for Priority Review if the product candidate has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Additionally, product candidates 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 confirmatory studies to verify and describe the product's clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory studies in a timely manner or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast Track designation, Breakthrough Therapy designation, Priority Review designation and Accelerated Approval do not change the standards for approval but may expedite the development or review process.

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 marketed pursuant to approved applications.

Any biologics manufactured or distributed pursuant to FDA approvals remain subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences associated with the product. Manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon manufacturers and contract manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. 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 programs. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, untitled lets, or holds on clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

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

Biosimilars and Regulatory Exclusivity

The Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Orphan Drug Designation

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

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity during which the FDA may not approve any other applications to market the same therapeutic agent for the same indication, except in limited circumstances, such as a subsequent product's showing of clinical superiority over the product with orphan exclusivity or where the original applicant cannot produce sufficient quantities of product. 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. 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.

Government Regulation Outside of the United States

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, manufacturing, commercial sales and distribution of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries. Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical studies or marketing of the product in those countries. The requirements and process governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Non-clinical studies and clinical trials

Similar to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in EU Directive 2004/10/EC. In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization, or ICH, guidelines on Good Clinical Practices, or GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products, or ATMPs. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The

CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practice, or GMP. Other national and EU-wide regulatory requirements may also apply.

During the development of a medicinal product, the EMA and national regulators provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use, or CHMP. A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical trials, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future marketing authorization application of the product concerned.

Marketing Authorizations

In the EU, medicinal products can only be placed on the market after obtaining a marketing authorization, or MA. To obtain regulatory approval of an investigational biological product in the EU, we must submit a marketing authorization application, or MAA. The process for doing this depends, among other things, on the nature of the medicinal product.

Centralized procedure—Under the centralized procedure, following the opining of the EMA's CHMP the European Commission issues a single MA valid throughout the EU. The centralized procedure is compulsory for certain types of products, such as (i) medicinal products derived from biotechnology processes, such as genetic engineering, (ii) designated orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs, such as gene therapy, somatic cell therapy and tissue engineered products, and (iv) medicinal products that contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative diseases, diabetes, autoimmune diseases and other immune dysfunctions, and viral diseases. The centralized procedure is optional for any products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or for which the granting of a MA would be in the interest of public health in the EU.

Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA's CHMP is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. At the end of the review period, the CHMP provides an opinion to the European Commission. If this opinion is favorable, the Commission may then adopt a decision to grant an MA. In exceptional cases, the CHMP might perform an accelerated review of a MAA in no more than 150 days (excluding clock stops), when a medicinal product targets an unmet medical need and is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding clock stops.

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. In March 2016, the EMA launched an initiative, the Priority Medicines, or PRIME, scheme, a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is not guaranteed. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

National authorization procedures—There are also two other possible routes to authorize medicinal products in several member states, which are available for products that fall outside the scope of the centralized procedure:

- *Decentralized procedure*. Using the decentralized procedure, an applicant may apply for simultaneous authorizations in more than one EU member states of medicinal products that have not yet been authorized in any EU member states and that do not fall within the mandatory scope of the centralized procedure. Under the decentralized procedure an identical dossier is submitted to the national competent authority of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state. National MAs are issued by competent authorities of the EU member states for their respective territory.
- *Mutual recognition procedure*. In the mutual recognition procedure, a medicine is first authorized in one EU member state, in accordance with the national procedures of that member state. Following this, further MAs can be sought from other EU member states in a procedure whereby the countries concerned recognize the validity of the original national MA.

MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the European Commission or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal.

Data and Marketing Exclusivity

In the EU, upon receiving a MA, reference medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of the market exclusivity period a generic or biosimilar MA can be submitted, and the innovator's data may be referenced but no generic or biosimilar can be marketed in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The overall ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

Orphan Medicinal Products

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. A medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. The application for orphan drug designation must be submitted before the MAA. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a MA, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten-year orphan market exclusivity period, the competent authorities cannot accept another MAA, or grant a MA, or accept an application to extend a MA for a similar product for the same indication. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan, or PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, a MA may be granted to a similar product for the same indication at any time if (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

Pediatric Development

In the EU, MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which an MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all member states and study results are included in the product information, even when negative, the product is eligible for a six-months supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan pharmaceutical products, a two year extension of the orphan market exclusivity is granted.

Post-Approval Requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general

requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA (comprised of the 27 EU member states plus Iceland, Liechtenstein and Norway).

Brexit and the Regulatory Framework in the United Kingdom

Since the end of the Brexit transition period on January 1, 2021, Great Britain (England, Scotland and Wales) has not been directly subject to EU laws, however under the terms of the Ireland/Northern Ireland Protocol, EU laws generally apply to Northern Ireland. The EU laws that have been transposed into United Kingdom, or UK, law through secondary legislation remain applicable in Great Britain. However, under the Retained EU Law (Revocation and Reform) Bill 2022, which is currently before the UK parliament, any retained EU law not expressly preserved and "assimilated" into domestic law or extended by ministerial regulations (to no later than June 23, 2026) will automatically expire and be revoked by December 31, 2023. New legislation such as the EU CTR or in relation to orphan medicines will not be applicable in Great Britain. The UK government has passed a new Medicines and Medical Devices Act 2021, which introduces delegated powers in favor of the Secretary of State or an 'appropriate authority' to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, is the UK's standalone medicines and medical devices regulator. Whilst Northern Ireland will continue to follow the EU regulatory regime, but its national competent authority will remain the MHRA.

The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment and a rolling review procedure. All existing EU MAs for centrally authorized products were automatically converted or grandfathered into UK MAs, effective in GB (only), free of charge on January 1, 2021, unless the MA holder chooses to opt-out. After Brexit, companies established in the UK cannot use the centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain an MA to commercialize products in the UK. The MHRA may rely on a decision taken by the European Commission on the approval of a new (centralized procedure) MA when determining an application for a GB authorization; or use the MHRA's decentralized or mutual recognition procedures which enable MAs approved in EU member states (or Iceland, Liechtenstein, Norway) to be granted in GB.

Other Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical and biological products, other healthcare regulatory laws restrict business practices in the biotechnology industry, which include, but are not limited to, anti-kickback, false claims, and transparency laws regarding drug pricing and payments and other transfers of value made to physicians and other healthcare providers. The federal Anti-Kickback Statute prohibits the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal healthcare programs. Remuneration has been broadly interpreted to include anything of value, including cash, improper discounts and free or reduced-price items and services. 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. Many states have similar laws that apply to their state healthcare programs as well as private payors.

The False Claims Act, or FCA, imposes liability on persons who, among other things, knowingly present or cause to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government, knowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly make a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. 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. In addition, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. 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. 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, and has obtained multi-million and multi–billion-dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. In addition, companies

have been forced to implement extensive corrective action plans and have often become subject to consent decrees or corporate integrity agreements, severely restricting the manner in which they conduct their business. Given the significant size of actual and potential settlements, it is expected that the government authorities will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The ACA, among other things, imposed new reporting requirements through the Physician Payments Sunshine Act on certain manufacturers of drugs covered by a federal healthcare program for payments made by them to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiology assistants, and certified nurse midwives) 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 for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Manufacturers must submit reports by the 90th day of each 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, and pricing information and marketing expenditures.

To the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

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. Violations of any of such laws or any other governmental regulations that apply to drug manufacturers may result in significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, exclusion from participation in federal and state healthcare programs, reporting obligations and integrity oversight, and imprisonment.

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, or hinder, coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Additionally, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products, as well as provide rebates and discounts which may impact the net selling price of our products. If third-party payors do not consider our products to be cost-effective compared to other therapies, the payors may not cover our products as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis.

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

Outside the United States, ensuring adequate coverage and payment for our products will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. Conducting such a clinical trial could be expensive and result in delays in our commercialization efforts. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly approved healthcare products. Recent budgetary pressures in many countries are also causing governments to consider or implement various cost-containment measures,

such as price freezes, increased price cuts and rebates. If budget pressures continue, governments may implement additional cost-containment measures. Cost-control initiatives could decrease the price we might establish for products that we may develop or sell, which would result in lower product revenues or royalties payable to us. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. The downward pressure on healthcare costs in general, particularly prescription products, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from low priced markets exert a commercial pressure on pricing within a country.

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 ACA was signed into law, which, among other things, includes changes to the coverage and payment for pharmaceutical and biological products under government health care programs. Among other things, the ACA:

- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of ''average manufacturer price,'' or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- extended Medicaid drug rebates, previously due only on fee-for-service utilization, to Medicaid managed care utilization, and created an alternate rebate formula for new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs;
- expanded the types of entities eligible for the 340B drug discount program that mandates discounts to certain hospitals, community centers and other qualifying providers. With the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, because 340B pricing is determined based on AMP and Medicaid drug rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discounts to increase; and
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 70% 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.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021, through August 15, 2021, for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In For example, the Budget Control Act of 2011, enacted in August 2011, among other things, included reductions of Medicare payments to providers, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, 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 types of providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, the American Rescue Plan Act of 2021 as signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's AMP, beginning January 1, 2024.

More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical and biological products. Most recently, on August 16, 2022 the Inflation Reduction Act of 2022 ("IRA") was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated, and the impact of the IRA on the pharmaceutical industry cannot yet be fully determined. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Adoption of other new legislation at the federal, state, or foreign level could further limit reimbursement for pharmaceuticals, including our product candidates if approved.

Data Privacy and Security

We may also be subject to U.S. federal, state and laws, regulations and standards governing the collection, use, access to, confidentiality, and security of health-related and other personal information, that could apply now or in the future to our operations or the operations of our partners. Numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations, govern the collection, use, disclosure, and protection of health-related and other personal information.

In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Human Capital

Employees

As of December 31, 2022, we had 431 full-time permanent employees. Sixty-four employees work in administration, operations, and commercial and 367 work in research and development. None of our employees in the U.S. are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good. During 2022, we enhanced our capabilities by significantly expanding our employee base. The new employees were hired to support a variety of functions and key initiatives, including extending our research, clinical and pre-clinical pipeline development, as well as our medical affairs, manufacturing and commercialization capabilities, with hires in commercial, clinical development and operations, research, medical affairs, manufacturing, and general and administrative functions. We expect to continue to add additional employees in 2023, with a focus on further enhancing our capabilities and increasing our capacities in these areas as we continue our focus on gaining FDA approval for SER-109 for recurrent CDI.

Talent Acquisition and Development

We consider the intellectual capital, skills and experience of our employees to be an essential driver of our business and key to our future prospects. We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions, and we believe that our future success will depend in large part on our continued ability to attract and retain highly skilled employees. To attract qualified applicants to our company and retain our employees, we offer a total rewards package consisting of base salary and cash target bonus targeting the 50th to 75th percentile of the market based on geography, a comprehensive benefit package and equity compensation for every employee. Annual cash bonus opportunity and equity compensation increase as a percentage of total compensation based on level of responsibility. Any actual bonus payout is based on a combination of individual performance and corporate performance.

Diversity, Inclusion, and Belonging

As a microbiome therapeutics company developing a novel class of live biotherapeutic drugs, we believe that our long-term success and ability to deliver innovative, safe and effective medicines to patients requires a diverse and inclusive workforce. We value diversity at all levels of the organization and continue to focus on extending our diversity, equity and inclusion initiatives across our entire workforce, from: working with managers to develop strategies for building diverse, high performing teams; to ensuring that we attract, develop and retain diverse talent from all backgrounds; to increasing awareness within our company of unconscious biases, and supporting affinity groups comprised of individuals who are underrepresented in our company, industry or society, such as women, members of the LGBTQ community and people of color. In addition, we pride ourselves on an open culture that respects co-workers, values employees' health and well-being and fosters professional development. We support employee growth and development in a variety of ways including with group training, individual mentoring and coaching, conference attendance and tuition reimbursement. Our management conducts annual employee engagement surveys and reports to our board of directors on human capital management topics, including corporate culture, diversity, equity and inclusion, employee development and retention, and compensation and benefits. Similarly, our board of directors regularly provides input on important decisions relating to these matters, including with respect to employee compensation and benefits, talent retention and development.

Our Corporate Information

We were incorporated in the State of Delaware in 2010 under the name Newco LS21, Inc. In October 2011, we changed our name to Seres Health, Inc., and in May 2015, we changed our name to Seres Therapeutics, Inc. Our principal executive offices are located at 200 Sidney Street, Cambridge, Massachusetts 02139 and our telephone number is (617) 945-9626. Our website address is *www.serestherapeutics.com*. The information contained in, or accessible through, our website does not constitute a part of this Annual Report on Form 10-K.

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and, accordingly, file reports, proxy statements and other information with the Securities and Exchange Commission, or SEC. The SEC maintains a web site (http://www.sec.gov) that contains material regarding issuers that file electronically, such as ourselves, with the SEC.

We make available free of charge on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Item 1A. Risk Factors

Our business faces significant risks and uncertainties. Accordingly, in evaluating our business, you should carefully consider the risk factors discussed below, as well as the other information included or incorporated by reference in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below or elsewhere in this report could harm our business, financial condition, results of operations or growth prospects.

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 $250.2 million for the year ended December 31, 2022, $65.6 million for the year ended December 31, 2021, and $89.1 million for the year ended December 31, 2020. As of December 31, 2022, we had an accumulated deficit of $864.5 million. As noted elsewhere in this Annual Report on Form 10-K, we have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. To date, we have financed our operations through the public offerings of our common stock, private placements of our common stock and preferred stock, payments under our collaboration agreements, and loan facility. We have devoted substantially all of our financial resources and efforts to developing our reverse translational microbiome therapeutics platform, identifying potential product candidates and conducting preclinical studies and clinical trials. We have not completed development of any of our product candidates, which we call microbiome therapeutic candidates, or other drugs or biologics. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses may increase substantially as we:

- complete the clinical development, seek regulatory approval, and prepare for potential commercialization of SER-109 for patients with recurrent CDI;
- continue the clinical development of SER-155 to reduce incidences of gastrointestinal infections, bloodstream infections and GvHD in patients receiving allo-HSCT;
- continue evaluating preclinical stage programs to reduce incidence of infection, in indications such as cancer neutropenia, chronic liver disease, solid organ transplant, and antimicrobial resistant infections more broadly;
- continue translational research activities, informed by the SER-287 Phase 2b and SER-301 Phase 1b study data, to evaluate the potential to utilize biomarker-based patient selection and stratification in future clinical development efforts;
- make strategic investments in our research discovery and development platforms and capabilities to advance our priority programs;
- make strategic investments in manufacturing capabilities;
- maintain and augment our intellectual property portfolio and opportunistically acquire complementary intellectual property;
- potentially establish a sales and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- perform our obligations under our agreements with our collaborators;
- seek to obtain regulatory approvals for our product candidates; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical 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 in the preliminary stages of many 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.

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

We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern.

Based on our currently available cash resources and our current level of operations and cash flows for the 12-month period subsequent to the date of issuance of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe it is reasonably likely that we will require additional funding in early 2024. There are certain contingent payments associated with the approval of our BLA for SER-109, which is currently under priority review by the FDA, including the potential to receive a $125.0 million milestone payment from Nestlé pursuant to the 2021 License Agreement, and a $25.0 million tranche under our New Credit Facility with Hercules, which becomes available upon the satisfaction of certain conditions, including FDA approval of SER-109. While we anticipate receiving these contingent payments in the first half of 2023, there is no assurance we will receive them. Because these contingent payments, and the ability to obtain sufficient additional equity or debt financing with terms favorable or acceptable to us, cannot be considered probable according to the applicable accounting standards because they are outside our control, there is substantial doubt about our ability to continue as a going concern for at least 12 months from the date that our consolidated financial statements for the year ended December 31, 2022 were issued.

Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing. If potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

We have prepared our consolidated financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our audited consolidated financial statements included in this Annual Report on Form 10-K do not include any adjustments to reflect the possible inability of the Company to continue as a going concern within 12 months after the issuance of such financial statements.

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

Our expenses may increase in connection with our ongoing activities, particularly as we complete clinical development, scale up manufacturing operations, seek regulatory approval, and prepare for commercialization of SER-109 if approved, continue the SER-155 Phase 1b study, continue research activities evaluating UC, and continue to research, develop and initiate clinical trials of 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, and may not generate meaningful product revenues or collaboration profit in the near future. Furthermore, we have incurred and expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

As noted above, we have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. Our future capital requirements will depend on many factors, including:

- the ongoing and long-term impact of the COVID-19 pandemic;
- the impact of a continued increase in inflation rates or interest rates;
- the progress and results of our clinical studies;
- the cost of manufacturing our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Additionally, market volatility resulting from current macroeconomic conditions, the COVID-19 pandemic, or other factors could also adversely impact our ability to access capital as and when needed. 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 and may decrease our stock price. 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 adversely affect our business, financial condition and results of operations.

Our limited operating history may make it difficult 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 our clinical and preclinical program, building our intellectual property portfolio, developing our supply chain, planning our business, raising capital and providing general and administrative support for these operations. We have not yet demonstrated our ability to 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 made 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

Other than SER-109, we are early in our development efforts and may not be successful in our efforts to use our reverse translational microbiome therapeutics platform to build a pipeline of product candidates and develop marketable drugs.

We are using our reverse translational microbiome therapeutics platform to develop microbiome therapeutic candidates. Other than SER-109, 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 reduce infection and treat diseases where the microbiome is implicated. We may have problems applying our technologies to these areas, and our product candidates may not be effective in reducing infection and disease. Our product candidates may not be suitable for clinical development, including as a result of their harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance.

The success of our product candidates will depend on several factors, including the following:

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

- maintaining a continued acceptable safety profile of our products following approval; and
- maintaining and growing an organization of scientists and business people who can develop and commercialize our products and technology.

If we or our collaborators do not successfully develop and commercialize product candidates 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 therapeutics, a novel potential class of biological drugs, which are designed to treat disease by modulating the microbiome to restore health by repairing the function of a disrupted microbiome to a non-disease state. We have not, nor to our knowledge has any other company, received regulatory approval for, or manufactured on a commercial scale, a therapeutic based on this approach. We cannot be certain that our approach will lead to the development of approvable or marketable products or that we will be able to manufacture at commercial scale, if approved. In addition, our microbiome therapeutic candidates may have different effectiveness rates in various indications and in different geographical areas. Finally, the FDA or other regulatory authorities 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 reverse translational 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 materials or products, which could delay the development or commercialization of our product candidates.

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

It is difficult to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval, and the risk of failure through the development process is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical 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 failure of one or more clinical trials can occur at any stage of testing, and our clinical trials may not be successful. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim or preliminary results of a clinical trial, that we may from time to time announce, do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks.

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

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:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- regulatory authorities or institutional review boards or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- failures or delays in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidates may demonstrate undesirable side effects or produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulatory authorities or institutional review boards or ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- regulatory authorities may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- regarding trials managed by any current or future collaborators, our collaborators may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but potentially suboptimal for us.

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

- be delayed in obtaining marketing approval for our product candidates;
- lose the support of current or any future collaborators, requiring us to bear more of the burden of development of certain compounds;
- not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as we intend or desire;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be subject to increased pricing pressure; or
- have the product removed from the market after obtaining marketing approval.

Additional clinical trials or changes in our development plans could cause us to incur significant development costs, delay or prevent the commercialization of SER-109 or otherwise adversely affect our business. In addition, prolonged disruptions caused by the COVID-19 pandemic could severely impact our preclinical studies and clinical trials, including by causing further difficulties or delays in initiating, enrolling, conducting, or completing our planned and ongoing clinical trials. See "—Risks Related to Our Operations—The COVID-19 pandemic has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition."

Our product development costs will increase if we continue to experience delays in clinical testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical 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.

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted with respect to clinical trials. For instance, the regulatory landscape related to clinical trials in the European Union, or EU, recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as contract research organizations, or CROs, may impact our developments plans.

The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). However, on January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency, or MHRA, launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed on March 14, 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The Government has not yet published a response to the consultation but the outcome will be closely watched and will determine whether the UK chooses to align with the CTR or diverge from it to maintain regulatory flexibility. Under the terms of the Protocol on Ireland/Northern Ireland, provisions of the CTR which relate to the manufacture and import of investigational medicinal products and auxiliary medicinal products apply in Northern Ireland. A decision by the UK Government not to closely align its regulations with the new approach that has been adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our business may be impacted.

Delays or difficulties in the enrollment of patients in clinical trials, could result in our receipt of necessary regulatory approvals being delayed or prevented.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. These trials and other trials we conduct may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, patient withdrawal or adverse events. These types of developments could cause us to delay the trial or halt further development.

Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. In addition, there may be limited patient pools from which to draw for clinical studies. In addition to the rarity of some diseases, the eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study.

Patient enrollment is also affected by other factors including:

- the severity of the disease under investigation;
- the patient eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the availability of other treatments for the disease under investigation, including the use of fecal microbiota transplant, or FMT;
- the existence of competing clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- our payments for conducting clinical trials;
- the patient referral practices of physicians;
- the burden, or perceived burden, of the clinical study;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials or a delayed rate of enrollment would result in significant delays and could require us to abandon one or more clinical trials altogether.

Interim "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, top-line or preliminary data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or our collaborators 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 similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate in any jurisdiction will prevent us and our collaborators 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 preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product

candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, risky and may take many years. The scope and amount of clinical data required to obtain marketing approvals can vary substantially from jurisdiction to jurisdiction, and it may be difficult to predict whether a particular regulatory body will require additional or different studies than those conducted by a sponsor, especially for novel product candidates such as our microbiome therapeutic candidates. 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 authority's requirement that we conduct additional preclinical 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. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. A proposal for revision of several legislative instruments related to medicinal products (potentially revising the duration of regulatory exclusivity, eligibility for expedited pathways, etc.) is currently expected to be adopted by the European Commission in the first quarter of 2023. The proposed revisions, once they are agreed and adopted by the European Parliament and European Council (currently not expected before the end of 2024 or early 2025) may have a significant impact on the biopharmaceutical industry in the long term.

There may also be interruptions or delays in the operations of the FDA or other foreign regulatory authorities due to the COVID-19 pandemic, which may impact approval timelines. The FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Additionally, regulatory authorities have substantial discretion in the approval process and may refuse to accept a marketing application if deficient. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Of the large number of drugs in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized.

Furthermore, our product candidates may not receive marketing approval even if they achieve their specified endpoints in clinical trials. Clinical data is often susceptible to varying interpretations and many companies that have believed that their products performed satisfactorily in clinical trials have nonetheless failed to obtain regulatory authority 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, or they may require additional confirmatory or safety evidence beyond our existing 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 or gather more 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 authority 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 authority may also approve our product candidates for a more limited indication and/or a narrower patient population than we originally request, and the FDA, or applicable foreign regulatory authority, may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of our product candidates and would materially adversely impact our business and prospects.

The development of therapeutic products targeting the underlying biology of the human microbiome is an emerging field, and it is possible that the FDA and other regulatory authorities could issue regulations or new policies in the future that could adversely affect our microbiome therapeutic 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 Fast Track designation. SER-287 received Fast Track designation from the FDA for the induction and maintenance of clinical remission in adults with mild-to-moderate UC. Fast Track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in addition to the potential for rolling review of a BLA for such product candidate. The FDA has broad discretion whether or not to grant this designation, and even if we

believe another particular product candidate is eligible for this designation, we cannot be certain that the FDA would decide to grant it. Even with Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Fast Track designation does not assure ultimate approval by the FDA. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

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

We have received Breakthrough Therapy designation for SER-109 for treatment of CDI, and we may seek a Breakthrough Therapy designation for our other product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed in early clinical development. For drugs or biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development. Drugs designated as breakthrough therapies by the FDA are also eligible for rolling review of the associated marketing application.

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 receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, not all products designated as breakthrough therapies ultimately will be shown to have the substantial improvement over available therapies suggested by the preliminary clinical evidence at the time of designation. As a result, if the Breakthrough Therapy designation for SER-109 or any future designation we receive is no longer supported by subsequent data, the FDA may rescind the designation.

We may seek PRIME designation by EMA or other designations, schemes or tools in the EU for one or more of our product candidates, which we may not receive. Such designations may not lead to a faster development or regulatory review or approval process and do not increase the likelihood that our product candidates will receive marketing authorization.

We may seek EMA PRIME (Priority Medicines) designation or other designations, schemes or tools for one or more of our product candidates. In the EU, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the Breakthrough Therapy designation in the United States. PRIME is a voluntary scheme aimed at enhancing the European Medicines Agency's, or EMA, support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. The benefits of a PRIME designation include the appointment of a rapporteur before submission of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.

Even if we believe one of our product candidates is eligible for PRIME, the EMA may disagree and instead determine not to make such designation. The EMA PRIME scheme or other schemes, designations, or tools, even if obtained or used for any of our product candidates may not lead to a faster development, regulatory review or approval process compared to therapies considered for approval under conventional procedures and do not assure ultimate approval. In addition, even if one or more of our product candidates is eligible to the PRIME scheme, the EMA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for review or approval will not be shortened.

Product developers that benefit from PRIME designation may be eligible for accelerated assessment (in 150 days instead of 210 days), which may be granted for medicinal products of major interest from a public health perspective or that target an unmet medical need, but this is not guaranteed.

The competent regulatory authorities in the EU have broad discretion whether to grant such an accelerated assessment, and, even if such assessment is granted, we may not experience a faster development process, review or authorization compared to conventional procedures. Moreover, the removal or threat of removal of such an accelerated assessment may create uncertainty or delay in the clinical development of our product candidates and threaten the commercialization prospects of our products and product candidates, if approved. Such an occurrence could materially impact our business, financial condition and results of operations.

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

We have obtained orphan drug designation from the FDA for SER-109 for recurrent CDI and SER-287 for pediatric UC and may seek orphan drug designation and exclusivity for some of our future product candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and biologics for relatively small patient populations as orphan drugs. In the United States, the FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, which is defined as a disease or condition that affects fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation must be requested before submitting a BLA. In the United

States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA.

In addition, if a product with an orphan drug designation subsequently receives the first marketing approval for the disease or condition for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or other regulatory authorities from approving another marketing application for the same drug or biologic for that time period, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. 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, at the end of the fifth year, it is established that 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 other regulatory authorities determine that the request for designation was materially defective or if the manufacturer is unable to assure a sufficient quantity of the drug or biologic to meet the needs of patients with the rare disease or condition. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective.

Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity for a product may not effectively protect the product from competition because different drugs and biologics can be approved for the same disease or condition. Even after an orphan drug or biologic is approved, the FDA or other regulatory authorities can subsequently approve the same drug or biologic for the same disease or condition if the FDA or other regulatory authorities conclude 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. Orphan drug designation neither shortens the development time or regulatory review time nor gives the drug any advantage in the regulatory review or approval process.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and other regulatory authorities to review and or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's and other regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's and other regulatory authorities' ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other regulatory authorities, such as the EMA, following its relocation to Amsterdam and resulting staff changes, may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary regulatory authorities, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States, including the EMA, have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to our Dependence on Third Parties and Manufacturing

The collaboration and license agreements with Société des Produits Nestlé S.A. and NHSc Rx License GmbH (collectively, and together with their affiliates and subsidiaries, Nestlé) are important to our business. If we or Nestlé fail to adequately perform under these agreements, or if we or Nestlé terminate the agreements, the development and commercialization of our CDI and IBD product candidates, including SER-109, SER-287 and SER-301, could be delayed or terminated and our business would be adversely affected.

In January 2016, we entered into a Collaboration and License Agreement with Nestlé, or the 2016 License Agreement. The 2016 License Agreement may be terminated:

- by Nestlé in the event of serious safety issues related to SER-109, SER-287, SER-301 or other specific products added under the 2016 License Agreement, or, collectively, the 2016 Collaboration Products;

- by us if Nestlé challenges the validity or enforceability of any of our licensed patents; and
- by either Nestlé or us in the event of the other party's uncured material breach or insolvency.

Upon termination of the 2016 License Agreement, all licenses granted to Nestlé by us will terminate, and all rights in and to the 2016 Collaboration Products held by Nestlé will revert to us. If we commit a material breach of the 2016 License Agreement, Nestlé may elect not to terminate the 2016 License Agreement but instead apply specified adjustments to its payment obligations and other terms and conditions of the 2016 License Agreement. If Nestlé were to make such adjustments, the funding from and benefits of the 2016 License Agreement could be diminished, which could adversely affect our financial condition. Unless the 2016 License Agreement is terminated by us for Nestlé's uncured material breach, upon termination of the 2016 License Agreement, Nestlé will be eligible to receive post-termination royalties from us until Nestlé has recouped certain development costs related to the 2016 Collaboration Products and specified percentages of any milestone payments paid to us under the 2016 License Agreement prior to termination, which could have a material adverse effect on our business.

In July 2021, we entered into a License Agreement with Nestlé, or the 2021 License Agreement. The 2021 License Agreement may be terminated:

- by Nestlé with twelve months' prior written notice, effective only on or after the third anniversary of first commercial sale of our SER-109 product and any improvements and modifications thereto developed pursuant to the terms of the 2021 License Agreement, or the 2021 Collaboration Products;
- by Nestlé if first commercial sale of the first 2021 Collaboration Product has not occurred by the fifth anniversary of the effective date of the 2021 License Agreement, with 180 days' prior written notice, which must be provided during a specified period set forth in the 2021 License Agreement;
- by Nestlé if regulatory approval for SER-109 is not granted after submission by us of a filing seeking first regulatory approval as set forth in the development and regulatory activity plan, and the parties fail to agree on further development of SER-109 in accordance with the terms of the 2021 License Agreement, with 180 days' prior written notice, which must be provided within a specified period set forth in the 2021 License Agreement;
- by us if Nestlé challenges the validity or enforceability of any of our licensed patents; and
- by either Nestlé or us in the event of the other party's uncured material breach or insolvency.

Upon termination of the 2021 License Agreement, all licenses granted to Nestlé by us will terminate. If we commit a material breach of the 2021 License Agreement, Nestlé may elect not to terminate the 2021 License Agreement but instead apply specified adjustments to the payment terms and other terms and conditions of the agreement. If Nestlé were to make such adjustments, the funding from and benefits of the 2021 License Agreement could be diminished, which could adversely affect our financial condition. In the event we materially breach the 2021 License Agreement or file for bankruptcy, the share of profits and milestones due to us will be reduced by a specified percentage until Nestlé has recouped twice the losses caused by our material breach or bankruptcy.

Termination of these agreements could cause significant delays in our product development and commercialization efforts that could prevent us from commercializing our CDI and IBD product candidates without first expanding our internal capabilities or entering into another agreement with a third party. Any alternative collaboration or license could also be on less favorable terms to us. In addition, under the agreements, Nestlé agreed to provide funding for certain clinical development activities. If either of the agreements were terminated, we may need to refund those payments and seek additional financing to support the research and development of any terminated products or discontinue any terminated products, which could have a material adverse effect on our business.

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

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

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

Our reliance on these third parties for research and development activities will reduce our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as good clinical practices, 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. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations or similar regulatory requirements outside the United States. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. Other countries' regulatory authorities also have requirements for clinical trials with which we must comply. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, *ClinicalTrials.gov*, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

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

We rely on third parties for certain aspects of the manufacture of our product candidates for preclinical and clinical testing and for potential commercial manufacture, and we 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, including GenIbet and Bacthera, for certain aspects of materials supply for our product candidates in preclinical 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. For example, certain of our product candidates rely on human stool from third-party donors. If we do not obtain an adequate supply of donor-derived material to meet clinical or commercial demand, our ability to manufacture our product candidates may be delayed or adversely impacted.

We rely on third-party manufacturers, which entails additional risks, including:

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

Third-party manufacturers may not be able to comply with current good manufacturing processes, or cGMP, regulations or similar regulatory requirements inside or 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. Some of the contract manufacturers we rely on to produce our product candidates have never produced an FDA-approved therapeutic. One of the contract manufacturers on which we rely will be constructing a building in which to manufacture our product candidates, which may not be completed on time or at all or, upon completion, may not be approved by the FDA. If our manufacturers are unable to comply with cGMP regulation or similar regulatory requirements outside the United States or if the FDA or other regulatory authorities do not approve their facility upon a pre-approval inspection, our therapeutic candidates may not be approved or may be delayed in obtaining approval. In addition, there are a limited number of manufacturers that operate under cGMP regulations and similar regulatory requirements outside the United States 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. We do not currently have a second source for certain required materials used for the manufacture of finished product. If our current 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. Moreover, as a result of the COVID-19 pandemic, third-party manufacturers may be affected, which could disrupt their activities and as a result we could face difficulty sourcing key components necessary to produce supply of our product candidates, which may negatively affect our preclinical and clinical development activities.

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

We have manufacturing facilities at our Cambridge, Massachusetts locations where we conduct process development, scale-up activities and a portion of the manufacture of microbiome therapeutics. The FDA and other comparable foreign regulatory authorities must, pursuant to inspections that are conducted after submitting a BLA or relevant foreign marketing submission, confirm that the manufacturing processes for the product meet cGMP or similar regulatory requirements outside the United States. We have not yet received the final results of any inspections of our manufacturing facilities.

We currently intend to rely in part on third-party manufacturers for the commercial manufacturing of SER-109 and may establish a manufacturing facility for SER-109 or any of our other product candidates for production at a commercial scale. We have no experience in manufacturing sufficient volume of our product candidates to meet potential market demands. We may not be able to develop commercial-scale manufacturing facilities that are adequate to produce materials for 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.

In addition, some of our product candidates require donor material, of which we may not be able to collect sufficient quantities for commercial-scale or other manufacturing.

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

Even if any of our product candidates receive 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 FMT, and physicians may continue to rely on these treatments. If our product candidates receive approval but do not achieve an adequate level of acceptance, we or our collaborators may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our approved product candidates, if any, will depend on a number of factors, including:

- their efficacy, safety and other potential advantages compared to alternative treatments;
- the clinical indications for which our products are approved;
- our ability to offer them for sale at competitive prices;
- their convenience and ease of administration compared to alternative treatments;

- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for our product candidates;
- the prevalence and severity of their side effects and their overall safety profiles;
- any restrictions on the use of our products together with other medications;
- interactions of our products with other medicines patients are taking; and
- the ability of patients to take our products.

If we or our collaborators are unable to establish effective sales, marketing and distribution capabilities or enter into agreements with third parties with such capabilities, we or our collaborators may not be successful in commercializing our product candidates if and when they are approved.

We have employees with experience in sales and marketing, but we have limited sales or marketing infrastructure and, as a company, 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 July 2021, we entered into the 2021 License Agreement with Nestlé, pursuant to which we granted Nestlé, under certain of our patent rights and know how, a co-exclusive, sublicensable (under certain conditions) license to develop, commercialize and conduct medical affairs activities for the 2021 Collaboration Products in the United States and Canada. Under the 2021 License Agreement, Nestlé has the sole right to commercialize the 2021 Collaboration Products in the 2021 Licensed Territory in accordance with a commercialization plan, subject to our right to elect to provide up to a specified percentage of all promotional details for a certain target audience. Each party will use commercially reasonable efforts to commercialize the 2021 Collaboration Products in the 2021 Licensed Territory in accordance with the commercialization plan. Both parties will perform medical affairs activities for 2021 Collaboration Products in the 2021 Licensed Territory in accordance with a medical affairs plan. We will be responsible for commercialization and medical affairs activities costs incurred by the parties until first commercial sale of the first 2021 Collaboration Product in the 2021 Licensed Territory and in accordance with a pre-launch plan, up to a specified cap.

In the future, we expect to build a focused sales and marketing infrastructure, or certain components of such 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 or our collaborators cannot retain or reposition sales and marketing personnel.

Factors that may inhibit efforts to commercialize our products include:

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

Outside the United States, we rely and may increasingly rely on third parties, including Nestlé, 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 and our collaborators face competition with respect to our

current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. We are aware of a number of large pharmaceutical and biotechnology companies, as well as smaller, early-stage companies, that are pursuing the development or commercialization of products, including microbiome therapeutics, for reducing 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 reports of high success rates for recurrent CDI. Potential competitors also include academic institutions, government agencies, not-for-profits, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

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

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

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

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

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

Obtaining and maintaining adequate reimbursement for our products may be difficult. We cannot be certain if and when we will obtain an adequate level of reimbursement for our products by third-party payors. Even if we do obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review, and increasingly question the coverage of, and challenge the prices charged for, drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. We may also be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval, and the royalties resulting from the sales of those products may also be adversely impacted.

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

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve

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

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

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

- regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently hold $5.0 million in product liability insurance coverage in the aggregate, with a per occurrence limit of $5.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

Even if we and our collaborators 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 BPCIA, enacted in 2010 as part of the Patient Protection and Affordable Care Act, created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar," or biosimilar, to or "interchangeable" with an FDA-approved biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. This pathway could allow competitors to reference data from innovative biological products 12 years after the time of approval of the innovative biological product. This data exclusivity does not prevent another company from developing a product that is highly similar to the innovative product, generating its own data and seeking approval. Data exclusivity only assures that another company cannot rely upon the data within the innovator's application to support the biosimilar product's approval.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. It is possible that Congress or the FDA may take these or other measures to reduce or eliminate periods of exclusivity. The BPCIA is complex and continues to be interpreted and implemented by the FDA, and such FDA implementation could have a material adverse effect on the future commercial prospects for our product candidates.

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

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

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

Any product candidate for which we obtain marketing approval will remain subject to significant post-marketing regulatory requirements and oversight.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to the continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP and similar foreign 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 and similar foreign requirements. Accordingly, we, and our collaborators 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, 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 or other regulatory authorities 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 or other regulatory authorities 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. Violations of the FDA's and other regulatory authorities' restrictions relating to the promotion of prescription drugs by us or our collaborators 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 authority, we or our collaborators 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 authority may impose restrictions on the products or us and our collaborators, including requiring withdrawal of the product from the market. Any failure by us or our collaborators to comply with applicable regulatory requirements may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;

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

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

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity.

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. It is difficult to predict whether or how any executive orders will be implemented, or whether they will be rescinded and replaced under future administrations. The policies and priorities of the new administrations are unknown and could materially impact the regulations governing our product candidates.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

The FDA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we or our collaborators are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory authorities strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory authorities as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we or our collaborators are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Our relationships and any collaborators' relationships with customers, physicians and third-party payors are and will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us or our collaborators 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 and our collaborators' current and future arrangements with third-party payors, physicians and customers expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may restrict the business or financial arrangements and relationships through which we market, sell and distribute any products for

which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program, such as Medicare and Medicaid; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the False Claims Act, imposes, among other things, impose criminal and civil penalties, including through 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, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them to have committed a violation;
- the federal Physician Payment Sunshine Act requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiology assistants, and certified nurse midwives), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; manufacturers are required to submit reports to the government by the 90th day of each calendar year; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to our business practices, including but not limited to, research, distribution, 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 (or foreign governments) and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, pricing information or marketing expenditures.

The risk of our or our collaborators 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 or our collaborators for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain a robust system to comply with multiple jurisdictions with different compliance and reporting requirements increases the possibility that we 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 laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement, 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA, is 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 ACA of importance to our potential product candidates are the following:

- establishment of a new pathway for approval of lower-cost biosimilars to compete with biologic products, such as those we are developing;
- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, enacted in August 2011, required sequestration that included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2030, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will increase in future years of the sequester. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and an increase in the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, in March 2021, the American Rescue Plan Act of 2021 was signed into law, which, among other things, eliminated the statutory cap on drug manufacturers' Medicaid Drug Rebate Program rebate liability, effective January 1, 2024. Under current law enacted as part of the ACA, drug manufacturers' Medicaid Drug Rebate Program rebate liability is capped at 100% of the average manufacturer price for a covered outpatient drug. We expect that other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies 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 product candidates, if approved.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Individual states in the United States have become increasingly active in implementing regulations designed to contain pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Most significantly, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated, and while the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

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 or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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

In some countries, particularly the EU member states, the pricing of certain pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various EU member states and parallel distribution or arbitrage between low-priced and high-priced member states, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. Even if a pharmaceutical product obtains a marketing authorization in the EU, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all. 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.

Risks Related to Our Intellectual Property

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

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

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions. Prosecution of our patent portfolio is at a very early stage. For some patent applications in our portfolio, we have filed national stage applications based on our Patent Cooperation Treaty, or PCT, applications, thereby limiting the jurisdictions in which we can pursue patent protection for the various inventions claimed in those applications. 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.

We have obtained licenses and options to obtain licenses from third parties and may obtain additional licenses and options in the future. 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.

We have had in the past, and may have in the future, certain funding arrangements. Such funding arrangements impose various obligations on us, including reporting obligations, and may subject certain of our intellectual property, such as intellectual property made using the applicable funding, to the rights of the U.S. government under the Bayh-Dole Act. Any failure to comply with our obligations under a funding arrangement may have an adverse effect on our rights under the applicable agreement or our rights in the applicable intellectual property. Compliance with our obligations or the exercise by the government or other funder of its rights, may limit certain opportunities or otherwise have an adverse effect on our business.

Our patent portfolio currently includes 24 active patent application families (which includes an option to license certain IP from MD Anderson and exclusive licenses to certain IP from Memorial Sloan Kettering Cancer Center). Of these, 22 applications have been nationalized and two are pending at the PCT stage. While we have obtained 24 issued U.S. patents with one currently allowed, we cannot provide any assurances that any of our pending patent applications will mature into issued patents and, if they do, that such patents or our current patents will include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. For example, we are pursuing claims to therapeutic, binary compositions of certain bacterial populations. Any claims that may issue may provide coverage for such binary compositions and/or their use. However, such claims would not prevent a third party from commercializing alternative compositions that do not include both of the bacterial populations claimed in pending applications, potential applications or patents that have or may issue. There can be no assurance that any such alternative composition will not be equally effective. Further, given that our SER-109 product candidate is a complex composition with some variation from lot-to-lot and that, likewise, third-party compositions may have similar complexity and variability, it is possible that a patent claim may provide coverage for some but not all lots of a product candidate or third-party product. These and other factors may provide opportunities for our competitors to design around our patents, should they issue.

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

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in any owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions, nor can we know whether those from whom we may license patents were the first to make the inventions claimed or were the first to file. For these and other reasons, the issuance, scope, validity, enforceability and commercial value of our patent rights are subject to a level of uncertainty. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

We may be subject to third-party preissuance submissions of prior art to the United States Patent and Trademark Office, or USPTO, or in a foreign jurisdiction in which our applications are filed, 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. For example, on April 25, 2017, we filed a notice of opposition in the European Patent Office challenging the validity of a patent issued to The University of Tokyo. See "*—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*." The oral proceedings were held at the European Patent Office on February 18, 2019 and the Opposition Division required The University of Tokyo to narrow the scope of the claims of the patent. The University of Tokyo appealed certain aspects of the Opposition Division's decision, as did we and other opponents. On November 18, 2022, The University of Tokyo requested termination of the appeal proceeding and revocation of its patent. On December 19, 2022, the Opposition Division officially terminated the appeal proceeding, and European Patent No. 2 575 835 B1 has been revoked in its entirety.

An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates. The issuance, scope, validity, enforceability and commercial value of our patents are subject to a level of uncertainty.

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

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

- any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our product candidates or any other products or product candidates;
- any of our pending patent applications will issue as patents at all;
- we will be able to successfully commercialize our product candidates, if approved, before our relevant patents expire;
- we were the first to make the inventions covered by any existing patent and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe or design around our patents;
- others will not use pre-existing technology to effectively compete against us;
- any of our patents, if issued, will be found to ultimately be valid and enforceable;
- third parties will not compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we will be able to obtain and/or maintain necessary or useful licenses on reasonable terms or at all;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- our commercial activities or products will not infringe upon the patents or proprietary rights of others.

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

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

In addition to seeking patents for some of our technology and product candidates, we also utilize our 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, 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 developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular the first to file provisions, only became effective on March 16, 2013. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Thus, for our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. Moreover, some of the patent applications in our portfolio will be subject to examination under the pre-Leahy- Smith Act law and regulations, while other patent 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, 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 Supreme Court, other federal courts, 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 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); *Alice Corp. v. CLS Bank International*, 573 U.S. 13-298 (2014); and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 10-1150 (2012). In response to these cases, the USPTO has issued guidance to the examining corps.

The USPTO first issued a memorandum reflecting the USPTO's interpretation of the cases related to patent eligibility of natural products on March 4, 2014, which it subsequently revised and expanded upon in several additional updates now incorporated into its Manual of Patent Examination Procedure. The USPTO's interpretation of the case law and new guidelines for examination may influence, possibly adversely, prosecution and defense of certain types of claims in our portfolio.

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

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

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

We are aware of numerous patents and pending applications owned by third parties in the fields in which we are developing product candidates, both in the United States and elsewhere. However, we may have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is

imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products. We are aware of several pending patent applications containing one or more claims that could be construed to cover some of our product candidates or technology, should those claims issue in their original form or in the form presently being pursued. In addition, we are aware of third-party patent families that include issued and allowed patents, including in the United States, including claims that, if valid and enforceable, could be construed to cover some of our product candidates or their methods of use. On April 25, 2017, we filed a notice of opposition in the European Patent Office challenging the validity of a patent issued to The University of Tokyo and requesting that it be revoked in its entirety for the reasons set forth in our opposition. The oral proceedings were held at the European Patent Office on February 18, 2019 and the Opposition Division required The University of Tokyo to narrow the scope of the claims of the patent. The University of Tokyo appealed certain aspects of the Oppositions Division's decision, as did we and other opponents. On November 18, 2022, The University of Tokyo requested termination of the appeal proceeding and revocation of its patent. On December 19, 2022, the Opposition Division officially terminated the appeal proceeding, and European Patent No. 2 575 835 B1 has been revoked in its entirety.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than in the United States, assuming that rights are obtained in the United States and assuming that rights are pursued outside the United States. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications. For each of the patent families that we believe provide coverage for our product candidates, we 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.

Additionally, Europe's planned Unified Patent Court, or UPC, may present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. Although this new court is being implemented to provide more certainty and efficiency to patent enforcement throughout Europe, it will also provide our competitors with a new forum to use to centrally challenge our patents if opted into the UPC, rather than having to seek invalidity or non-infringement decisions on a country-by-country basis. Once the UPC is established, it will be several years before the scope of patent rights that will be recognized and the strength of patent remedies that will be provided is known.

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 Our Operations

The COVID-19 pandemic has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition.

The COVID-19 pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, and facilities and production have been suspended. We are continuing to monitor the impact of the COVID-19 pandemic on our operations and ongoing clinical development activity. Our mitigation activities to minimize COVID-19-related operation disruptions are ongoing, however, given the severity and evolving nature of the situation, the timing of clinical readouts is uncertain. As a result of the COVID-19 pandemic, including any resurgence or the emergence of new variants, we or our collaborators may experience further disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns, global shipping delays or stoppages and disruptions in delivery systems;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.
- refusal of the FDA or other regulatory authorities to accept data from clinical trials in affected geographies;
- impacts from prolonged remote work arrangements, such as increased cybersecurity risks and strains on our business continuity plans; and
- delays or difficulties with equity offerings due to disruptions and uncertainties in the securities market.

In addition, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of the COVID-19 pandemic and the continued increase in inflation rates and interest rates. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic further impacts our business, including our preclinical studies and clinical trials, results of operations and financial condition will depend on future developments which are highly uncertain and cannot be predicted with confidence. Such factors include but are not limited to the duration and severity of the pandemic, the impact of variants, travel restrictions, quarantines, shelter-in-place orders and social distancing recommendations and regulations in the U.S. and other countries, business closures or business disruptions, the adoption and effectiveness of vaccines and vaccine distribution efforts, and the effectiveness of other actions taken in the U.S. and other countries to contain and treat the disease.

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

We are highly dependent on Eric Shaff, our President and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

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

We may expand our operational capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We may 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 potential 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 potential 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 have conducted clinical studies in Australia and New Zealand in the past, and may in the future conduct clinical studies in other countries as well. We currently plan to rely on collaborators, including Nestlé, to commercialize certain approved products outside of North America. Also, for certain manufacturing services for SER-109, we rely on GenIbet in Portugal, and Bacthera, which is constructing a dedicated full-scale production suite for us in Switzerland. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;

- limits in our ability to penetrate international markets;
- global macroeconomic conditions, including a continued increase in inflation rates or interest rates, labor shortages, supply chain shortages, or other economic, political or legal uncertainties or adverse developments;
- 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;
- political unrest and wars, such as the current situation with Ukraine and Russia, which could delay or disrupt our business, and if such political unrest escalates or spills over to or otherwise impacts additional regions it could heighten many of the other risk factors included in this Item 1A;
- natural disasters, political and economic instability, including terrorism and political unrest, outbreak of disease or epidemics such as the COVID-19 pandemic, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, 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 may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity.

In the ordinary course of our business, we collect and store sensitive data, including personally identifiable information, intellectual property and proprietary business information owned or controlled by ourselves or our employees, customers and other parties. We manage and maintain our applications and data utilizing a combination of on-site systems and cloud-based data centers. We utilize external security and infrastructure vendors to manage parts of our data centers, and as a result a number of third-party vendors may or could have access to our confidential information. These applications and data encompass a wide variety of business-critical information, including research and development information, customer information, commercial information and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate use or disclosure, unauthorized access, inappropriate modification and the risk of our being unable to adequately monitor and audit and modify our controls over our critical information. This risk extends to the third-party vendors and subcontractors we use to manage this sensitive data or otherwise process it on our behalf. The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take reasonable measures to protect sensitive data from unauthorized access, use or disclosure, our information technology systems and those of our third-party service providers, strategic partners and other contractors or consultants are vulnerable to attack, damage and interruption from computer viruses and malware (e.g. ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization.

We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. 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, whether due to a loss, corruption or unauthorized disclosure of our trade secrets, personal information or other proprietary or sensitive information or other similar disruptions. If we or our third-party vendors were to experience a significant cybersecurity breach of our or their information systems or data, the costs associated with the investigation and remediation could be material. Any such access, breach, or other loss of information could also result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, and regulatory penalties. Notice of breaches may be required to affected individuals or other state, federal or foreign regulators, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete. Although we have implemented security measures to prevent unauthorized access, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials in the U.S. and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our results of operations, financial performance and business.

In the U.S., HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, or collectively HIPAA, imposes privacy, security and breach notification obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. Most healthcare providers, including research institutions from which we obtain clinical trial information, are subject to privacy and security regulations promulgated under HIPAA. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not regulated under HIPAA. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act of 2018, or CCPA, went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches has increased the likelihood of, and risks associated with data breach litigation. Further, the California Privacy Rights Act, or CPRA, generally went into effect on January 1, 2023, and significantly amends the CCPA. It imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may also be required. Similar laws have passed in Virginia, Colorado, Connecticut and Utah, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. For example, in Europe, European Union General Data Protection Regulation, or the GDPR, went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the European Economic Area, or EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States; in July 2020, the Court of Justice of the EU, or CJEU, limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses, or SCCs. In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 16, 2020 have taken a restrictive approach to international data transfers. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which

we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Since the beginning of 2021, after the end of the transition period following the UK's departure from the European Union, we are also subject to the UK data protection regime, which imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to £17.5 million or 4% of a noncompliant company's global annual revenue for the preceding financial year, whichever is greater. Additionally, the EU adopted the EU Clinical Trials Regulation, which came into effect on January 31, 2022. This regulation imposes new obligations on the use of data generated from clinical trials and enables European patients to have the opportunity to access information about clinical trials. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

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

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

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

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

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

We have in the past been subject to securities class action litigation and may be subject to similar or other litigation in the future, which may harm our business.

Securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. On September 28, 2016, a purported stockholder filed a putative class action lawsuit in the U.S. District Court for the District of Massachusetts against us entitled Mariusz Mazurek v. Seres Therapeutics, Inc., et.al. alleging false and misleading statements and omissions about our clinical trials for our product candidate SER-109 in our public disclosures between June 25, 2015 and July 29, 2016. Although this lawsuit has been dismissed by the court, should we face similar or other litigation again, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business. In addition, the uncertainty of a pending lawsuit or potential filing of additional lawsuits could lead to more volatility and a reduction in our stock price.

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, including from the novel coronavirus SARS-CoV-2, which causes the COVID-19 disease, 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.

Our ability to use our net operating loss carryforwards and research and development credits to offset future taxable income or income tax liabilities may be subject to certain limitations.

As of December 31, 2022, we had net operating loss carryforwards, or NOLs, of $501.8 million for federal income tax purposes and $481.9 million for state income tax purposes, which may be available to offset our future taxable income, if any. Our federal and state NOLs begin to expire in various amounts in 2035, provided that federal NOLs generated in taxable years after December 31, 2017 will not be subject to expiration. As of December 31, 2022, we also had federal and state research and development and other tax credit carryforwards of approximately $42.1 million and $8.5 million, respectively, net of uncertain tax position reserves, available to reduce future income tax liabilities. Our federal and state tax credit carryforwards begin to expire in various amounts in 2031 and 2028, respectively. The federal research and development tax credit carryforwards include an orphan drug credit carryforward of $25.6 million. These NOLs and tax credit carryforwards could expire unused, to the extent subject to expiration, and be unavailable to offset future taxable income or income tax liabilities. In addition, in general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change" is subject to limitations on its ability to use its pre-change NOLs and tax credit carryforwards to offset future taxable income and income taxes. For these purposes, an ownership change generally occurs where the aggregate change in stock ownership of one or more stockholders or groups of stockholders owning at least 5% of a corporation's stock exceeds 50 percentage points over a three-year period. We have experienced ownership changes in the past, per the Section 382 study performed through December 31, 2020, and may experience ownership changes in the future because of future transactions in our stock, some of which may be outside our control. We believe that none of the existing tax attributes will expire unused as a result of the calculated limitations. If we undergo future ownership changes, our ability to use our NOLs and tax credit carryforwards could be further limited. For these reasons, we may not be able to use a material portion of our NOLs or tax credit carryforwards, even if we attain profitability. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future tax benefits of such assets. Federal NOLs arising in periods beginning after December 31, 2017 may generally only be used to offset 80% of taxable income in years beginning after December 31, 2020, which may require us to pay federal income taxes in future years despite generating federal NOLs in prior years.

The terms of our credit facility place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In October 2019, we entered into a loan and security agreement with Hercules Capital, Inc., or Hercules, pursuant to which a term loan in an aggregate principal amount of up to $50.0 million, or the Original Credit Facility, was available to us in three tranches, subject to certain terms and conditions. We received the first tranche of $25.0 million upon signing the agreement on October 29, 2019, but did not borrow either of the second two tranches, which were available at different times upon Hercules' approval until June 30, 2021.

In April 2020, we entered into an amendment to the loan and security agreement with Hercules, or the First Amendment, permitting us to enter into a promissory note under the Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Stability Act.

In February 2022, we entered into a second amendment to the loan and security agreement with Hercules, or the Second Amendment, which amended the Original Credit Facility. Pursuant to the Second Amendment, term loans in an aggregate principal amount of up to $100.0 million, or the New Credit Facility, have become available to us in five tranches, subject to certain terms and conditions: (i) the first tranche in an aggregate principal amount of $25.0 million that was outstanding as of the February 24, 2022 effective date, or the Effective Date, (ii) the second tranche in an aggregate principal amount of $12.5 million that has been advanced to us and was outstanding as of the Effective Date, (iii) the third tranche in an aggregate principal amount of $12.5 million that has been advanced to us and was outstanding as of the Effective Date, (iv) the fourth tranche in an aggregate principal amount of $25.0 million available upon satisfaction of certain conditions, including the approval by the FDA of a biologics license application in respect of SER-109 by no later than December 15, 2023, or the Regulatory Approval Milestone, and (v) the fifth tranche in an aggregate principal amount of up to $25.0 million that is available through the amortization date upon satisfaction of certain conditions, including the lenders' investment committee approval. The New Credit Facility is secured by a lien on substantially all of our assets, other than intellectual property. We also agreed not to pledge or secure our intellectual property to others.

The New Credit Facility includes affirmative and negative covenants and events of default applicable to us. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on our transferring collateral, making changes to the nature of our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, engaging in transactions with affiliates. The New Credit Facility also includes a conditional liquidity covenant commencing on June 15, 2023, which ceases to apply if certain conditions including the Regulatory Approval Milestone are satisfied. Events of default include, among other things and subject to customary exceptions: (i) insolvency, liquidation, bankruptcy or similar events; (ii) failure to pay any debts due under the loan and security agreement with Hercules or other loan documents on a timely basis; (iii) failure to observe certain covenants under the loan and security agreement with Hercules; (v) occurrence of a material adverse effect; (vi) material misrepresentation by us; (vii) occurrence of any default under any other agreement involving material indebtedness; and (viii) certain material money judgments. If we default under the loan and security agreement, Hercules may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Any declaration by Hercules of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Risks Related to Our Common Stock

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control or significantly influence all matters submitted to stockholders for approval.

Our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock and their respective affiliates, in the aggregate, hold shares representing approximately 68.5% of our outstanding voting stock as of December 31, 2022. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

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

A significant portion of our total outstanding shares are eligible to be sold into the market, 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. We have also registered and intend to continue 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.

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 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 stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In

addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing:

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

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware, subject to certain exceptions, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders and our bylaws designate the federal district courts of the United States as the exclusive forum for actions arising under the Securities Act of 1933, as amended, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our restated certificate of incorporation 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. In addition, our bylaws provide that the federal district courts of the United States are the exclusive forum for any complaint raising a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our restated certificate of incorporation and bylaws described above.

We believe these choice of forum provisions benefit us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes and in the application of the Securities Act by federal judges, as applicable, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provisions 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 or bylaws to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provisions contained in our restated certificate of incorporation or bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, our loan and security agreement with Hercules Capital 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 our stockholders' sole source of gain for the foreseeable future.

General Risk Factors

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

Our stock price is likely to be volatile. Furthermore, 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, our stockholders may not be able to sell their common stock at or above the price they paid for their common stock. The market price for our common stock may be influenced by many factors, including:

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

If securities or industry analysts issue an adverse or misleading opinion regarding our business, our common stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. 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 clinical 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.

We will continue to incur costs as a result of being a public company, and our management will continue to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote and will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, we expect that these rules and regulations will continue to make it more difficult and more expensive for us to maintain 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.

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 future uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations.

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. Additionally, we are no longer a non-accelerated filer, so we are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are unable to maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a public company or comply with the requirements of the Securities and Exchange Commission or Section 404. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Failure to keep up with evolving trends and shareholder expectations relating to environmental, social and governance, or ESG, practices or reporting could adversely impact our reputation, share price and access to and cost of capital.

Certain institutional investors, investor advocacy groups, investment funds, creditors and other influential financial market participants have become increasingly focused on companies' ESG practices in evaluating their investments and business relationships, including the impact of business on the environment. Certain organizations also provide ESG ratings, scores and benchmarking studies that assess companies' ESG practices. Although there are no universal standards for such ratings, scores or benchmarking studies, they are used by some investors to inform their investment and voting decisions. It is possible that our future stockholders or organizations that report on, rate or score ESG practices will not be satisfied with our ESG strategy or performance. Unfavorable press about or ratings or assessments of our ESG strategies or practices, regardless of whether or not we comply with applicable legal requirements, may lead to negative investor sentiment toward us, which could have a negative impact on our share price and our access to and cost of capital.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Research and Offices

Our corporate headquarters is located in Cambridge, Massachusetts, where we lease approximately 83,396 square feet of office, laboratory, and pilot manufacturing space under a lease that was originally set to expire in November 2023. In December 2022, we amended the lease to extend the expiration date with respect to 68,636 square feet of office, laboratory, and pilot manufacturing space to January 2030.

Clinical Manufacturing

We currently conduct part of our manufacturing operations in our leased facilities in Cambridge, Massachusetts, which contain manufacturing facilities for clinical products. We believe our current laboratory facilities and contract relationships are sufficient to meet our current bioprocess development and manufacturing needs. Product candidates may be brought into the facilities for economies of operation, or may remain external with contract manufacturing organizations, depending on business dynamics and development needs.

We plan to control the production of all products under current good manufacturing practices by making strategic investments in manufacturing, which may include collaborations with third parties, the design and renovation of existing facilities and the construction of additional new facilities for commercial supply.

Item 3. Legal Proceedings

Opposition Proceeding

On October 19, 2016, the European Patent Office granted European Patent No. 2 575 835 B1 to The University of Tokyo. On April 25, 2017, we filed a notice of opposition to this patent in the European Patent Office, requesting that it be revoked in its entirety for the reasons set forth in our opposition. The oral proceedings were held at the European Patent Office on February 18, 2019 and the Opposition Division required The University of Tokyo to narrow the scope of the claims of the patent. The University of Tokyo appealed certain aspects of the Opposition Division's decision, as did we and other opponents. On November 18, 2022, The University of Tokyo requested termination of the appeal proceeding and revocation of its patent. On December 19, 2022, the Opposition Division officially terminated the appeal proceeding, and European Patent No. 2 575 835 B1 has been revoked in its entirety.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

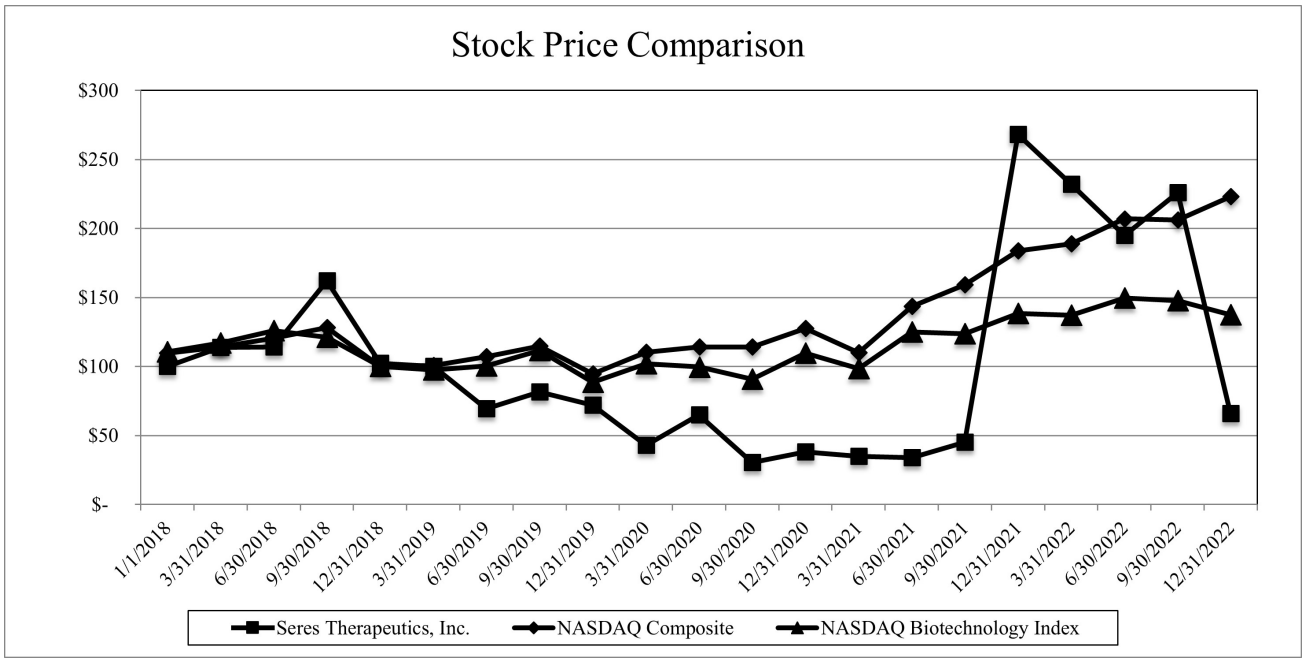
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock has been publicly traded on the Nasdaq Global Select Market under the symbol "MCRB" since June 26, 2015. Prior to that time, there was no public market for our common stock.

Stock Performance Graph

The graph set forth below compares the cumulative total stockholder return on our common stock between January 1, 2018 and December 31, 2022, with the cumulative total return of (a) the Nasdaq Biotechnology Index and (b) the Nasdaq Composite Index, over the same period. This graph assumes the investment of $100 on December 31, 2017 in each of our common stock, the Nasdaq Biotechnology Index and the Nasdaq Composite Index and assumes the reinvestment of dividends, if any. The comparisons reflected in the graph and table are not intended to forecast the future performance of our stock and may not be indicative of our future performance.



Holders

As of March 3, 2023, there were approximately nine holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. The number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have not paid any cash dividends on our common stock since inception and do not anticipate paying cash dividends in the foreseeable future. In addition, our loan and security agreement with Hercules Capital currently prohibits us from paying dividends on our equity securities, and any future debt agreements may likewise preclude us from paying dividends. See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

Recent Sales of Unregistered Securities

We did not make any sales of unregistered securities during the quarter ended December 31, 2022.

Purchases of Equity Securities by the Issuer or Affiliated Purchasers

There were no repurchases of shares of common stock made during the quarter ended December 31, 2022.

Item 6. [Reserved]

Item 7. 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 our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K 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. Important factors that could cause or contribute to such differences include, but are not limited to, those discussed in "Summary Risk Factors" and Part I and Item 1A. "Risk Factors" of this Annual Report on Form 10-K.

A discussion regarding our financial condition and results of operations for the years ended December 31, 2022 and 2021, including a year-to-year comparison between 2022 and 2021, is presented below. For a discussion regarding our financial condition and results of operations for the year ended December 31, 2020, including a year-to-year comparison between 2021 and 2020, refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on March 1, 2022.

Overview

We are a microbiome therapeutics company developing a novel class of biological drugs, which are designed to treat disease by modulating the microbiome to restore health by repairing the function of a disrupted microbiome to a non-disease state. We have an advanced drug pipeline with clinical assets that are formulated for oral delivery and a differentiated microbiome therapeutics drug discovery and development platform including good manufacturing practices, or GMP, manufacturing capabilities for this novel drug modality.

Our highest priority is preparing for potential commercialization of SER-109, an investigational oral microbiome therapeutic in development for recurrent *Clostridioides difficile infection*, or CDI. In October 2022, the FDA accepted for review our BLA for SER-109. The BLA has been granted Priority Review designation with a Prescription Drug User Fee Act, or PDUFA, target action date of April 26, 2023. If approved by the FDA, we plan to launch SER-109 with our collaborator, Nestlé Health Science, soon after approval.

We are also designing microbiome therapeutics to decolonize pathogens and modulate host function to reduce and prevent infections. We believe that the scientific and clinical data from our SER-109 program validate this novel approach, which we refer to as Infection Protection. We believe the Infection Protection approach may be replicable across different bacterial pathogens to develop microbiome therapeutics with the potential to protect a range of medically compromised patients from infections. We are evaluating SER-155 in a Phase 1b study in patients receiving allogeneic hematopoietic stem cell transplantation, or allo-HSCT, to reduce incidences of gastrointestinal infections, bloodstream infections and graft-versus-host disease, or GvHD. In December 2022, the study's Data and Safety Monitoring Board reviewed available clinical data for cohort 1 and cleared advancement to cohort 2. In February 2023, we announced the initiation of enrollment in cohort 2. We plan to announce initial safety and pharmacological data, including drug bacterial species engraftment from cohort 1, in May 2023. We are also progressing additional preclinical stage programs to evaluate how microbiome therapeutics may reduce incidence of infection in indications such as cancer neutropenia, chronic liver disease, solid organ transplant, and antimicrobial resistant infections more broadly in settings of high-risk such as intensive care units, or ICUs.

We continue our research activities in ulcerative colitis, or UC, including evaluating the potential to utilize biomarker-based patient selection and stratification for future studies. In addition, we continue to leverage microbiome pharmacokinetic and pharmacodynamic data from across our clinical and preclinical portfolios, using our reverse translational microbiome therapeutics development platform to conduct research on various indications, including inflammatory and immune diseases, cancer, and metabolic diseases.

We have built and deploy a reverse translational platform for the discovery and development of microbiome therapeutics. This platform incorporates high-resolution analysis of human clinical data to identify microbiome biomarkers associated with disease and non-disease states; preclinical screening using human cell-based assays and in vitro/ex vivo and in vivo disease models customized for microbiome therapeutics; and microbiological capabilities and a strain library that spans broad biological and functional breadth to both identify specific microbes and microbial metabolites that are associated with disease and to design consortia of bacteria with specific pharmacological properties.

Since our inception in October 2010, we have devoted substantially all of our resources to developing our programs, platforms, and technologies, building our intellectual property portfolio, developing our supply chain, business planning, raising capital and providing general and administrative support for these operations.

Many of our product candidates are still in preclinical development or early-stage discovery. Our ability to generate product revenue or collaboration profit 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 $250.2 million for the year ended December 31, 2022 and as of December 31, 2022, we had an accumulated deficit of $864.5 million.

While we plan to focus our investment on our highest priority clinical programs in the near-term, our expenses may increase substantially in connection with our ongoing and planned activities, particularly as we:

- complete the clinical development, seek regulatory approval, and prepare for commercialization of SER-109 for patients with recurrent CDI;
- continue the clinical development of SER-155 to reduce incidences of gastrointestinal infections, bloodstream infections and GvHD in patients receiving allo-HSCT;
- continue evaluating preclinical stage programs to reduce incidence of infection, in indications such as cancer neutropenia, chronic liver disease, solid organ transplant, and antimicrobial resistant infections more broadly;
- continue translational research activities, informed by the SER-287 Phase 2b and SER-301 Phase 1b study data, to evaluate the potential to utilize biomarker-based patient selection and stratification in future clinical development efforts;
- make strategic investments in our research discovery and development platforms and capabilities, to advance our priority programs;
- make strategic investments in manufacturing capabilities;
- maintain and augment our intellectual property portfolio and opportunistically acquire complementary intellectual property;
- potentially establish a sales and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- perform our obligations under our agreements with our collaborators;
- seek to obtain regulatory approvals for our product candidates; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

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, we expect to continue to incur additional costs associated with operating as a public company.

As a result, we will need additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of factors such as the impacts of the COVID-19 pandemic, the continued increase in inflation, and rising interest rates. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. 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.

As of December 31, 2022, we had cash, cash equivalents and short- and long-term investments totaling $181.3 million. Based on our currently available cash resources and our current level of operations and cash flows for the 12-month period subsequent to the date of issuance of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K we will require additional funding in early 2024. In accordance with applicable accounting standards, we evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within 12 months after the date of the issuance of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. In performing this analysis, we excluded certain elements of our operating plan that cannot be considered probable of occurring. Under the applicable accounting standards, the receipt of potential funding from future equity or debt issuances, and certain contingent payments associated with the approval of our BLA for SER-109, which is currently under priority review by the FDA, cannot be considered probable, as these events are outside our control. These contingent payments include a $125.0 million milestone payment from Nestlé pursuant to the 2021 License Agreement, and a $25.0 million tranche under our New Credit Facility with Hercules, which becomes available upon the satisfaction of certain conditions, including FDA approval of SER-109. Accordingly, management has concluded that substantial doubt exists about the Company's ability to continue as a going concern for 12 months from the date the consolidated financial statements included elsewhere in this Annual Report on Form 10-K, are issued. See "Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital —We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern."

SER-109

SER-109 is an oral microbiome therapeutic candidate consisting of a consortium of purified Firmicutes spores. The SER-109 manufacturing purification process is designed to remove unwanted microbes in an effort to reduce the risk of pathogen transmission beyond donor screening alone. SER-109 is designed to reduce recurrent CDI in patients with a history of CDI by modulating the microbiome to a state that resists *C. difficile* germination and growth. SER-109, if approved, is intended to treat individuals with recurrent CDI, a patient population that is estimated to include approximately 156,000 cases in the United States during 2023.

The Phase 3 ECOSPOR III study was a multicenter, randomized, placebo-controlled study that enrolled 182 patients with multiply recurrent CDI. All patients who entered ECOSPOR III must have tested positive for *C. difficile* toxin. This inclusion criterion was implemented in an effort to ensure enrollment of only patients with active infection rather than simple colonization. The study was designed to evaluate patients for 24 weeks, with the primary endpoint comparing the *C. difficile* recurrence rate in subjects who received SER-109 verses placebo at up to eight weeks after dosing.

ECOSPOR III data demonstrated that the study achieved its primary endpoint where SER-109 was superior to placebo in reducing CDI recurrence at eight weeks, reflecting a recurrence-free rate of approximately 88% at eight weeks post-treatment. SER-109 resulted in a 27% absolute reduction of recurrence of CDI compared to placebo at eight weeks post-treatment, which is a relative risk reduction of 68%. The number-needed-to treat was 3.6. The rate of recurrence at 12 weeks in the SER-109 arm was 18.0%, compared to a rate of 46.2% in the placebo arm, representing an absolute risk reduction of 28% (relative risk 0.40; 95% CI 0.24-0.65; $p < 0.001$ and $p < 0.002$ for the test sequence), and thereby consistent with the results seen at eight weeks. Results across stratifications of age and antibiotics remained similar. The study's efficacy results related to the primary endpoint from all analyses exceeded the statistical threshold previously provided in consultation with the FDA that could allow this single clinical study to fulfill efficacy requirements for a BLA. The efficacy results remained durable through 24 weeks of follow-up, as SER-109 was observed to significantly reduced recurrence rates compared to placebo over 24 weeks, 21.3% vs. 47.3%, respectively. These data were published in the *New England Journal of Medicine* in January 2022 and in the *Journal of the American Medical Association* in October 2022.

In November 2021, we initiated a SER-109 expanded access program across the United States. The program is designed to enable eligible adults with recurrent CDI to obtain access to SER-109 prior to a potential FDA product approval.

In June 2022, we announced confirmatory results from the ECOSPOR IV open-label study. The overall safety profile observed in ECOSPOR IV through 24 weeks indicated that SER-109 was well tolerated, consistent with the safety profile observed in the prior completed Phase 3 study, ECOSPOR III. In ECOSPOR IV, subjects treated with SER-109 had a recurrence rate of 8.7% at eight weeks, which indicates a 91.3% recurrence-free rate, consistent with the 88% rate observed in the ECOSPOR III study. Subjects with a first recurrence of CDI (29% of subjects in the ECOSPOR IV study) had a CDI recurrence rate of 6.5%, and subjects with ≥ two prior CDI episodes (ECOSPOR III inclusion criteria) had a CDI recurrence rate of 9.7% at eight weeks. At 24 weeks, 13.7% of all subjects treated with SER-109 had a recurrence of CDI. In addition to data from the ECOSPOR III study, the ECOSPOR IV data was included as part of the rolling submission of the BLA to the FDA.

In October 2022, the FDA accepted for review our BLA for SER-109. The BLA has been granted Priority Review designation with a PDUFA target action date of April 26, 2023. If approved by the FDA, we plan to launch SER-109 with our collaborator, Nestlé Health Science, soon after approval.

In addition, we plan on initiating a Phase 3 trial in the European Union, or EU, in order to expand access to the EU market upon potential approval.

SER-155

SER-155, an oral microbiome therapeutic candidate consisting of a consortium of cultivated bacteria, is designed to decrease infection and translocation of antibiotic resistant bacteria in the gastrointestinal tract and modulate host immune responses to decrease GvHD. The rationale for this program is based in part on published clinical evidence from our collaborators at Memorial Sloan Kettering Cancer Center showing that allo-HSCT patients with decreased diversity of commensal microbes are significantly more likely to die due to infection and/or lethal GvHD. SER-155 was designed using our reverse translational discovery platform to reduce incidences of gastrointestinal infections, bloodstream infections and GvHD in patients receiving allo-HSCT. The SER-155 Phase 1b study is designed to include approximately 70 patients in both an open-label and a randomized, double-blind, placebo-controlled cohort that will evaluate safety and tolerability before and after HSCT. Additionally, the engraftment of SER-155 bacteria (a measure of pharmacokinetics) and the efficacy of SER-155 in preventing infections and GvHD will be evaluated. In December 2022, the study's Data and Safety Monitoring Board reviewed available clinical data for cohort 1 and cleared advancement to cohort 2. In February 2023, we announced the initiation of enrollment in cohort 2. We plan to announce initial safety and pharmacological data, including drug bacterial species engraftment from cohort 1, in May 2023. The study is being conducted at a number of leading cancer centers across the U.S.

Irritable Bowel Disease, Ulcerative Colitis, SER-287 and SER-301

We continue our research activities in irritable bowel disease, or IBD, including evaluating the potential to utilize biomarker-based patient selection and stratification in future clinical studies in UC. UC patient populations are generally heterogeneous in their

disease manifestation, and we believe biomarker-based strategies may enable targeting more homogeneous patient populations in future studies.

In July 2021, we announced topline results from our SER-287 Phase 2b study in mild-to-moderate UC patients, which did not meet its primary endpoint of improving clinical remission rates compared to placebo. Following the data readout, in December 2021, we completed preliminary microbiome drug pharmacology analyses that demonstrated the engraftment of SER-287 bacterial species, however, unlike the Phase 1b study, anticipated changes in disease-relevant metabolites post-administration with SER-287 in the Phase 2b study were not observed to the same extent across the patients treated in the Phase 1b study.

In addition, we have completed preliminary analysis of data from the first cohort of our SER-301 Phase 1b study in mild-to moderate UC patients, which included 15 subjects. Evaluation of the first cohort data by an independent Data Safety Monitoring Board indicated that it would be safe to proceed to the placebo-controlled second cohort. While efficacy was not a defined endpoint in the first cohort, evaluation of clinical outcome data collected as part of the study indicated that no subjects in the first cohort achieved clinical remission as defined by the FDA using the Three-Component Modified Mayo Score after 10 weeks of treatment, though there were improvements in one or more individual components (endoscopic, stool frequency and rectal bleeding subscores) in some patients. SER-301 was optimized relative to SER-287 to incorporate bacterial strains that engrafted across the majority of patients in our previous trials, and strains that were significantly associated with positive clinical outcomes and the modulation of key microbial-associated metabolites. In the Phase 1b study, strains in SER-301 were observed to engraft in subjects across the trial period, and based on the assessment of metabolomic data, SER-301 demonstrated pharmacological properties consistent with its design and further led to baseline-dependent modulation of the metabolic landscape in the gastrointestinal tract of patients treated. In April 2022, we announced our decision not to proceed with the planned SER-301 Phase 1b second study cohort. In aggregate, our clinical and preclinical data suggest that there are IBD patient populations that may be more amenable to microbiome therapeutic intervention, and we continue to conduct analyses of data from our UC clinical stage programs and conduct preclinical studies to inform next steps for further development in UC and IBD more broadly.

Intellectual Property

Patent Portfolio

We have an extensive patent portfolio directed to rationally designed ecologies of spores and microbes. The portfolio includes both company-owned patents and applications, and those that we have rights to as licensee. For example, our portfolio includes an option to license foundational intellectual property related to the use of bacteria in combination with checkpoint inhibitors from MD Anderson. The patents and applications included in our portfolio cover both composition of matter and methods (*e.g.*, method of treating). Our intellectual property rights related to SER-109, SER-155, SER-287 and SER-301 extend through 2034. We plan on continuing to broaden our patent portfolio. Currently, we have 24 active patent application families, which includes 22 nationalized applications and two pending at the PCT stage. To date, we have obtained 24 issued U.S. patents and one U.S. patent application has been currently allowed.

Regulatory Exclusivity

If we obtain marketing approval for any of our product candidates, we expect to receive marketing exclusivity against biosimilar products. For a new biological composition approved by the FDA, a 12-year period of exclusivity in the United States may be obtained. In Europe, the European Medicines Agency awards 10 years of exclusivity for new molecular entities.

Financial Operations Overview

Revenue

To date we have not generated any revenues from the sale of products. Our revenues have been derived primarily from our agreements with our collaborators. See "—Liquidity and Capital Resources."

Operating Expenses

Our operating expenses since inception have consisted primarily of research and development activities and general and administrative costs.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our product candidates, which include:

- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct research, preclinical activities and clinical trials on our behalf as well as contract manufacturing organizations that manufacture drug products for use in our preclinical and clinical trials;
- salaries, benefits and other related costs, including stock-based compensation expense, for personnel in our research and development functions;

- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- the cost of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- costs related to compliance with regulatory requirements; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors and our clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid or accrued research and development expenses.

Our primary focus of research and development since inception has been on our reverse translational microbiome therapeutics platform and the subsequent development of our product candidates. 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, CROs in connection with our preclinical studies and clinical trials, lab supplies and consumables, 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.

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 near future as we scale up manufacturing operations, support the BLA review process by the FDA, and prepare for commercialization of SER-109, however in the event of approval of our BLA for SER-109, we expect the potential decline in research and development expenses related to SER-109 as the majority of commercial manufacturing costs will be capitalized. We expect to continue to discover and develop additional product candidates, including SER-155, and pursue later stages of clinical development of our product candidates. We also expect to continue conducting analyses of data from our UC clinical stage programs to inform next steps for further development.

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, commercial, business development and administrative functions. General and administrative expenses also include professional service fees for marketing and market access activities in preparation for the commercial launch of SER-109; 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 expect that our general and administrative expenses will increase in the future as we increase our headcount and expand our infrastructure to support the potential growth in our research and development activities and the potential commercialization of our product candidates, and as we conduct pre-launch activities to prepare for commercialization of SER-109. We also may continue to incur increased expenses associated with being a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing rules and the requirements of the Securities and Exchange Commission, director and officer insurance costs and investor and public relations costs.

Collaboration (Profit) Loss Sharing - related party

Collaboration (profit) loss sharing – related party includes 50% sharing of the profit or loss related to the pre-launch activities and commercialization activities associated with the 2021 License Agreement with Nestlé as discussed in Note 11 to our consolidated financial statements.

Other (Expense) Income, Net

Interest Income, Net

Interest income consists of interest earned on our cash, cash equivalents and investments.

Interest Expense

Interest expense consists of interest incurred under our loan and security agreement with Hercules.

Other (Expense) Income

Other (expense) income primarily consists of amortization of premiums on investments, amortization of debt issuance costs, and sublease income.

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, 2022, we had federal and state net operating loss carryforwards of $501.8 million and $481.9 million, respectively, both of which begin to expire in 2035. As of December 31, 2022, we also had federal and state research and development tax credit carryforwards of $42.1 million and $8.5 million, respectively, net of uncertain tax position reserves, which begin to expire in 2031 and 2028, respectively. The federal research and development tax credits include an orphan drug credit carryforward of $25.6 million.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles, or GAAP, in the United States. The preparation of our consolidated financial statements and related disclosures requires the application of appropriate technical accounting rules and guidance, as well as the use of estimates. The application of these policies necessarily involves judgments regarding future events. These estimates and judgments, in and of themselves, could materially impact the consolidated financial statements and disclosures based on varying assumptions. We believe that the estimates and assumptions involved in the accounting policies described below may have the greatest potential impact on our consolidated financial statements and, therefore, consider these to be our critical accounting policies. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.

Revenue Recognition

We recognize revenue in accordance with the guidance under ASC 606, *Revenue from Contracts with Customers*. ASC 606 applies to all contracts with customers, except those contracts that are within the scope of other guidance, such as leases, insurance, and financial instruments. We enter into agreements that are within the scope of ASC 606, under which we license certain of our product candidates and perform research and development services in connection with such arrangements. The terms of these arrangements typically include payment of one or more of the following: nonrefundable up-front fees, reimbursement of research and development costs, development, clinical, regulatory and commercial sales milestone payments, and royalties on net sales of licensed products. Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. When determining the timing and extent of revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligation(s) in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligation(s) in the contract; and

(v) recognize revenue when (or as) the entity satisfies a performance obligation.

We only apply the five-step model to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services transferred to our customer.

At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. The promised goods or services in our arrangements typically consist of a license to our intellectual property and/or research and development services. We may provide options to additional items in such arrangements, which are accounted for as separate contracts when our customer elects to exercise such options, unless the option provides a material right to our customer. Performance obligations are promises in a contract to transfer a distinct good or service to our customer that (i) our customer can benefit from on its own or together with other readily available resources, and (ii) is separately identifiable from other promises in the contract. Goods or services that are not individually distinct performance obligations are combined with other promised goods or services until such combined group of promises meets the requirements of a performance obligation.

We determine transaction price based on the amount of consideration we expect to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. At contract inception for arrangements that include variable consideration, we estimate the probability and extent of consideration we expect to receive under the contract utilizing either the most likely amount method or expected amount method, whichever best estimates the amount expected to be received. We then consider any constraints on the variable consideration and include in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

We then allocate the transaction price to each performance obligation based on the relative standalone selling price and recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to our customer and the performance obligation is satisfied. For performance obligations which consist of licenses and

other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

We record amounts as accounts receivable when the right to consideration is deemed unconditional. When consideration is received, or such consideration is unconditionally due, from our customer prior to transferring goods or services to our customer under the terms of a contract, a contract liability is recorded for deferred revenue.

We do not assess whether a contract has a significant financing component if the expectation at contract inception is that the period between payment by our customer and the transfer of the promised goods or services to our customer will be one year or less. Incremental costs of obtaining a contract are expensed as and when incurred if the expected period over which we would have amortized the asset is one year or less, or the amount is immaterial.

Collaboration Revenue

Arrangements with collaborators may include licenses to intellectual property, research and development services, manufacturing services for clinical and commercial supply, and participation on joint steering committees. We evaluate the promised goods or services to determine which promises, or group of promises, represent performance obligations. In contemplation of whether a promised good or service meets the criteria required of a performance obligation, we consider the stage of development of the underlying intellectual property, the capabilities and expertise of our customer relative to the underlying intellectual property, and whether the promised goods or services are integral to or dependent on other promises in the contract. When accounting for an arrangement that contains multiple performance obligations, we must develop judgmental assumptions, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success to determine the stand-alone selling price for each performance obligation identified in the contract.

When we conclude that a contract should be accounted for as a combined performance obligation and recognized over time, we must then determine the period over which revenue should be recognized and the method by which to measure revenue. We generally recognize revenue using a cost-based input method.

Licenses of Intellectual Property

If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue allocated to the license when the license is transferred to our customer and our customer is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue associated with the bundled performance obligation. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of progress and related revenue recognition.

Milestone Payments

At the inception of each arrangement that includes developmental and regulatory milestone payments, we evaluate whether the achievement of each milestone specifically relates to our efforts to satisfy a performance obligation or transfer a distinct good or service within a performance obligation. If the achievement of a milestone is considered a direct result of our efforts to satisfy a performance obligation or transfer a distinct good or service and the receipt of the payment is based upon the achievement of the milestone, the associated milestone value is allocated to that distinct good or service, otherwise it will be allocated to all performance obligations of the arrangement based on the initial allocation.

We evaluate each milestone to determine when and how much of the milestone to include in the transaction price. We first estimate the amount of the milestone payment that we could receive using either the expected value or the most likely amount approach. We primarily use the most likely amount approach as that approach is generally most predictive for milestone payments with a binary outcome. Then, we consider whether any portion of that estimated amount is subject to the variable consideration constraint (that is, whether it is probable that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty). We update the estimate of variable consideration included in the transaction price at each reporting date which includes updating the assessment of the likely amount of consideration and the application of the constraint to reflect current facts and circumstances.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any revenue related to sales-based royalties or milestone payments based on the level of sales.

Manufacturing Supply Services

For arrangements that include a promise of supply of clinical or commercial product, we determine if the supply is a promise in the contract or a future obligation at our customer's option. If determined to be a promise at inception of the contract, we evaluate the promise to determine whether it is a separate performance obligation or a component of a bundled performance obligation. If determined to be an option, we determine if the option provides a material right to our customer and if so, account for the option as a separate performance obligation. If determined to be an option but not a material right, we account for the option as a separate contract when our customer elects to exercise the option.

Application of the above guidance requires significant judgment and requires us to make determinations based on the facts and circumstances under each arrangement.

Accrued Research and Development Expenses

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

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

We base our expenses related to preclinical 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.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021.

	Year Ended December 31,		
	2022	2021	Change
		(in thousands)	
Revenue:			
Collaboration revenue - related party	$ 7,128	$ 143,857	$ (136,729)
Grant revenue	—	1,070	(1,070)
Total revenue	7,128	144,927	(137,799)
Operating expenses:			
Research and development	172,920	141,891	31,029
General and administrative	79,694	69,261	10,433
Collaboration (profit) loss sharing - related party	1,004	(1,732)	2,736
Total operating expenses	253,618	209,420	44,198
Loss from operations	(246,490)	(64,493)	(181,997)
Other (expense) income:			
Interest income	3,058	2,870	188
Interest expense	(6,020)	(2,910)	(3,110)
Other (expense) income	(705)	(1,045)	340
Total other expense, net	(3,667)	(1,085)	(2,582)
Net loss	$ (250,157)	$ (65,578)	$ (184,579)

Revenue

Total revenue was $7.1 million and $144.9 million for the years ended December 31, 2022 and 2021, respectively. The decrease in total revenue of $137.8 million was primarily due to the collaboration revenue that was recognized during the year ended December 31, 2021 upon on the transfer of control of the license by the Company to Nestlé, pursuant to the 2021 License Agreement. In addition, the decrease was partially driven by a $7.4 million decrease in collaboration revenue attributable to the services performed pursuant to the 2016 License Agreement, partially offset by an increase of $2.0 million attributable to the services performed pursuant to the 2021 License Agreement. Revenue for the year ended December 31, 2021 also included $1.1 million of grant revenue related to our CARB-X grant for SER-155, from which we will receive no additional funding.

Research and Development Expenses

	Year Ended December 31,		
	2022	2021	Change
		(in thousands)	
Microbiome therapeutics platform	$ 36,142	$ 34,784	$ 1,358
SER-109	48,649	40,510	8,139
SER-287	1,715	9,881	(8,166)
Early stage programs	6,828	4,953	1,875
Total direct research and development expenses	93,334	90,128	3,206
Personnel-related (including stock-based compensation)	79,586	51,763	27,823
Total research and development expenses	$ 172,920	$ 141,891	$ 31,029

Research and development expenses were $172.9 million for the year ended December 31, 2022, compared to $141.9 million for the year ended December 31, 2021. The increase of $31.0 million was due primarily to the following:

- an increase in personnel-related costs of $27.8 million primarily due to an increase of $24.5 million in salaries, bonus, payroll taxes and employee benefits expenses as well as a $3.3 million increase in stock-based compensation expense;
- an increase of $8.1 million in expenses related to our SER-109 program, due primarily to an increase of $8.7 million in lab supplies and consumables, and facility-related costs, primarily from the opening of both the new donor collection facility in Tempe and the quality control lab in Waltham, as we advance development and scale SER-109 manufacturing to prepare for commercialization. The total increase is also attributable to an increase of $1.2 million in other manufacturing

costs, and an increase of $0.8 million in professional fees, partially offset by a decrease in clinical trial costs of $1.9 million, and analytical testing of $0.7 million;

- an increase of $1.9 million in expenses of our early stage programs primarily driven by an increase of $1.5 million in external consulting expenses, lab supplies and consumables of $0.3 million, and professional fees of $0.1 million;
- an increase of $1.4 million in research expenses related to our reverse translational microbiome therapeutics platform due primarily to an increase of $1.6 million in lab supplies and consumables and $2.1 million in analytical testing, offset by a decrease of $1.6 million in professional fees and $0.7 million in clinical trials costs; partially offset by
- a decrease of $8.2 million in expenses of our SER-287 program primarily driven by a decrease of $7.2 million in clinical trial costs and $1.2 million in analytical testing, offset by an increase of $0.3 million in materials storage costs.

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 near future as we scale up manufacturing operations, support the BLA review process by the FDA, and prepare for commercialization of SER-109, however in the event of approval of our BLA for SER-109, we expect the potential decline in research and development expenses related to SER-109 as the majority of commercial manufacturing costs will be capitalized. We expect to continue to discover and develop additional product candidates, including SER-155, and pursue later stages of clinical development of our product candidates. We also expect to continue conducting analyses of data from our UC clinical stage programs to inform next steps for further development.

General and Administrative Expenses

	Year Ended December 31,		
	2022	2021	Change
		(in thousands)	
Personnel-related (including stock-based compensation)	$ 31,277	$ 23,933	$ 7,344
Professional fees	32,260	33,754	(1,494)
Facility-related and other	16,157	11,574	4,583
Total general and administrative expenses	$ 79,694	$ 69,261	$ 10,433

General and administrative expenses were $79.7 million for the year ended December 31, 2022, compared to $69.3 million for the year ended December 31, 2021. The increase of $10.4 million was primarily due to the following:

- an increase in personnel-related costs of $7.3 million, due to an increase of $5.3 million in salaries, bonus, payroll taxes and employee benefit expenses, and a $2.0 million increase in stock-based compensation expense; and
- an increase in facility-related and other costs of $4.6 million due primarily to increases in licenses, computer expenses and office supplies of $5.4 million, offset by a decrease in information technology costs of $0.9 million; partially offset by
- a decrease in professional fees of $1.5 million primarily due to a $2.0 million decrease in consulting and recruiting fees, offset by a $0.5 million increase in legal expenses.

Collaboration (Profit) Loss Sharing - related party

Collaboration (profit) loss sharing – related party was $1.0 million of expense for the year ended December 31, 2022, compared to $1.7 million of income for the year ended December 31, 2021. For the year ended December 31, 2022 we incurred $15.1 million of pre-launch expenses which we recorded within research and development expense or general and administrative expense based on the nature of the underlying expense, and our collaborative partner incurred $17.1 million of pre-launch expenses. Pre-launch expenses incurred by us and our collaborative partners increased from $5.6 million and $2.1 million, respectively, for the year ended December 31, 2021, due to 2022 being the first full year of the agreement. The $1.0 million of expense and $1.7 million of income recorded for the years ended December 31, 2022 and 2021, respectively, represent the sharing of 50% of the pre-launch expenses. These amounts represent expense to us in 2022 because our collaborative partner performed more of the pre-launch activities than we, and income to us in 2021 because we performed more of the pre-launch activities than our collaborative partner.

Other (Expense) Income, Net

Other (expense) income, net was $3.7 million of expense for the year ended December 31, 2022 compared to $1.1 million of expense for the year ended December 31, 2021. This increase was primarily driven by the increase in interest expense on the New Credit Facility, as a result of the increased outstanding balance and increasing interest rate throughout the year ended December 31, 2022.

Liquidity and Capital Resources

Since our inception, we have generated revenue only from collaborations and have incurred recurring net losses. We anticipate that we will continue to incur losses for at least the next several years. Our research and development and general and administrative expenses may continue to increase and, as a result, we will need additional capital to fund our operations, which we may obtain from additional financings, public offerings, research funding, additional collaborations, contract and grant revenue or other sources.

In November 2019, we entered into a common stock sales agreement, or the 2019 Sales Agreement, with Cowen to sell shares of our common stock with aggregate gross sales proceeds of up to $25.0 million, from time to time, through an "at the market" equity offering program, or ATM, under which Cowen acts as sales agent. In March 2020, in connection with filing an updated registration statement on Form S-3 (File No. 333-237033), we entered into a new common stock sales agreement, or the 2020 Sales Agreement, with Cowen on substantially the same terms as the 2019 Sales Agreement and terminated the 2019 Sales Agreement. In May 2021, we entered into a new common stock sales agreement, or the 2021 Sales Agreement, with Cowen to sell shares of our common stock with aggregate gross sales proceeds of up to $150.0 million, from time to time, through an ATM under which Cowen acts as sales agent, and terminated the 2020 Sales Agreement. During the year ended December 31, 2022, we sold approximately 655 thousand shares of common stock under the 2021 Sales Agreement, at an average price of approximately $7.26 per share, raising aggregate net proceeds of approximately $4.4 million after deducting an aggregate commission of approximately 3%. During the year ended December 31, 2021, we did not sell any shares of common stock under the 2020 Sales Agreement or the 2021 Sales Agreement. During the year ended December 31, 2020, we sold approximately 5.8 million shares of common stock under the 2019 Sales Agreement and the 2020 Sales Agreement, as applicable, at an average price of approximately $4.40 per share, raising aggregate net proceeds of approximately $24.8 million after deducting an aggregate commission of approximately 3%.

On June 29, 2022, we entered into securities purchase agreements with new and existing investors and certain directors and officers in a registered direct offering, or the Registered Direct Offering, of an aggregate of 31,746,030 shares of our common stock at a purchase price of $3.15 per share for total net proceeds of approximately $96.7 million, after deducting placement agent's fees and other estimated offering expenses. Net proceeds included an aggregate of $27.5 million received from Flagship Pioneering Fund VII, L.P. and Nutritional Health LTP Fund, L.P., affiliates of Flagship Pioneering, or Flagship, one of our significant stockholders, in exchange for 8,738,243 shares. The closing date of the Registered Direct Offering was July 5, 2022.

As of December 31, 2022, we had cash, cash equivalents and short- and long-term investments totaling $181.3 million and an accumulated deficit of $864.5 million. For the year ended December 31, 2022, we incurred a net loss of $250.2 million, and used cash in operations of $228.8 million. We expect that our operating losses and negative cash flows will continue for the foreseeable future. We are eligible to receive contingent milestone payments under the 2021 License Agreement if certain development, regulatory approval or sales target milestones are achieved. In the event of the approval of our BLA for SER-109, which is currently under priority review by the FDA, we will receive an additional $125.0 million payment from Nestlé pursuant to the 2021 License Agreement (see Note 11, *Collaboration Revenue*, to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K), and become eligible to receive a $25.0 million tranche under our New Credit Facility with Hercules, which becomes available upon the satisfaction of certain conditions, including FDA approval of SER-109. Additionally, following approval, we will be eligible to receive payments from Nestlé for the supply of SER-109. Following first commercial sale of SER-109, we will be entitled to share equally in its commercial profits and losses.

Under applicable accounting standards, we have the responsibility to evaluate whether conditions or events raise substantial doubt about our ability to meet our future financial obligations as they become due within 12 months after the date the consolidated financial statements are issued. The receipt of certain contingent payments associated with the FDA approval of our BLA for SER-109, which include the $125.0 million milestone payment from Nestlé and the $25.0 million tranche under our New Credit Facility with Hercules, cannot be considered probable, as these events are outside of our control. Based on its currently available cash resources, we believe it is reasonably likely that we will require additional funding in early 2024. Accordingly, management has concluded that these circumstances raise substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing. If potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. We will need to generate significant revenues to achieve profitability, and we may never do so. Because of the numerous risks and uncertainties associated with the development of our current and any future product candidates, the development of our platform and technology and because the extent to which we may enter into collaborations with third parties for development of any of our product candidates is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses required for completing the research and development of our product candidates.

Collaboration and Manufacturing Agreements

License Agreement with Société des Produits Nestlé S.A. (Nestlé)

In January 2016, we entered into the 2016 License Agreement with Nestec, Ltd., as succeeded by Société des Produits Nestlé S.A., or, together with NHSc Rx License GmbH, their affiliates, and their subsidiaries, Nestlé, for the development and commercialization of certain of our product candidates in development for the treatment and management of CDI and IBD, including

UC and Crohn's disease. In exchange for the license, Nestlé agreed to pay us an upfront cash payment of $120.0 million, which we received in February 2016. Nestlé has also agreed to pay us tiered royalties, at percentages ranging from the high single digits to high teens, of net sales of certain products based on our microbiome technology that are being developed for the treatment of CDI and IBD, including SER-109, SER-262, SER-287 and SER-301, or collectively, the 2016 Collaboration Products, in markets outside of the United States and Canada, or the 2016 Licensed Territory. We are eligible to receive up to $285.0 million in development milestone payments, $375.0 million in regulatory payments and up to an aggregate of $1.1 billion for the achievement of certain commercial milestones related to the sales of 2016 Collaboration Products. The full potential value of the up-front payment and milestone payments payable by Nestlé is over $1.9 billion, assuming all products receive regulatory approval and are successfully commercialized. In September 2016, we received a $10.0 million milestone payment associated with the initiation of the Phase 1b clinical study for SER-262 in CDI. In June 2017, we initiated a Phase 3 clinical study of SER-109 (ECOSPOR III) in patients with multiply recurrent CDI. In July 2017, we received $20.0 million based on the achievement of this milestone under the 2016 License Agreement. In November 2018, we executed a letter agreement with Nestlé, or the Letter Agreement, modifying certain terms of the 2016 License Agreement. Under the Letter Agreement, Nestlé agreed to pay us the $20.0 million Phase 3 milestone payment upon commencement of the Phase 2b study for SER-287. In December 2018, we received $40.0 million in milestone payments in connection with the commencement of the Phase 2b study for SER-287. In August 2020, we received $10.0 million from Nestlé in connection with the initiation of the Phase 1b SER-301 study. To date, we have received $80.0 million in development milestones under the 2016 License Agreement with Nestlé.

For the development of 2016 Collaboration Products for IBD under a global development plan, we agreed to pay the costs of clinical trials of such products up to and including Phase 2 clinical trials, and 67% of the costs for Phase 3 and other clinical trials of such products, with Nestlé bearing the remaining 33% of such costs. The Letter Agreement also provides scenarios under which Nestlé's reimbursement to us for certain Phase 3 development costs would be reduced or delayed depending on the outcomes of the SER-287 Phase 2b study. For other clinical development of 2016 Collaboration Products for IBD, we agreed to pay the costs of such activities to support approval in the United States and Canada, and Nestlé agreed to bear the cost of such activities to support approval of 2016 Collaboration Products in the 2016 Licensed Territory.

With respect to development of 2016 Collaboration Products for CDI under a global development plan, we agreed to pay all costs of Phase 2 clinical trials for SER-109 and for Phase 3 clinical trials for SER-109. We agreed to bear all costs of conducting any Phase 1 or Phase 2 clinical trials under a global development plan for 2016 Collaboration Products other than SER-109 for CDI. We agreed to pay 67% and Nestlé agreed to pay 33% of other costs of Phase 3 clinical trials conducted for 2016 Collaboration Products other than SER-109 for CDI under a global development plan. For other clinical development of 2016 Collaboration Products for CDI, we agreed to pay costs of such development activities to support approval in the United States and Canada, and Nestlé agreed to bear the cost of such activities to support approval of 2016 Collaboration Products in the 2016 Licensed Territory.

The 2016 License Agreement continues in effect until terminated by either party on the following bases: (i) Nestlé may terminate the 2016 License Agreement in the event of serious safety issues related to any of the 2016 Collaboration Products; (ii) we may terminate the 2016 License Agreement if Nestlé challenges the validity or enforceability of any of our licensed patents; and (iii) either party may terminate the 2016 License Agreement in the event of the other party's uncured material breach or insolvency. Upon termination of the 2016 License Agreement, all licenses granted to Nestlé by us will terminate, and all rights in and to the 2016 Collaboration Products in the 2016 Licensed Territory will revert to us. If we commit a material breach of the 2016 License Agreement, Nestlé may elect not to terminate the 2016 License Agreement but instead apply specified adjustments to its payment obligations and other terms and conditions of the 2016 License Agreement.

License Agreement with NHSc Rx License GmbH (Nestlé)

On July 1, 2021, we entered into a License Agreement, or the 2021 License Agreement, with NHSc Pharma Partners, succeeded by NHSc Rx License GmbH, or, together with Société des Produits Nestlé S.A., their affiliates, and their subsidiaries, Nestlé. Pursuant to the 2021 License Agreement, we granted to Nestlé, under certain of our patent rights and know how, a co-exclusive, sublicensable (under certain circumstances) license to develop, commercialize and conduct medical affairs activities for (i) therapeutic products based on our microbiome technology (including our SER-109 product candidate) that are developed by us or on our behalf for the treatment of CDI and recurrent CDI, as well as any other indications pursued for the products upon mutual agreement of the parties, or the 2021 Field, in the United States and Canada, or the 2021 Licensed Territory, and (ii) our SER-109 product candidate and any improvements and modifications thereto developed pursuant to the terms of the 2021 License Agreement, or the 2021 Collaboration Products, for any indications in the 2021 Licensed Territory.

The 2021 License Agreement sets forth the parties' respective obligations for development, regulatory, commercialization, medical affairs, and manufacturing and supply activities for the 2021 Collaboration Products with respect to the 2021 Field and the 2021 Licensed Territory. Pursuant to the 2021 License Agreement, we are responsible for, and will use commercially reasonable efforts in, conducting development of SER-109 in the 2021 Field in the United States until first regulatory approval for SER-109 is obtained in the 2021 Field in the United States and in accordance with a development and regulatory activity plan, at our cost, subject to certain exceptions specified in the 2021 License Agreement. We are also responsible for all regulatory affairs related to 2021 Collaboration Products in the 2021 Field in the 2021 Licensed Territory, at its cost, except that expenses incurred for regulatory activities approved by a joint steering committee pursuant to a life cycle management plan for 2021 Collaboration Products are shared

equally between the parties. We will be solely responsible for manufacturing and supplying 2021 Collaboration Products for development in the 2021 Field in the 2021 Licensed Territory.

Nestlé has the sole right to commercialize the 2021 Collaboration Products in the 2021 Licensed Territory in accordance with a commercialization plan, subject to our right to elect to provide up to a specified percentage of all promotional details for a certain target audience. Each party will use commercially reasonable efforts to commercialize the 2021 Collaboration Products in the 2021 Licensed Territory in accordance with the commercialization plan. Both parties will perform medical affairs activities for 2021 Collaboration Products in the 2021 Licensed Territory in accordance with a medical affairs plan. We will be solely responsible for the manufacturing and supply of 2021 Collaboration Products for commercialization under a supply agreement that will be entered into between the parties. We are responsible for commercialization and medical affairs activities costs incurred by the parties until first commercial sale of the first 2021 Collaboration Product in the 2021 Licensed Territory and in accordance with a pre-launch plan, up to a specified cap. Following first commercial sale of the first 2021 Collaboration Product, we will be entitled to share equally in its commercial profits and losses.

In exchange for the grant of the licenses under the 2021 License Agreement, Nestlé agreed to pay us a non-refundable, non-creditable and non-cancelable upfront payment of $175.0 million, which was received in July 2021. Nestlé also agreed to pay us an additional $125.0 million due upon FDA approval of SER-109, $10.0 million upon Canadian regulatory approval of SER-109, and sales target milestones payments totaling up to $225.0 million.

The 2021 License Agreement continues in effect until all development and commercialization activities for all 2021 Collaboration Products in the 2021 Licensed Territory have permanently ceased. The 2021 License Agreement may be terminated by either party upon sixty days' written notice for the other party's material breach that remains uncured during such sixty-day period, or immediately upon written notice for the other party's insolvency. Nestlé may also terminate the 2021 License Agreement at-will (i) with twelve months' prior written notice, effective only on or after the third anniversary of first commercial sale of the first 2021 Collaboration Product in the 2021 Licensed Territory, (ii) if first commercial sale of the first 2021 Collaboration Product in the 2021 Licensed Territory has not occurred by the fifth anniversary of the effective date of the 2021 License Agreement, with one hundred eighty days' prior written notice, which must be provided during a specified period set forth in the 2021 License Agreement, or (iii) if regulatory approval for SER-109 is not granted after submission by us of a filing seeking first regulatory approval as set forth in the development and regulatory activity plan, and the parties fail to agree on further development of SER-109 in accordance with the terms of the 2021 License Agreement, with one hundred eighty days' prior written notice, which must be provided within a specified period set forth in the 2021 License Agreement. We may also terminate the 2021 License Agreement immediately upon written notice if Nestlé challenges any licensed patent in the 2021 Licensed Territory.

Upon termination of the 2021 License Agreement, all licenses granted to Nestlé by us will terminate. If we commit a material breach of the 2021 License Agreement, Nestlé may elect not to terminate the 2021 License Agreement but instead apply specified adjustments to the payment terms and other terms and conditions of the 2021 License Agreement. The 2021 License Agreement contains customary representations and warranties by the parties, intellectual property provisions including ownership, patent prosecution, enforcement and defense, certain indemnification rights in favor of each party, and customary confidentiality provisions and limitations of liability.

Long Term Manufacturing Agreement with Bacthera

In November 2021, we entered into a Long Term Manufacturing Agreement with BacThera AG, or Bacthera, a joint venture between Chr. Hansen and a Lonza Group affiliate, which was amended on December 14, 2022, or the Bacthera Agreement. The Bacthera Agreement governs the general terms under which Bacthera, or one of its affiliates, will (i) construct a dedicated full-scale production suite for us at Bacthera's Microbiome Center of Excellence in Visp, Switzerland, which is currently under construction; and (ii) provide manufacturing services to us for our SER-109 product and other products, as agreed to by the parties.

Under the terms of the Bacthera Agreement, we agreed to pay Bacthera a total of at least 256 million CHF (or approximately $277 million) for the initial term of the agreement, inclusive of the construction fees and annual operating fees. Bacthera is funding the majority of the construction costs and will own and control the manufacturing suite during construction. The construction fees that we are responsible for represent a small percentage of the overall construction costs and are payable upon the achievement of certain milestones related to the construction of the dedicated manufacturing suite. The annual operating fee includes the cost of a baseline annual batch production volume. We have also agreed to pay certain other ancillary fees and a per-batch fee in excess of the baseline batches. These fees are subject to adjustment during construction for certain items outside of Bacthera's control and annually against an agreed index. We will supply the active pharmaceutical ingredients to Bacthera to enable it to perform the services and pay for certain other raw materials and manufacturing components, which will be acquired by Bacthera.

The Bacthera Agreement has an initial term that continues until the tenth anniversary of the earlier of (a) successful completion of construction and demonstration of Bacthera's readiness for commercial production or (b) the commencement of manufacturing. The initial term is subject to renewals, which could extend the term to 16 years, and additional three-year terms thereafter. Each party has the ability to terminate the Bacthera Agreement upon the occurrence of certain customary conditions. We may also terminate the Bacthera Agreement for convenience after a defined period. In the event of a termination, we have certain financial obligations that would apply, and Bacthera has agreed to grant a license to Bacthera-developed manufacturing know how, if any, and provide technical

assistance to us, so that we could transfer the manufacturing operations to ourselves or a third party. The Bacthera Agreement also contains representations, warranties and indemnity obligations as well as limitations of liability that are customary for agreements of this type.

Indebtedness

Loan and Security Agreement with Hercules

In October 2019, we entered into a loan and security agreement with Hercules Capital, Inc., or Hercules, pursuant to which a term loan in an aggregate principal amount of up to $50.0 million, or the Original Credit Facility, was available to us in three tranches, subject to certain terms and conditions. We received the first tranche of $25.0 million upon signing the agreement on October 29, 2019, but did not borrow either of the second two tranches, which were available at different times upon Hercules' approval until June 30, 2021.

On April 16, 2020, we entered into an amendment to the Loan Agreement, or the First Amendment, permitting us to enter into a promissory note under the Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Stability Act. On April 17, 2020 we issued a Promissory Note to Bank of America, NA, or the Loan, pursuant to which we received loan proceeds of $2.9 million, however, based on updated guidance related to this program, we decided to repay the full amount of the Loan, and repaid the Loan on May 4, 2020.

Effective as of February 24, 2022, or the Effective Date, we entered into a Second Amendment to the Original Credit Facility (as amended by the First Amendment), or the New Credit Facility, pursuant to which term loans in an aggregate principal amount of up to $100.0 million have become available to us in five tranches including the first tranche under the Original Credit Facility, subject to certain terms and conditions.

The first tranche in an aggregate principal amount of $25.0 million was outstanding as of the Effective Date, after taking into account reborrowing by us on the Effective Date of a previously-repaid principal amount of approximately $2.9 million. The second tranche in an aggregate principal amount of $12.5 million and the third tranche in an aggregate principal amount of $12.5 million have been advanced to us and were outstanding as of the Effective Date. The fourth tranche in an aggregate principal amount of $25.0 million is available upon satisfaction of certain conditions, including the approval by the FDA of a biologics license application in respect of SER-109, or the Regulatory Approval Milestone, by no later than December 15, 2023. The fifth tranche in an aggregate principal amount of up to $25.0 million is available through the Amortization Date (as defined below) upon satisfaction of certain conditions, including the Lenders' investment committee approval.

All advances outstanding under the New Credit Facility bear interest at a rate equal to the greater of either (i) the Prime Rate (as reported in The Wall Street Journal) plus 6.40%, and (ii) 9.65%. For all advances outstanding under the New Credit Facility, we will make interest only payments through December 31, 2023, extendable to December 31, 2024 upon satisfaction of certain conditions, such applicable date, the Amortization Date. The principal balance and interest of the advances will be repaid in equal monthly installments after the Amortization Date and continuing through October 1, 2024, extendable to October 1, 2025, upon satisfaction of certain conditions, such applicable date, the Maturity Date.

We may prepay advances under the New Credit Facility, in whole or in part, at any time subject to a prepayment charge equal to: (a) 2.0% of amounts so prepaid, if such prepayment occurs during the first year following the Effective Date; (b) 1.5% of the amount so prepaid, if such prepayment occurs during the second year following the Effective Date, and (c) 1.0% of the amount so prepaid, if such prepayment occurs during the third year following the Effective Date.

We will pay an end of term charge of 4.85% of the aggregate amount of the advances made under the Old Credit Facility on the earliest date of (i) November 1, 2023; (ii) the date that we prepay all of the outstanding principal in full, or (iii) the date the loan payments are accelerated due to an event of default. We will pay an additional end of term charge of 1.75% of the aggregate amount of the advances under the New Credit Facility (including the first tranche of $25.0 million) on the earliest date of (i) the Maturity Date; (ii) the date that we prepay all of the outstanding principal in full, or (iii) the date the loan payments are accelerated due to an event of default.

Other terms of the New Credit Facility remain generally identical to those under the Old Credit Facility, with certain covenants amended by the Second Amendment to provide us with additional operational flexibility, including the ability for us to issue up to $350.0 million in convertible notes. The New Credit Facility includes a conditional liquidity covenant commencing on June 15, 2023, which ceases to apply if certain conditions including the Regulatory Approval Milestone are satisfied.

The New Credit Facility is secured by substantially all of our assets, other than our intellectual property. We have agreed to not pledge or secure our intellectual property to others.

As of December 31, 2022 and 2021, the outstanding principal under the New Credit Facility was $50.0 million and $24.1 million, respectively. For a further description of the New Credit Facility, see Note 8 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Cash Flows

The following table summarizes our sources and uses of cash, cash equivalents and restricted cash for the years ended December 31, 2022 and 2021.

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Cash (used in) provided by operating activities	$ (228,816)	$ 6,688
Cash provided by investing activities	$ 82,428	$ 64,088
Cash provided by financing activities	$ 129,602	$ 1,178
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (16,786)	$ 71,954

Operating Activities

During the year ended December 31, 2022, net cash used in operating activities was $228.8 million, primarily due to net loss of $250.2 million and changes in our operating assets and liabilities of $18.4 million, partially offset by non-cash charges of $39.7 million. Non-cash charges consisted of $25.5 million of stock-based compensation expense, $5.2 million related to the amortization of right-of-use assets, $6.6 million of depreciation, $1.4 million of net amortization of premiums related to our investments and amortization of debt issuance costs, and collaboration loss sharing of $1.0 million related to the 2021 License Agreement with Nestlé. Changes in our operating assets and liabilities during the year ended December 31, 2022 primarily consisted of a $12.6 million increase in prepaid expenses and other current and non-current assets, a $7.1 million decrease in deferred revenue and a $4.2 million decrease in operating lease liabilities, partially offset by a $3.3 million increase in accrued expenses and other liabilities and a $2.2 million increase in accounts payable. The increase in prepaid expenses and other current and non-current assets was primarily due to the remittance of the second milestone payment pursuant to the Bacthera Agreement. The decrease in deferred revenue is due to recognition of revenue during the year for services performed under both the 2021 License Agreement and the 2016 License Agreement. The decrease in operating lease liabilities was due to the cash payment of lease obligations.

During the year ended December 31, 2021, net cash provided by operating activities was $6.7 million, primarily due to changes in our operating assets and liabilities of $41.5 million and non-cash charges of $30.7 million, partially offset by a net loss of $65.6 million. Non-cash charges consisted primarily of $20.2 million of stock-based compensation expense, $3.3 million related to the amortization of right-of-use assets, $5.9 million of depreciation, and $2.5 million of net amortization of premiums related to our investments, partially offset by collaboration profit sharing of $1.7 million related to the 2021 License Agreement with Nestlé. Changes in our operating assets and liabilities during the year ended December 31, 2021 primarily consisted of a $43.0 million increase in accrued expenses and other liabilities, a $9.4 million increase in accounts payable and a $9.4 million decrease in accounts receivable, partially offset by a $12.3 million increase in prepaid expenses and other current and non-current assets, a $4.4 million decrease in deferred revenue and a $3.6 million decrease in operating lease liabilities. The increase in accrued expenses and other current and long-term liabilities was primarily due to the liability established for pre-launch activities in conjunction with the 2021 License Agreement with Nestlé. The decrease in deferred revenue is due to recognition of revenue during the year, partially offset by an increase of $8.2 million, which represents the portion of the transaction price for the 2021 License Agreement allocated to the research and development services. The decrease in operating lease liabilities was due to the cash payment of lease obligations.

Investing Activities

During the year ended December 31, 2022, net cash provided by investing activities was $82.4 million, primarily due to maturities of investments of $140.5 million, partially offset by purchases of investments of $48.2 million and purchases of property and equipment of $9.8 million.

During the year ended December 31, 2021, net cash provided by investing activities was $64.1 million, primarily due to maturities of investments of $169.6 million, partially offset by purchases of investments of $96.0 million and purchases of property and equipment of $9.6 million.

Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities was $129.6 million, consisting of $96.7 million of net proceeds received from the Registered Direct Offering that we completed in July 2022, $27.6 million of proceeds received from the New Credit Facility, and $4.4 million from the issuance of common stock via our at the market equity program, net of issuance costs. We also received $1.0 million from the issuance of common stock associated with the exercise of stock options and $1.8 million in connection with the issuance of common stock under our 2015 Employee Stock Purchase Plan, or ESPP. These cash inflows were partially offset by principal payments under the Original Credit Facility of $1.9 million.

During the year ended December 31, 2021, net cash provided by financing activities was $1.2 million. This was a result of $1.3 million from the exercise of stock options and $0.8 million from the issuance of common stock under the ESPP, partially offset by $0.9 million of principal payments relating to our term loan.

Funding Requirements

Our expenses may increase substantially in connection with our ongoing clinical development activities and our research and development activities. In addition, we expect to continue to incur additional costs associated with operating as a public company. We anticipate that our expenses will increase substantially if and as we:

- complete the clinical development, seek regulatory approval, and prepare for commercialization of SER-109 for patients with recurrent CDI;
- continue the clinical development of SER-155 to reduce incidences of gastrointestinal infections, bloodstream infections and GvHD in patients receiving allo-HSCT;
- continue evaluating preclinical stage programs to reduce incidence of infection, in indications such as cancer neutropenia, chronic liver disease, solid organ transplant, and antimicrobial resistant infections more broadly;
- continue translational research activities, informed by the SER-287 Phase 2b and SER-301 Phase 1b study data, to evaluate the potential to utilize biomarker-based patient selection and stratification in future clinical development efforts;
- make strategic investments in our research discovery and development platforms and capabilities to advance our priority programs;
- make strategic investments in manufacturing capabilities;
- maintain and augment our intellectual property portfolio and opportunistically acquire complementary intellectual property;
- potentially establish a sales and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- perform our obligations under our agreements with our collaborators;
- seek to obtain regulatory approvals for our product candidates; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

Because of the numerous risks and uncertainties associated with the development of our product candidates, 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 will depend on many factors, including:

- the impact of the COVID-19 pandemic, including any resurgence or the emergence of new variants;
- the impact of continued increase in inflation rates or interest rates;
- the progress and results of our clinical studies and preclinical development;
- the cost of manufacturing our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates and research activities;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

Identifying potential product candidates and conducting preclinical 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. Additionally, market volatility resulting from macroeconomic conditions, the COVID-19 pandemic, or other factors could also adversely impact our ability to access capital as

and when needed. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our shareholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our shareholders' rights as common stockholders. Our loan and security agreement with Hercules currently includes, and any 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. Additional debt or preferred equity financing may also require the issuance of warrants, which could potentially dilute our shareholders' ownership interest.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, in addition to our existing collaboration agreements, 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.

As noted above, the magnitude and duration of the COVID-19 pandemic and its impact on our liquidity and future funding requirements is uncertain as of the filing date of this Annual Report on Form 10-K as this continues to evolve globally. See "Risk Factors—Risks Related to Our Operations—The COVID-19 pandemic has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition" in Part I, Item 1A of this Annual Report on Form 10-K for a further discussion of the possible impact of the COVID-19 pandemic on our business.

As discussed in Note 1 of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we have the responsibility to evaluate whether conditions or events raise substantial doubt about our ability to meet our future financial obligations as they become due within 12 months after the date the consolidated financial statements are issued. The receipt of potential funding from future equity or debt issuances and certain contingent payments associated with the FDA approval of our BLA for SER-109, which is currently under priority review by the FDA, which include the potential to receive a $125.0 million milestone payment from Nestlé pursuant to the 2021 License Agreement, and a $25.0 million tranche under our New Credit Facility with Hercules, cannot be considered probable, as these events are outside of our control. Based on our currently available cash resources and our current level of operations and cash flow analysis for the 12-month period subsequent to the date of issuance of the consolidated financial statements, we believe it is reasonably likely that it will require additional funding in early 2024. Accordingly, management has concluded that these circumstances raise substantial doubt about our ability to continue as a going concern.

Contractual Obligations and Commitments

We have entered into arrangements that contractually obligate us to make payments that will affect our liquidity and cash flows in future periods. Such arrangements include those related to our lease commitments, long-term debt, and long-term manufacturing agreements.

Lease Commitments

Our lease commitments reflect payments due under our operating lease agreements for our corporate headquarters, office and laboratory space, and donor collection facilities, that expire between May 2028 and April 2033. As of December 31, 2022, our contractual commitments for our leases were $187.2 million, of which $16.8 million is expected to be paid within one year, and $170.5 million will be paid over the remaining term of such leases. Our lease commitments also include $5.5 million for leases that had not yet commenced as of December 31, 2022. For additional information on our leases and timing of future payments, please read Note 7, *Leases*, to the consolidated financial statements included in this Form 10-K.

Loan Agreement

Our commitments due for our term loan under our arrangement with Hercules total $7.0 million in interest-only payments through January 1, 2024, and a backend fee of $1.2 million due in November 2023. Our remaining commitments are due through October 2024, and include principal and interest payments of $53.3 million, and an additional fee upon maturity of the loan of $0.9 million. The interest rate in effect at December 31, 2022 was 13.40%. See Note 8, *Notes Payable*, to the consolidated financial statements for further discussion of the Hercules term loan.

Bacthera Long Term Manufacturing Agreement

Our commitments due under our long-term manufacturing agreement with Bacthera, inclusive of construction fees and annual operating fees, total $263.1 million, of which $65.5 million in construction fees are expected to be paid within one year, and the remaining $197.6 million in operating fees will be paid over the remaining 10 years, beginning in 2024 upon completion of the construction of the facility.

Other Obligations

We enter into contracts in the normal course of business with CROs for clinical trials, preclinical 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.

Recently Issued and Adopted Accounting Pronouncements

For a discussion of recent accounting standards see Note 2, Summary of Significant Accounting Policies, to our consolidated financial statements included in this report.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Fluctuation Risk

We are exposed to market risk related to changes in interest rates.

As of December 31, 2022, our cash and cash equivalents consisted of cash and money market accounts. Our interest income is sensitive to changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, an immediate 10% change in market interest rates would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

As of December 31, 2022, we had outstanding borrowings under the New Credit Facility. We accrue interest at a rate equal to the greater of either (i) the Prime Rate (as reported in The Wall Street Journal) plus 6.40%, and (ii) 9.65%. An immediate 10% change in the Prime Rate would not have a material impact on our debt-related obligations, financial position or results of operations

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Annual Report on Form 10-K. Based on such evaluation, our principal executive officer and principal financial officer has concluded that as of December 31, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control – Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on this assessment, our management concluded that, as of December 31, 2022, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting as of December 31, 2022, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report included in this Annual Report on Form 10-K on page F-1.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Director Biographical Information

Name	Age	Position
Dennis A. Ausiello, M.D. (3)(4)	77	Director
Grégory Behar (3)	53	Director
Stephen Berenson (3)	62	Chairman of the Board of Directors
Paul R. Biondi (2)	53	Director
Willard H. Dere, M.D. (4)	69	Director
Claire M. Fraser, Ph.D. (1)(4)	67	Director
Kurt C. Graves (2)	55	Director
Richard N. Kender (1)(2)	67	Director
Eric D. Shaff	47	President, Chief Executive Officer and Director
Meryl S. Zausner (1)(2)	66	Director

(1) Member of the audit committee.

(2) Member of the compensation and talent committee.

(3) Member of the nominating and corporate governance committee.

(4) Member of the science and clinical development committee.

Dennis A. Ausiello, M.D. has served as a member of our board of directors since April 2015. Dr. Ausiello has served as the Jackson Distinguished Professor of Clinical Medicine at Harvard Medical School and Director, Emeritus of Harvard Medical School's M.D./Ph.D. Program since 1996, Chair of Medicine, Emeritus, and Director of the Center for Assessment Technology and Continuous Health (CATCH) at Massachusetts General Hospital, which he co-founded, since 2012, and Physician-in-Chief Emeritus at Massachusetts General Hospital since 2013. From 1996 to April 2013, Dr. Ausiello served as the Chief of Medicine at Massachusetts General Hospital. Dr. Ausiello is a member of the Institute of Medicine of the National Academy of Sciences and a fellow of the American Academy of Arts and Sciences. Dr. Ausiello has served on the board of directors of Alnylam Pharmaceuticals since April 2012 and previously served on the board of directors of Pfizer Inc. from 2006 to 2020, where he currently serves on the advisory board since 2019. Dr. Ausiello also serves on the boards of directors of numerous privately held companies. Dr. Ausiello received a B.A. in Biochemistry from Harvard College and an M.D. from the University of Pennsylvania. We believe that Dr. Ausiello is qualified to serve on our board of directors because of his extensive experience as a physician and as a director of pharmaceutical companies.

Grégory Behar has served as a member of our board of directors since December 2014. Mr. Behar has served as Chief Executive Officer of Nestlé Health Science, a business unit of Société des Produits Nestlé S.A., a health sciences company, since July 2014. From August 2011 to May 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 has served on the boards of directors of Nestlé Health Science since July 2014, Axcella Health, Inc. since February 2016 and Sonova AG since April 2021 and previously served on the board of directors of Aimmune Therapeutics, Inc. from November 2016 until its acquisition in October 2020. Mr. Behar received his B.S. in Mechanical Engineering from the University of California, Los Angeles, an M.S. in Mechanical Engineering and Manufacturing from EPFL in Switzerland and an M.B.A. 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.

Stephen Berenson has served as Chairman of our board of directors since December 2019 and as a member of our board of directors since August 2019. Mr. Berenson has been a Managing Partner at Flagship Pioneering, a life sciences innovation firm which conceives, creates, resources and develops first-in-category life sciences companies, since June 2017. Prior to Flagship, Mr. Berenson spent 33 years in various roles as an investment banker at J.P. Morgan, most recently serving in the role of Vice Chairman of Investment Banking from 2005 to April 2017, where he focused on providing high-touch strategic advice and complex transaction execution to leading companies across all industries globally. He was co-founder of J.P. Morgan's Global Strategic Advisory Council and co-founder of the firm's Board Initiative. Mr. Berenson has served as chairman of the board of directors of Cellarity, a privately held company, since July 2021, and has served on the boards of directors of Moderna, Inc. since October 2017 and Repertoire Immune Medicines, a privately held company, since May 2021. Mr. Berenson received an S.B. in Mathematics from the Massachusetts Institute of Technology. We believe that Mr. Berenson is qualified to serve on our board of directors because of his extensive experience working with rapidly-growing companies across various industries.

Paul R. Biondi has served as a member of our board of directors since March 2020. Mr. Biondi is an Executive Partner and President of Pioneering Medicines at Flagship Pioneering, roles he has held since November 2019. Mr. Biondi joined Flagship Pioneering

following a seventeen-year tenure at Bristol-Myers Squibb, or BMS, a pharmaceutical company, where he was most recently the Senior Vice President of Strategy and Business Development from October 2015 to November 2019. Prior to serving in the role of Senior Vice President of Strategy, from 2002 to 2015, Mr. Biondi held a series of other leadership roles within BMS' Research and Development organization overseeing strategy, portfolio, and project management, as well as clinical and business operations. Mr. Biondi holds a bachelor's degree from Dartmouth College and an M.B.A. from the J.L. Kellogg School of Management at Northwestern University. We believe that Mr. Biondi is qualified to serve on our board of directors because of his extensive experience in biopharmaceutical strategy and corporate development.

Willard H. Dere, M.D. has served as a member our board of directors since July 2017. Dr. Dere has been Professor Emeritus, Department of Internal Medicine, at the University of Utah School of Medicine since July 2022. Prior to retirement, and beginning in November 2014, Dr. Dere held multiple roles at the University of Utah Health Sciences Center, including Associate Vice President for Research, Co-Director of the Utah Clinical and Translational Science Institute, and Co-Director of the Center for Genomic Medicine. Prior to his professorship, from 2003 until 2014, Dr. Dere worked at Amgen, where he was Senior Vice President and head of Global Development, and led development programs in multiple therapeutic areas. From 1989 to 2014, he worked at Eli Lilly and led multiple development programs, and also worked in clinical pharmacology, regulatory affairs and safety. Dr. Dere has served on the boards of directors of BioMarin Pharmaceutical, Inc. since 2016 and Mersana Therapeutics, Inc. since 2018, and previously served on the boards of directors of Ocera Therapeutics and Radius Health. Dr. Dere received his B.A. in History and Zoology and M.D. from the University of California, Davis, completed his internal medicine residency training at the University of Utah, and his postdoctoral training in endocrinology and metabolism at the University of California, San Francisco. We believe Dr. Dere is qualified to serve on our board of directors due to his extensive academic experience and his knowledge of the biotechnology industry.

Claire M. Fraser, Ph.D. has served as a member of our board of directors since January 2023. Since 2007, Dr. Fraser has been the director of the Institute for Genome Sciences and a Professor of Medicine and Microbiology and Immunology at the University of Maryland School of Medicine in Baltimore, Maryland. From 1998 to 2007, she served as president and director of The Institute for Genomic Research, a not-for-profit research organization engaged in human and microbial genomics studies. Dr. Fraser has served on the board of directors of Becton, Dickinson, and Company since 2006, and previously served as the Chair of the Board and a director of the American Association for the Advancement of Science. Dr. Fraser received her bachelor's degree in Biology from Rensselaer Polytechnic Institute and her Ph.D. in Pharmacology from State University of New York-Buffalo. We believe Dr. Fraser is qualified to serve on our board of directors due to her extensive academic experience and her knowledge of the microbiome industry.

Kurt C. Graves has served as a member of our board of directors since November 2015. Mr. Graves has served as the Executive Chairman of i20 Therapeutics, Inc., a biotechnology company, since August 2021. Mr. Graves was previously the Chairman, President and Chief Executive Officer of Intarcia Therapeutics, Inc., a biotechnology company, from September 2010 to December 2020 and on its board of directors from August 2010 to December 2020. Previously, he served as Executive Vice President, Chief Commercial Officer and Head of Strategic Development at Vertex Pharmaceuticals Inc., or Vertex, from July 2007 to October 2009. Prior to joining Vertex, Mr. Graves held various leadership positions at Novartis Pharmaceuticals Corporation, or Novartis Corp., from 1999 to June 2007, including the Global General Medicines Business Unit Head and Chief Marketing Officer for the pharmaceuticals division of Novartis Corp. from September 2003 to June 2007. He served on the boards directors of Radius Health, Inc. from May 2011 to March 2020, and Achillion Pharmaceuticals, Inc. from June 2012 to January 2020. Mr. Graves received a B.S. in Biology from Hillsdale College. We believe Mr. Graves is qualified to serve as a member of our board of directors because of his extensive experience in the life sciences industry, membership on various boards of directors and his leadership and management experience.

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., or Merck, a pharmaceutical company, most recently serving as Senior Vice President of Business Development and Corporate Licensing. Mr. Kender has served on the boards of directors of Poxel S.A. since March 2015 and Bicycle Therapeutics PLC since July 2019. He previously served on the boards of directors of INC Research Holdings, Inc. between December 2014 and August 2017, Abide Therapeutics, Inc., a privately held company, between December 2015 and May 2019, and ReViral Ltd., a privately held company, from November 2019 to June 2022. Mr. Kender received a B.S. in Accounting from Villanova University and an M.B.A. from Fairleigh Dickinson University. We believe Mr. Kender is qualified to serve on our board of directors because of his finance experience and knowledge of the biotechnology industry.

Eric D. Shaff has served as our President and Chief Executive Officer and a member of our board of directors since January 2019. Previously, he served as our Chief Operating and Financial Officer and Executive Vice President from January 2018 until January 2019 and as our Chief Financial Officer from November 2014 until January 2019. From January 2012 to November 2014, Mr. Shaff was Vice President of Corporate Finance for Momenta Pharmaceuticals, or Momenta, a biotechnology company, where he helped manage Momenta's accounting, finance, planning, and procurement functions, as well as contributing to Momenta's investor relations efforts. Prior to Momenta, 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 has served on the board of directors of Sigilon Therapeutics, Inc. since November 2017. Mr. Shaff received his B.A. from the University of Pennsylvania and his M.B.A. from Cornell University. We believe Mr. Shaff is qualified to serve on our board of directors because of his extensive business and finance experience and his knowledge of the biotechnology industry.

Meryl Zausner has served as a member of our board of directors since August 2018. Ms. Zausner worked for Novartis Pharmaceuticals, Inc., or Novartis, a pharmaceutical company, from 1988 until her retirement in 2017, most recently serving as Chief Financial and Administrative Officer and a member of the Pharmaceutical Executive Committee and Global Finance Leadership Team of Novartis in the United States. At Novartis, she helped launch the Oncology Business Unit, as well as the company's shared services organization. Prior to serving as Chief Financial and Administrative Officer, Ms. Zausner was a member of the Novartis Global Oncology leadership team, where she contributed to the development and commercialization of therapies, including Gleevec® (imatinib). Ms. Zausner previously served on the boards of directors of Goldfinch Bio, Inc., a privately held company, from February 2021 to December 2022, the Multiple Myeloma Research Foundation from September 2009 to June 2021, and Neon Therapeutics, Inc. from December 2017 to May 2020. Ms. Zausner received a B.S. in Accounting and Economics from the University at Albany, SUNY. We believe Ms. Zausner is qualified to serve on our board of directors because of her finance and leadership experience and knowledge of the pharmaceutical industry.

Information about our Executive Officers

Name	Age	Position
Eric D. Shaff	47	President, Chief Executive Officer and Director
David Arkowitz	61	Executive Vice President, Chief Financial Officer and Head of Business Development
Paula A. Cloghessy	52	Executive Vice President and Chief People Officer
Thomas J. DesRosier	68	Executive Vice President and Chief Legal Officer
David S. Ege, Ph.D.	48	Executive Vice President and Chief Technology Officer
Matthew Henn, Ph.D.	48	Executive Vice President and Chief Scientific Officer
Lisa von Moltke, M.D.	64	Executive Vice President and Chief Medical Officer
Teresa L. Young, Ph.D.	56	Executive Vice President, Chief Commercial and Strategy Officer

Information concerning Eric D. Shaff, our President and Chief Executive Officer, may be found above in the section entitled "Director Biographical Information."

David Arkowitz has served as our Executive Vice President, Chief Financial Officer and Head of Business Development since June 2021. Previously, he served as the Chief Financial Officer of Flexion Therapeutics, Inc., a biotechnology company, from May 2018 to May 2021. From September 2013 to May 2018, Mr. Arkowitz served as Chief Operating Officer and Chief Financial Officer at Visterra, Inc., a biotechnology company that was acquired by Otsuka Pharmaceutical Co. He also previously served as Chief Financial Officer at each of Mascoma Corporation, AMAG Pharmaceuticals Inc., and Idenix Pharmaceuticals LLC and held additional leadership positions within each company. Preceding his tenure at Idenix, Mr. Arkowitz spent more than 13 years at Merck & Co., Inc. where he held roles of increasing responsibility, including Vice President and Controller of the U.S. operations, Controller of the global research and development division, and the Chief Financial Officer of Merck's Canadian subsidiary. Mr. Arkowitz has served on the boards of directors of F-star Therapeutics, Inc. since November 2020 and Kineta, Inc. since December 2022, and previously served on the boards of directors of Yumanity Therapeutics, Inc., Spring Bank Pharmaceuticals, Inc. and Proteostasis Therapeutics, Inc. He obtained his B.A. in mathematics at Brandeis University and his M.B.A. in finance at Columbia University Business School.

Paula A. Cloghessy has served as our Executive Vice President and Chief People Officer since February 2022. Previously, Ms. Cloghessy served in roles of increasing seniority at Translate Bio, Inc., or Translate Bio, a biotechnology company acquired by Sanofi S.A., or Sanofi, a global biopharmaceutical company, from 2016 to December 2021, culminating in her role as Chief People Officer. In these roles, Ms. Cloghessy was responsible for leading human resources and organizational development and performance. Prior to Translate Bio, Ms. Cloghessy held senior roles at Joule Unlimited Technologies, Inc. and Interleukin Genetics, Inc. Ms. Cloghessy received her B.A. in Psychology from University of Massachusetts, Boston.

Thomas J. DesRosier has served as our Chief Legal Officer, Executive Vice President, and Secretary since May 2016. Previously, he served as Executive Vice President, Chief Legal and Administrative Officer and Secretary of ARIAD Pharmaceuticals, Inc., a biopharmaceutical company, from 2015 to 2016, Executive Vice President, Chief Legal and Administrative Officer and Secretary of Cubist Pharmaceuticals, Inc., or Cubist, a biopharmaceutical company, from 2014 to 2015 and Senior Vice President, Chief Legal Officer and Secretary of Cubist from 2013 to 2014. Before that, Mr. DesRosier served as Senior Vice President, General Counsel North America of Sanofi from 2011 to 2013. From 1999 to 2011, Mr. DesRosier held leadership roles of increasing seniority within the legal group of Genzyme Corporation, a biotechnology company, culminating in his role as Senior Vice President, Chief Legal Officer. Mr. DesRosier has served as a member of the board of directors of Avanir Pharmaceuticals, a privately held company and wholly-owned subsidiary of Otsuka Pharmaceutical Company, Ltd., since June 2017. Mr. DesRosier earned a B.A. in Chemistry from the University of Vermont and a J.D. from Wake Forest University School of Law.

David S. Ege, Ph.D. has served as our Executive Vice President and Chief Technology Officer since October 2020. Previously, Dr. Ege served in a variety of technical and leadership roles in R&D and manufacturing at Merck from November 2003 to October 2020, most recently as global lead for digital strategy in Merck's Manufacturing Division from June 2019 to October 2020. From April 2015 to June 2019, Dr. Ege served as Executive Director of Vaccines & Biologics Manufacturing at Merck's plant in Elkton, Virginia,

where he led bulk manufacturing operations for Gardasil®, Gardasil9® and Cancidas®. He has contributed to the successful first-in-class licensure and launch of cervical cancer vaccines, Gardasil® (2006) and Gardasil9® (2014), and a breakthrough cancer immunotherapy, Keytruda® (2014). He graduated summa cum laude from Princeton with a B.S.E. in chemical engineering and earned his Ph.D. in chemical engineering from the University of Pennsylvania.

Matthew Henn, Ph.D. has served as our Executive Vice President and Chief Scientific Officer since February 2019. Since joining our company at its launch in June 2012, he has held positions of increasing seniority, most recently as Executive Vice President, Head of Discovery and Microbiome R&D from January 2018 to February 2019, and previously as Senior Vice President, Head of Discovery and Bioinformatics from June 2012 to January 2018. 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 the Massachusetts Institute of Technology and Harvard. He currently serves on the scientific advisory boards of the Forsyth Institute and Growcentia, Inc., an agricultural microbiome company. Dr. Henn earned his B.S. in Ecology and Evolutionary Sciences from the University of New Hampshire and his Ph.D. in Ecosystem Sciences from the University of California at Berkeley, where he was a NASA Earth Systems Sciences Fellow, and trained as a NSF Postdoctoral Fellow in Microbiology at Duke University.

Lisa von Moltke, M.D. has served as our Executive Vice President and Chief Medical Officer since March 2020. Previously, Dr. von Moltke worked for Alkermes, Inc., a pharmaceutical company, from June 2015 to December 2019, where she served in roles of increasing seniority, culminating as Senior Vice President and Head of Clinical Development. Beginning in June 2015, Dr. Moltke served as VP Clinical Pharmacology, DMPK and Bioanalytics, was promoted to Head of Clinical Development in November 2015, and became SVP in June 2018. Prior to joining Alkermes, Dr. von Moltke served as Vice President Clinical Pharmacology at Sanofi/Genzyme Corporation, a biotechnology company, from 2009 to 2015 and was US Head Clinical & Exploratory Pharmacology Sciences (CEP) and Early Development. Starting in 2014 she was Head CEP for Japan and China regions. From 2006 to 2009, Dr. von Moltke was Head, Translational Medicine for the Takeda Oncology Company, a biopharmaceutical company, in Cambridge, MA. Dr. von Moltke has served on the board of directors of Cara Therapeutics, Inc. since November 2022. She has served as President of the American College of Clinical Pharmacology, and as the Editor-in-Chief of The Journal of Clinical Pharmacology. Dr. von Moltke earned a B.A. degree at Wellesley College and her M.D. from Michigan State University, College of Human Medicine.

Teresa L. Young, Ph.D. has served as our Executive Vice President, Chief Commercial and Strategy Officer since June 2020. Previously, Dr. Young served as Vice President, Global Commercial Strategy at Sage Therapeutics from March 2018 to June 2020, where she led development of Sage's global commercial capabilities, including global marketing, insights and analytics and new product planning. Prior to that, she held commercial leadership roles of increasing responsibility at Bristol-Myers Squibb from November 2010 to March 2018, culminating in her role as Vice President and General Manager, Cardiovascular, in which she led the global ELIQUIS® business to become the company's largest product by revenue. Earlier in her career, Dr. Young held marketing and sales roles at GlaxoSmithKline from June 1993 to November 2010, where she catalyzed growth for the company's Urology, Diabetes and NeuroHealth organizations. Dr. Young is a member of the Women in Bio and Healthcare Businesswomen's Association and served on the Advisory Board of the Healthcare Businesswomen's Association. Dr. Young received her B.S. in pharmacy and her Ph.D. in healthcare marketing from the University of South Carolina.

Code of Ethics

Our board of directors has adopted a Code of Business Conduct and Ethics applicable to all officers, directors and employees, which is available on our website at www.serestherapeutics.com in the "Investors and News" section under "Corporate Governance." We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics, as well as Nasdaq's requirement to disclose waivers with respect to directors and executive officers, by posting such information on our website at the address and location specified in the preceding sentence. The information contained on our website is not incorporated by reference into this Annual Report on Form 10-K.

Other

The remainder of the information required to be disclosed by this item will be contained in the Proxy Statement for our Annual Meeting of Stockholders to be held in 2023 and is incorporated herein by reference.

Item 11. Executive Compensation

The information required to be disclosed by this item will be contained in the Proxy Statement for our Annual Meeting of Stockholders to be held in 2023 and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required to be disclosed by this item will be contained in the Proxy Statement for our Annual Meeting of Stockholders to be held in 2023 and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required to be disclosed by this item will be contained in the Proxy Statement for our Annual Meeting of Stockholders to be held in 2023 and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required to be disclosed by this item will be contained in the Proxy Statement for our Annual Meeting of Stockholders to be held in 2023 and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statements Schedules

(a)(1) Financial Statements.

See the "Index to Consolidated Financial Statements" on page F-1 below for the list of financial statements filed as part of this report.

(a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the Consolidated Financial Statements or Notes thereto set forth below beginning on page F-1.

(a)(3) Exhibits.

The following is a list of all exhibits filed as a part of this Annual Report on Form 10-K.

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Restated Certificate of Incorporation	8-K	001-37465	3.1	7/1/15	
3.2	Amended and Restated Bylaws	8-K	001-37465	3.2	12/7/20	
4.1	Specimen Stock Certificate evidencing the shares of common stock	S-1/A	333-204484	4.2	6/16/15	
4.2	Description of Capital Stock	10-K	001-37465	4.2	3/2/21	
10.1#	2015 Incentive Award Plan, as amended and forms of award agreements thereunder					*
10.2#	2015 Employee Stock Purchase Plan	S-1/A	333-204484	10.3	6/16/15	
10.3#	2012 Stock Incentive Plan, as amended and form of option agreement thereunder	S-1	333-204484	10.1	5/27/15	
10.4#	2022 Employment Inducement Award Plan and forms of award agreements thereunder					*
10.5#	Non-Employee Director Compensation Program					*
10.6	Lease Agreement, dated April 1, 2015, by and between the Registrant and ARE-MA Region No. 38, LLC	S-1	333-204484	10.13	5/27/15	
10.7	Lease, dated November 11, 2015, by and between the Registrant and BMR-Sidney Research Campus, LLC	10-K	001-37465	10.13	3/14/16	
10.8	First Amendment to Lease, dated December 9, 2022, by and between Registrant and BMR-Sidney Research Campus, LLC (f/k/a BMR 200-Sidney Street LLC)	8-K	001-37465	10.1	12/14/22	
10.9#	Second Amended and Restated Employment Agreement, dated January 29, 2021, by and between the Registrant and Eric D. Shaff	8-K	001-37465	10.1	2/1/21	
10.10#	Amended and Restated Employment Agreement, dated January 29, 2021 by and between the Registrant and Thomas J. DesRosier	8-K	001-37465	10.2	2/1/21	
10.11#	Second Amended and Restated Employment Agreement, dated January 29, 2021, by and between the Registrant and Matthew R. Henn, Ph.D.	8-K	001-37465	10.3	2/1/21	
10.12#	Amended and Restated Employment Agreement, dated January 29, 2021, by and between the Registrant and David S. Ege, Ph.D.	10-Q	001-37465	10.2	8/3/21	
10.13#	Letter Agreement, dated November 4, 2021, by and between the Registrant and David S. Ege, Ph.D.	10-Q	001-37465	10.2	11/10/21	

10.14#	Amended and Restated Employment Agreement, dated January 29, 2021, by and between the Registrant and Teresa L. Young	10-K	001-37465	10.13	3/2/21	
10.15#	Amended and Restated Employment Agreement, dated January 29, 2021, by and between the Registrant and Lisa von Moltke, M.D.	10-K	001-37465	10.14	3/2/21	
10.16#	Employment Agreement, dated May 10, 2021 by and between the Registrant and David Arkowitz	8-K	001-37465	10.1	5/20/21	
10.17#	Employment Agreement, dated January 5, 2022, by and between the Registrant and Paula Cloghessy	10-K	001-37465	10.16	3/1/22	
10.18	Loan and Security Agreement, dated October 29, 2019, between the Registrant and Hercules Capital, Inc.	8-K	001-37465	10.1	11/4/19	
10.19	First Amendment to Loan and Security Agreement by and between the Registrant and Hercules Capital, Inc., dated April 16, 2020	10-Q	001-37465	10.2	7/28/20	
10.20	Second Amendment to Loan and Security Agreement, dated February 24, 2022 by and between the Registrant and Hercules Capital, Inc.	10-K	001-37465	10.19	3/1/22	
10.21^	Collaboration and License Agreement, dated January 9, 2016, by and between the Registrant and Société des Produits Nestlé S.A.	10-Q	001-37465	10.1	5/16/16	
10.22	Amendment No. 1 to the Collaboration and License Agreement, dated August 10, 2016, by and between the Registrant and Nestec Ltd.	10-K	001-37465	10.22	3/6/19	
10.23^	Letter Agreement dated October 30, 2018, by and between the Registrant and Nestec Ltd.	10-K	001-37465	10.23	3/6/19	
10.24	Securities Purchase Agreement, dated August 12, 2020 by and between the Company and Société des Produits Nestlé S.A.	8-K	001-37465	10.1	8/14/20	
10.25†	License Agreement, dated July 1, 2021, by and between the Registrant and NHSc Pharma Partners	10-Q	001-37465	10.1	11/10/21	
10.26†	Amendment No. 1 to License Agreement, dated March 24, 2022, by and between the Registrant and NHSc Pharma Partners	10-Q	001-37465	10.3	5/4/222	
10.27†	Long Term Manufacturing Agreement, dated November 8, 2021, by and between the Registrant and BacThera AG	10-K	001-37465	10.25	3/1/22	
10.28†	Amendment to Long Term Manufacturing Agreement, dated December 14, 2022, by and between the Registrant and BacThera AG					*
10.29	Form of Non-Affiliate Purchase Agreement	8-K	001-37465	10.1	6/30/22	
10.30	Form of Affiliate Purchase Agreement	8-K	001-37465	10.2	6/30/22	
10.31	Placement Agency Agreement, dated June 29, 2022, by and between Registrant and J.P. Morgan Securities LLC	8-K	001-37465	10.3	6/30/22	
10.32†	Supply Agreement, dated September 15, 2015, by and between Registrant and GenIbet BioPharmaceuticals, SA, as amended	10-Q	001-37465	10.1	11/2/22	
21.1	Subsidiaries of Seres Therapeutics, Inc.	10-K	001-37465	21.1	3/2/20	
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm					*

31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer	*
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer	*
32.1	Section 1350 Certification of Chief Executive Officer	**
32.2	Section 1350 Certification of Chief Financial Officer	**
101.INS	Inline XBRL Instance Document- the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document	*
101.SCH	Inline XBRL Taxonomy Extension Schema Document	*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	*

* Filed herewith.
** Furnished herewith.
Indicates management contract or compensatory plan.
^ Confidential treatment has been granted with respect to redacted portions of this exhibit. Redacted portions of this exhibit have been filed separately with the SEC.
† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Regulation S-K, Item 601(b)(10)(iv). Such omitted information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SERES THERAPEUTICS, INC.

Date: March 7, 2023

By: /s/ Eric D. Shaff
Eric D. Shaff
President, Chief Executive Officer and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Eric D. Shaff Eric D. Shaff	President, Chief Executive Officer and Director (Principal Executive Officer)	March 7, 2023
/s/ David Arkowitz David Arkowitz	Executive Vice President, Chief Financial Officer, and Head of Business Development (Principal Financial and Accounting Officer)	March 7, 2023
/s/ Stephen Berenson Stephen Berenson	Chairman of the Board	March 7, 2023
/s/ Dennis A. Ausiello Dennis A. Ausiello, M.D.	Director	March 7, 2023
/s/ Grégory Behar Grégory Behar	Director	March 7, 2023
/s/ Paul R. Biondi Paul R. Biondi	Director	March 7, 2023
/s/ Willard H. Dere Willard H. Dere, M.D.	Director	March 7, 2023
/s/ Claire M. Fraser Claire M. Fraser, Ph.D.	Director	March 7, 2023
/s/ Kurt C. Graves Kurt C. Graves	Director	March 7, 2023
/s/ Richard N. Kender Richard N. Kender	Director	March 7, 2023
/s/ Meryl S. Zausner Meryl S. Zausner	Director	March 7, 2023

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Seres Therapeutics, Inc. and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity (deficit) and of cash flows for each of the three years in the period ended December 31, 2022, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred losses and negative cash flows from operations since its inception and needs to raise additional capital to fund future operations, which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding

prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue Recognition – Collaboration and License Agreement with Société des Produits Nestlé S.A. (Nestlé) Recognized Under an Input Method

As described in Notes 2 and 11 to the consolidated financial statements, the Company recognizes revenue arising from a collaboration and license agreement with Nestlé, which totaled $3.0 million for the year ended December 31, 2022. The promised goods and services represent one combined performance obligation and the entire transaction price was allocated to that single combined performance obligation. When management concludes that a contract should be accounted for as a combined performance obligation and recognized over-time, management must then determine the period over which revenue should be recognized and the method by which to measure revenue. Management generally recognizes revenue using a cost-based input method, which measures the extent of progress towards completion based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the performance obligation.

The principal considerations for our determination that performing procedures relating to revenue recognition for the collaboration and license agreement with Nestlé recognized under an input method is a critical audit matter are the significant judgment by management when determining the total estimated costs expected upon satisfying the performance obligation, which in turn led to significant auditor judgment, subjectivity and effort in performing procedures to evaluate the total estimated costs expected upon satisfying the performance obligation.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the revenue arising from the collaboration and license agreement with Nestlé, including controls over the total estimated costs expected upon satisfying the performance obligation. These procedures also included, among others, evaluating and testing management's process for determining the total estimated costs expected upon satisfying the performance obligation, which included testing actual costs incurred and evaluating the reasonableness of estimated costs to satisfy the performance obligation. Evaluating the reasonableness of estimated costs to satisfy the performance obligation involved assessing management's ability to reasonably estimate costs to satisfy the performance obligation by (i) evaluating the appropriateness of changes to management's estimates of total costs to satisfy the performance obligation; (ii) performing a comparison of management's prior period cost estimates to actual costs incurred; and (iii) evaluating whether the cost estimates used by management were reasonable considering consistency with industry and company-specific data.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 7, 2023

We have served as the Company's auditor since 2014.

SERES THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 163,030	$ 180,002
Short term investments	18,311	110,704
Prepaid expenses and other current assets	13,423	12,922
Total current assets	194,764	303,628
Property and equipment, net	22,985	17,938
Operating lease assets	110,984	18,208
Restricted cash	8,185	8,000
Restricted investments	1,401	1,401
Long term investments	—	495
Other non-current assets	10,465	5,189
Total assets	$ 348,784	$ 354,859
Liabilities and Stockholder's Equity		
Current liabilities:		
Accounts payable	$ 17,440	$ 13,735
Accrued expenses and other current liabilities (1)	59,840	45,094
Operating lease liabilities	3,601	6,610
Short term portion of note payable, net of discount	456	—
Deferred revenue - related party	4,259	16,819
Total current liabilities	85,596	82,258
Long term portion of note payable, net of discount	50,591	24,643
Operating lease liabilities, net of current portion	107,942	17,958
Deferred revenue, net of current portion - related party	92,430	86,998
Other long-term liabilities (2)	1,442	11,495
Total liabilities	338,001	223,352
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2022 and 2021; no shares issued and outstanding at December 31, 2022 and 2021, respectively	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at December 31, 2022 and 2021; 125,222,273 and 91,889,418 shares issued and outstanding at December 31, 2022 and 2021, respectively	125	92
Additional paid-in capital	875,181	745,829
Accumulated other comprehensive loss	(12)	(60)
Accumulated deficit	(864,511)	(614,354)
Total stockholders' equity	10,783	131,507
Total liabilities and stockholders' equity	$ 348,784	$ 354,859

[1] Includes related party amounts of $34,770 and $21,098 at December 31, 2022 and December 31, 2021, respectively (see Note 11)
[2] Includes related party amounts of $0 and $10,585 at December 31, 2022 and December 31, 2021, respectively (see Note 11)

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

SERES THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Year Ended December 31,		
	2022	2021	2020
Revenue:			
Collaboration revenue - related party	$ 7,128	$ 143,857	$ 11,897
Grant revenue	—	1,070	4,157
Collaboration revenue	—	—	17,161
Total revenue	7,128	144,927	33,215
Operating expenses:			
Research and development expenses	$ 172,920	$ 141,891	$ 90,570
General and administrative expenses	79,694	69,261	30,775
Collaboration (profit) loss sharing - related party	1,004	(1,732)	—
Total operating expenses	253,618	209,420	121,345
Loss from operations	(246,490)	(64,493)	(88,130)
Other (expense) income:			
Interest income	3,058	2,870	946
Interest expense	(6,020)	(2,910)	(2,924)
Other (expense) income	(705)	(1,045)	981
Total other (expense) income, net	(3,667)	(1,085)	(997)
Net loss	$ (250,157)	$ (65,578)	$ (89,127)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.31)	$ (0.72)	$ (1.12)
Weighted average common shares outstanding, basic and diluted	108,077,043	91,702,866	79,789,220
Other comprehensive loss:			
Unrealized gain (loss) on investments, net of tax of $0	49	(12)	(47)
Currency translation adjustment	(1)	(1)	—
Total other comprehensive income (loss)	48	(13)	(47)
Comprehensive loss	$ (250,109)	$ (65,591)	$ (89,174)

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

SERES THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share data)

	Common Stock		Additional	Accumulated Other		Total
	Shares	Par Value	Paid-in Capital	Comprehensive Loss	Accumulated Deficit	Stockholders Equity (Deficit)
Balance at December 31, 2019	70,143,252	$ 70	$ 411,255	$ -	$ (459,649)	$ (48,324)
Issuance of common stock from public offering, net of commissions, underwriting discounts and offering costs of $288	12,075,000	12	243,736	—	—	243,748
Issuance of common stock from Securities Purchase Agreement, net of offering costs - related party of $100	959,002	1	19,899	—		19,900
Issuance of common stock from at the market equity offering, net of issuance costs of $673	5,787,681	6	24,767	—	—	24,773
Issuance of common stock upon exercise of stock options	2,214,011	2	14,419	—	—	14,421
Issuance of common stock upon vesting of RSUs, net of tax withholdings	125,000	—	120	—	—	120
Issuance of common stock under ESPP plan	155,293	—	462	—	—	462
Stock-based compensation expense	—	—	8,824	—	—	8,824
Other comprehensive loss	—	—	—	(47)	—	(47)
Net loss	—	—	—	—	(89,127)	(89,127)
Balance at December 31, 2020	91,459,239	91	723,482	(47)	(548,776)	174,750
Issuance of common stock upon exercise of stock options	329,112	1	1,298	—	—	1,299
Issuance of common stock under ESPP plan	100,417	—	827	—	—	827
Issuance of common stock upon vesting of RSUs, net of tax withholdings	650	—	—	—	—	—
Stock-based compensation expense	—	—	20,222	—	—	20,222
Other comprehensive loss	—	—	—	(13)	—	(13)
Net loss	—	—	—	—	(65,578)	(65,578)
Balance at December 31, 2021	91,889,418	92	745,829	(60)	(614,354)	131,507
Issuance of common stock upon exercise of stock options	326,864	—	966	—	—	966
Issuance of common stock upon vesting of RSUs and PSUs, net of tax withholdings	282,401	—	—	—	—	—
Issuance of common stock under ESPP	322,560	—	1,769	—	—	1,769
Issuance of common stock net of issuance costs of $3,279	31,746,030	32	96,689	—	—	96,721
Issuance of common stock from at the market equity offering, net of issuance costs of $310	655,000	1	4,446	—	—	4,447
Stock-based compensation expense	—	—	25,482	—	—	25,482
Other comprehensive loss	—	—	—	48	—	48
Net loss	—	—	—	—	(250,157)	(250,157)
Balance at December 31, 2022	125,222,273	$ 125	$ 875,181	$ (12)	$ (864,511)	$ 10,783

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

SERES THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2022	**2021**	**2020**
Cash flows from operating activities:			
Net loss	$ (250,157)	$ (65,578)	$ (89,127)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Stock-based compensation expense	25,482	20,222	8,824
Depreciation and amortization expense	6,629	5,947	6,578
Non-cash operating lease cost	5,224	3,275	2,315
Amortization of premiums on investments	688	498	446
Amortization of debt issuance costs	705	2,526	551
Collaboration (profit) loss sharing - related party	1,004	(1,732)	-
Changes in operating assets and liabilities:			
Prepaid expenses and other current and non-current assets	(12,599)	(12,337)	(2,186)
Accounts receivable	—	9,387	(7,602)
Deferred revenue - related party	(7,128)	(4,357)	(11,565)
Accounts payable	2,203	9,362	(1,159)
Operating lease liabilities	(4,203)	(3,550)	(4,456)
Accrued expenses and other current and long-term liabilities (3)	3,336	43,025	3,771
Net cash (used in) provided by operating activities	(228,816)	6,688	(93,610)
Cash flows from investing activities:			
Purchases of property and equipment	(9,821)	(9,566)	(591)
Purchases of investments	(48,221)	(95,971)	(218,284)
Sales and maturities of investments	140,470	169,625	59,984
Net cash provided by (used in) investing activities	82,428	64,088	(158,891)
Cash flows from financing activities:			
Proceeds from issuance of common stock, net of issuance costs	96,721	—	243,748
Proceeds from Securities Purchase Agreement, net of issuance costs - related party	—	—	19,900
Proceeds from issuance of note payable	27,606	—	—
Proceeds from at the market equity offering, net of issuance costs	4,447	—	24,773
Proceeds from exercise of stock options	966	1,299	14,421
Proceeds from issuance of common stock and restricted common stock	—	—	120
Issuance of common stock under ESPP	1,769	827	462
Repayment of notes payable	(1,907)	(948)	—
Net cash provided by financing activities	129,602	1,178	303,424
Net (decrease) increase in cash, cash equivalents and restricted cash	(16,786)	71,954	50,923
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(1)	(1)	—
Cash, cash equivalents and restricted cash at beginning of year	188,002	116,049	65,126
Cash, cash equivalents and restricted cash at end of year	$ 171,215	$ 188,002	$ 116,049
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 4,926	$ 2,446	$ 2,453
Supplemental disclosure of non-cash investing and financing activities:			
Property and equipment purchases included in accounts payable and accrued expenses	$ 2,276	$ 874	$ 451
Lease liability arising from obtaining right-of-use assets	$ 91,412	$ 12,442	$ —
Prepaid rent reclassified to right-of-use assets	$ 6,822	$ —	$ —

[3] Includes related party amounts of $3,087 and $31,683 at December 31, 2022 and 2021 respectively (see Note 11)

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

1. Nature of the Business and Basis of Presentation

Seres Therapeutics, Inc. (the "Company") was incorporated under the laws of the State of Delaware in October 2010 under the name Newco LS21, Inc. In October 2011, the Company changed its name to Seres Health, Inc., and in May 2015, the Company changed its name to Seres Therapeutics, Inc. The Company is a microbiome therapeutics company developing a novel class of biological drugs, which are designed to treat disease by modulating the microbiome to restore health by repairing the function of a disrupted microbiome to a non-disease state. The Company's lead product candidate, SER-109, is designed to reduce further recurrences of *Clostridioides difficile* infection ("CDI"), a debilitating infection of the colon, in patients who have received antibiotic therapy for recurrent CDI by restructuring the colonic microbiome and changing its function. If approved by the U.S. Food and Drug Administration ("FDA"), the Company believes SER-109 will be a first-in-field oral microbiome drug. Building upon SER-109, the Company is developing therapeutic candidates, such as SER-155, to specifically target infections and antimicrobial resistance. SER-155, a microbiome therapeutic candidate consisting of a consortium of cultivated bacteria, is designed to reduce incidences of gastrointestinal infections, bloodstream infections and graft versus host disease ("GvHD") in patients receiving allogeneic hematopoietic stem cell transplantation ("allo-HSCT"). The Company is progressing additional preclinical stage programs to evaluate how microbiome therapeutics may reduce incidence of infection, which the Company refers to as Infection Protection, in indications such as cancer neutropenia, chronic liver disease, solid organ transplant, and antimicrobial resistant infections more broadly in settings of high-risk such as intensive care units. The Company is also continuing its research activities in ulcerative colitis ("UC"), including evaluating the potential to utilize biomarker-based patient selection and stratification for future studies. In addition, the Company continues to leverage microbiome pharmacokinetic and pharmacodynamic data from across its clinical and preclinical portfolios, using its reverse translational microbiome therapeutic development platform to conduct research on various indications, including inflammatory and immune diseases, cancer, and metabolic diseases. The Company has built and deploys a reverse translational platform for the discovery and development of microbiome therapeutics. This platform incorporates high-resolution analysis of human clinical data to identify microbiome biomarkers associated with disease and non-disease states; preclinical screening using human cell-based assays and in vitro/ex vivo and in vivo disease models customized for microbiome therapeutics; and microbiological capabilities and a strain library that spans broad biological and functional breadth to both identify specific microbes and microbial metabolites that are associated with disease and to design consortia of bacteria with specific pharmacological properties.

The accompanying consolidated financial statements have been prepared on a basis that assumes that the Company will continue as a going concern and that contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. As of December 31, 2022, the Company had an accumulated deficit of $864,511 and cash, cash equivalents and short- and long-term investments of $181,341.

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 preclinical and clinical testing and regulatory approval, prior to commercialization. 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 product candidates are in development. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, or maintained, that any product candidate developed will obtain necessary government regulatory approval or that any approved product 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's primary focus in recent months has been and will continue to be supporting the Biologics License Application ("BLA") submission for our lead product candidate, SER-109, and continuing to prepare for potential commercialization, including the manufacture of SER-109, until and continuing after the Prescription Drug User Fee Act ("PDUFA") target action date set by the FDA of April 26, 2023. The Company has commenced manufacture of SER-109 in consideration of potential commercialization, which requires capital and resources. Successful execution of the pre-commercialization activities required by our collaboration agreement with Société des Produits Nestlé S.A., successor in interest to Nestec Ltd., and NHSc Rx License GmbH, a significant stockholder of the Company and successor in interest to NHSc Pharma Partners (collectively, and together with their affiliates and subsidiaries, "Nestlé"), requires continued investment in readying for launch. Still, there can be no assurance that the BLA for SER-109, which is currently under priority review by the FDA, will be approved, that the FDA will complete its review of the BLA in the anticipated timeline, or that, in the event of approval, the demand for SER-109 will be sufficient to meet the Company's forecasted cash needs without raising significant additional capital.

The Company also has a credit facility (the "New Credit Facility") pursuant to a Loan and Security Agreement (the "Loan Agreement") with Hercules Capital, Inc. ("Hercules," see Note 8, *Notes Payable*), which is collateralized by substantially all of the

Company's assets excluding intellectual property. The Company is currently in compliance with the financial covenants in the New Credit Facility. The New Credit Facility includes a conditional liquidity covenant commencing on June 15, 2023, which ceases to apply if certain conditions are satisfied. Violation of any covenant under the New Credit Facility provides Hercules with the option to accelerate repayment of amounts borrowed and terminate its commitment to extend further credit, among other remedies as defined in the New Credit Facility.

Primarily as a result of the increased and costly efforts to prepare for potential commercialization of SER-109, in conjunction with the Company's research and development efforts for other preclinical and product candidates, for the year ended December 31, 2022, the Company incurred a net loss of $250,157, and had net operating cash outflows of $228,816. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future. The Company is eligible to receive contingent milestone payments under its license agreement with Nestlé executed in July 2021 (see Note 11, *Collaboration Revenue*) if certain development, regulatory approval or sales target milestones are achieved. Upon approval of the BLA, the Company is entitled to receive an additional $125,000 payment from Nestlé, and a $25,000 tranche under the New Credit Facility, which becomes available upon the satisfaction of certain conditions, including FDA approval of SER-109. Additionally, following FDA approval, the Company will be eligible to receive payments from Nestlé for the supply of SER-109. In the event of commercial sale of SER-109, the Company will be entitled to share equally in its commercial profits and losses. The payments under the 2021 License Agreement and the additional tranche under the New Credit Facility are uncertain and there is no assurance that the Company will receive any of them, because they are contingent upon approval of the Company's BLA, which is currently under priority review by the FDA. Based on the Company's currently available cash resources, current and forecasted level of operations, and forecasted cash flows for the 12 month period subsequent to the date of issuance of these consolidated financial statements, in the absence of approval of SER-109 by the FDA, and therefore, without the receipt of the approval milestone and other payments to which it is entitled to receive as a result thereof, the Company believes it is reasonably likely that it will require additional funding in early 2024. These factors raise substantial doubt about the Company's ability to continue as a going concern.

Management's plans to mitigate the conditions that raise substantial doubt about the Company's ability to continue as a going concern include continuing to seek regulatory approval of the BLA for SER-109 and therefore earning the $125,000 milestone payment from Nestlé and becoming eligible for the $25,000 tranche under the New Credit Facility, as well as the ability to commercialize SER-109 and receive payments from Nestlé for the supply of SER-109, and share equally in commercial profits and losses with Nestlé pursuant to the 2021 License Agreement. Management may also seek to raise additional capital through financing or other transactions, including the Company's at the market equity offering. Because certain elements of the Company's operating plan are outside of the Company's control, primarily the approval of its BLA for SER-109, which has not occurred as of the issuance of these consolidated financial statements, and the ability to raise capital through an equity or other financing, those elements cannot be considered probable according to Accounting Standards Codification ("ASC") 205-40, *Going Concern* ("ASC 205-40"), and therefore cannot be considered in the evaluation of mitigating factors. As a result, management has concluded that substantial doubt exists about the Company's ability to continue as a going concern for 12 months from the date these consolidated financial statements are issued.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company and its wholly owned subsidiaries after elimination of all intercompany accounts and transactions.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. In these consolidated financial statements, the Company uses estimates and assumptions related to revenue recognition and the accrual of research and development expenses. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Cash Equivalents

The Company considers all short-term, highly liquid investments with original maturities of 90 days or less at acquisition date to be cash equivalents. Cash equivalents, which consist of money market accounts, commercial paper and corporate bonds purchased with original maturities of less than 90 days from the date of purchase, are stated at fair value.

Investments

The Company classifies all of its marketable debt securities as available-for-sale securities. Accordingly, these marketable debt securities are recorded at fair value and unrealized gains and losses are reported as a separate component of accumulated other comprehensive loss in stockholders' equity (deficit), unless the Company has determined that the security has experienced a credit loss, or the Company expects to sell the security prior to the recovery of its unrealized losses. In such cases a security is considered impaired, and adjusted through a charge to the consolidated statement of operations and comprehensive loss. The cost of securities sold is determined on a specific identification basis, and realized gains and losses are included in other income (expense) within the consolidated statement of operations and comprehensive loss. No credit losses were recorded during the years ended December 31, 2022, 2021, and 2020.

The Company classifies its available-for-sale marketable debt securities as current assets on the consolidated balance sheet if they mature within one year from the balance sheet date. Any available-for-sale marketable debt securities with maturities greater than one year from the balance sheet date are classified as long-term assets on the consolidated balance sheet.

Restricted Investments

The Company held investments of $1,401 as of December 31, 2022 and 2021, in a separate restricted bank account as a security deposit for the lease of the Company's headquarters in Cambridge, Massachusetts. The Company has classified these deposits as long-term restricted investments on its consolidated balance sheet.

Restricted Cash

The Company held restricted cash of $8,185 and $8,000 as of December 31, 2022 and 2021, respectively, which represents cash held for the benefit of the landlord for the Company's other leases. The Company has classified the restricted cash as long-term on its consolidated balance sheet as the underlying leases are greater than 1 year.

Cash, cash equivalents and restricted cash were comprised of the following (in thousands):

	December 31,	
	2022	2021
Cash and cash equivalents	$ 163,030	$ 180,002
Restricted cash, non-current	8,185	8,000
Total cash, cash equivalents and restricted cash	$ 171,215	$ 188,002

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and investments. The Company has all cash, cash equivalents and investments balances at accredited financial institutions, 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.

Fair Value Measurements

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

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

The Company's cash equivalents and investments are carried at fair value, determined according to the fair value hierarchy described above. The Company's investments in certificates of deposit are carried at amortized cost, which approximates fair value. The carrying values of the Company's prepaid expenses and other current and non-current assets, accounts payable and accrued expenses approximate their respective fair values due to the short-term nature of these assets and liabilities. The carrying value of the Company's long-term debt approximates its fair value (a level 2 measurement) at each balance sheet date due to its variable interest rate, which approximates a market interest rate.

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, which are as follows:

	Estimated Useful Life (In Years)
Laboratory equipment	5
Computer equipment, furniture and office equipment	3
Leasehold improvements	Lesser of useful life or lease term

Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment and right-of-use assets associated with our lease agreements. All of the Company's long-lived assets are to be held and used and have definitive lives and accordingly 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 preclinical 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 and prepaid 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, non-employees, and directors based on the fair value on the date of the grant and recognizes compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues stock options, restricted stock units and restricted stock awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. For stock options or restricted stock units issued with performance-based vesting conditions, the stock compensation expense related to these awards is recognized based on the grant date fair value when achievement of the performance condition is deemed probable.

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

The Company accounts for forfeitures of stock-based awards as they occur rather than applying an estimated forfeiture rate to stock-based compensation expense.

The fair value of each stock option grant is estimated on the date of grant using the Black- Scholes option-pricing model. The Company estimates its expected common stock volatility based on its historical common stock volatility for the same time period. The Company uses 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, non-employees and directors. 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.

Revenue Recognition

The Company recognizes revenue in accordance with the guidance under ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). ASC 606 applies to all contracts with customers, except those contracts that are within the scope of other guidance, such as leases, insurance, and financial instruments. The Company enters into agreements that are within the scope of ASC 606, under which the Company licenses certain of the Company's product candidates and performs research and development services in connection with such arrangements. The terms of these arrangements typically include payment of one or more of the following: nonrefundable up-front fees, reimbursement of research and development costs, development, clinical, regulatory and commercial sales milestone payments, and royalties on net sales of licensed products. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. When determining the timing and extent of revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps:

a. identify the contract(s) with a customer;

b. identify the performance obligations in the contract;

c. determine the transaction price;

d. allocate the transaction price to the performance obligations in the contract; and

e. recognize revenue when (or as) the entity satisfies a performance obligation.

The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services transferred to the customer.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. The promised goods or services in the Company's arrangements typically consist of a license to the Company's intellectual property and/or research and development services. The Company may provide options to additional items in such arrangements, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources, and (ii) is separately identifiable from other promises in the contract. Goods or services that are not individually distinct performance obligations are combined with other promised goods or services until such combined group of promises meet the requirements of a performance obligation.

The Company determines the transaction price based on the amount of consideration the Company expects to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. At contract inception for arrangements that include variable consideration, the Company estimates the probability and extent of consideration it expects to receive under the contract utilizing either the most likely amount method or expected amount method, whichever best estimates the amount expected to be received. The Company then considers any constraints on the variable consideration and includes in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The Company then allocates the transaction price to each performance obligation based on the relative standalone selling price and recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company records amounts as accounts receivable when the right to consideration is deemed unconditional. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded for deferred revenue.

The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less. Incremental costs of obtaining a contract are expensed as and when incurred if the expected period over which the Company would have amortized the asset is one year or less, or the amount is immaterial.

Collaboration Revenue

Arrangements with collaborators may include licenses to intellectual property, research and development services, manufacturing services for clinical and commercial supply, and participation on joint steering committees. The Company evaluates the promised goods or services to determine which promises, or group of promises, represent performance obligations. In contemplation of whether a promised good or service meets the criteria required of a performance obligation, the Company considers the stage of development of the underlying intellectual property, the capabilities and expertise of the customer relative to the underlying intellectual property, and whether the promised goods or services are integral to or dependent on other promises in the contract. When accounting for an arrangement that contains multiple performance obligations, the Company must develop judgmental assumptions, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success to determine the stand-alone selling price for each performance obligation identified in the contract.

When the Company concludes that a contract should be accounted for as a combined performance obligation and recognized over time, the Company must then determine the period over which revenue should be recognized and the method by which to measure revenue. The Company generally recognizes revenue using a cost-based input method.

Licenses of intellectual property

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment

to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue associated with the bundled performance obligation. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of progress and related revenue recognition.

Milestone Payments

At the inception of each arrangement that includes developmental and regulatory milestone payments, the Company evaluates whether the achievement of each milestone specifically relates to the Company's efforts to satisfy a performance obligation or transfer a distinct good or service within a performance obligation. If the achievement of a milestone is considered a direct result of the Company's efforts to satisfy a performance obligation or transfer a distinct good or service and the receipt of the payment is based upon the achievement of the milestone, the associated milestone value is allocated to that distinct good or service, otherwise it will be allocated to all performance obligations of the arrangement based on the initial allocation.

The Company evaluates each milestone to determine when and how much of the milestone to include in the transaction price. The Company first estimates the amount of the milestone payment that the Company could receive using either the expected value or the most likely amount approach. The Company primarily uses the most likely amount approach as that approach is generally most predictive for milestone payments with a binary outcome. Then, the Company considers whether any portion of that estimated amount is subject to the variable consideration constraint (that is, whether it is probable that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty). The Company updates the estimate of variable consideration included in the transaction price at each reporting date which includes updating the assessment of the likely amount of consideration and the application of the constraint to reflect current facts and circumstances.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any revenue related to sales-based royalties or milestone payments based on the level of sales.

Manufacturing supply services

For arrangements that include a promise of supply of clinical or commercial product, the Company determines if the supply is a promise in the contract or a future obligation at the customer's option. If determined to be a promise at inception of the contract, the Company evaluates the promise to determine whether it is a separate performance obligation or a component of a bundled performance obligation. If determined to be an option, the Company determines if the option provides a material right to the customer and if so, accounts for the option as a separate performance obligation. If determined to be an option but not a material right, the Company accounts for the option as a separate contract when the customer elects to exercise the option.

Grant Revenue

The Company generates revenue from government contracts that reimburse the Company for certain allowable costs for funded projects. For contracts with government agencies, when the Company has concluded that it is the principal in conducting the research and development expenses, and where the funding arrangement is considered central to the Company's ongoing operations, the Company classifies the recognized funding received as revenue.

The Company has concluded to recognize funding received as revenue, rather than as a reduction of research and development expenses, because the Company is the principal in conducting the research and development activities and these contracts are central to its ongoing operations. Revenue is recognized as the qualifying expenses related to the contracts are incurred. Revenue recognized upon incurring qualifying expenses in advance of receipt of funding is recorded in the Company's consolidated balance sheet as accounts receivable. The related costs incurred by the Company are included in research and development expense in the Company's consolidated statements of operations and comprehensive loss.

Collaboration Profit and Loss

We analyze our collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808"), which includes determining whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, we first determine which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For those elements of the arrangement that are accounted for pursuant to ASC 606, we apply the five-step model prescribed in ASC 606, as described above. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to ASC 606. In arrangements where we do not deem our collaborator to be our customer, up-front payments from our collaborator are presented in the consolidated balance sheets as liabilities, and adjusted as we perform activities pursuant to the collaboration arrangement. As the Company and its collaborator perform activities pursuant to the arrangement, amounts due to or from the Company or the collaborator, based on the relative contributions of activities of each party, are recognized in the consolidated statements of operations and comprehensive loss as an increase or reduction in operating expenses based on the nature of the payments.

Income Taxes

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

The Company applies ASC 740-10, *Accounting for Uncertain Tax Positions*. 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.

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 microbiome therapeutics to treat the modulation of the colonic microbiome. Revenue to date has been generated solely through the Company's agreements with its collaborators, all of which has been earned in the United States. All tangible assets are held in the United States.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2022, 2021 and 2020, other comprehensive income (loss) consisted of changes in unrealized gains (losses) from available-for-sale investments and a currency translation adjustment.

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 unvested restricted stock. The Company applies the two-class method to calculate its basic and diluted net loss per share attributable to common stockholders. 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.

The Company's convertible preferred stock contractually entitle the holders of such shares to participate in dividends but do not contractually require the holders of such shares to participate in losses of the Company. Similarly, restricted stock awards entitle the holder of such awards to dividends declared or paid by the board of directors, regardless of whether such awards are unvested, as if such shares were outstanding common shares at the time of the dividend. However, the unvested restricted stock awards are not entitled to share in the residual net assets (deficit) of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Leases

In accordance with ASC 842, *Leases*, the Company determines if an arrangement is or contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company classifies leases at the lease commencement date as operating or finance leases and records a right-of-use asset and a lease liability on the consolidated balance sheet for all leases with an initial lease term of greater than 12 months. Leases with an initial term of 12 months or less are not recorded on the balance sheet, but payments are recognized as expense on a straight-line basis over the lease term. The Company has elected not to record a right-of-use asset or lease liability for leases with terms of 12 months or less.

A lease qualifies as a finance lease if any of the following criteria are met at the inception of the lease: (i) there is a transfer of ownership of the leased asset to the Company by the end of the lease term, (ii) the Company holds an option to purchase the leased asset that it is reasonably certain to exercise, (iii) the lease term is for a major part of the remaining economic life of the leased asset, (iv) the present value of the sum of lease payments equals or exceeds substantially all of the fair value of the leased asset, or (v) the nature of the leased asset is specialized to the point that it is expected to provide the lessor no alternative use at the end of the lease term.

The Company enters into contracts that contain both lease and non-lease components. Non-lease components may include maintenance, utilities, and other operating costs. The Company combines the lease and non-lease components of fixed costs in its lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.

Finance and operating lease assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease. If the rate implicit is not readily determinable, the Company utilizes an estimate of its incremental borrowing rate based upon the available information at the lease commencement date. Operating lease assets are further adjusted for prepaid or accrued lease payments. Operating lease payments are expensed using the straight-line method as an operating expense over the lease term. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Finance lease assets are amortized to depreciation expense using the straight-line method over the shorter of the useful life of the related asset or the lease term. Finance lease payments are bifurcated into (i) a portion that is recorded as imputed interest expense and (ii) a portion that reduces the finance liability associated with the lease.

Right-of-use assets and lease liabilities are reassessed and remeasured when amendments to the terms of the lease agreement require reassessment and remeasurement of the lease payments and other inputs to the calculation of right-of-use assets and lease liabilities. The Company accounts for remeasurements and modifications to lease liabilities using the present value of remaining lease payments and estimated incremental borrowing rate at the date of remeasurement. The adjustment to the lease liability is recognized as a gain or loss in operating expenses, or as an adjustment to the right-of-use asset, as appropriate, based on the terms and conditions within the lease that are amended.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses* (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"), which requires the measurement and recognition of expected credit losses for

financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes may result in earlier recognition of credit losses. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*, which narrowed the scope and changed the effective date for non-public entities for ASU 2016-13. The FASB subsequently issued supplemental guidance within ASU No. 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief* ("ASU 2019-05"). ASU 2019-05 provides an option to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost basis. For public entities that are Securities and Exchange Commission ("SEC") filers, excluding entities eligible to be smaller reporting companies, ASU 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. For all other entities, ASU 2016-13 is effective for annual periods beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. The Company adopted the new standard using a modified retrospective approach as of January 1, 2022. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements

The Company has considered all recent accounting pronouncements issued. The Company's management believes that these recent pronouncements will not have a material effect on the Company's financial statements.

3. Fair Value of Financial Assets and Liabilities

The following tables present the Company's fair value hierarchy for its assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements as of December 31, 2022 Using:			
	Level 1	Level 2	Level 3	Total
Cash Equivalents:				
Money market funds	$ 47,863	$ —	$ —	$ 47,863
Commercial paper	—	11,691	—	11,691
Government securities	—	4,966	—	4,966
Investments:				
Commercial paper	$ —	$ 2,465	$ —	$ 2,465
Corporate bonds	—	2,957	—	2,957
Government securities	—	12,889	—	12,889
	$ 47,863	$ 34,968	$ —	$ 82,831

	Fair Value Measurements as of December 31, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Cash Equivalents:				
Money market funds	$ 70,322	$ —	$ —	$ 70,322
Commercial paper	—	3,999	—	3,999
Investments:				
Commercial paper	$ —	$ 6,250	$ —	$ 6,250
Corporate bonds	—	40,095	—	40,095
Government securities	—	64,854	—	64,854
	$ 70,322	$ 115,198	$ —	$ 185,520

Money market funds are valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. Commercial paper, corporate bonds, and government securities are valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy. There were no transfers between Level 1 or Level 2 during the years ended December 31, 2022 and 2021.

As of December 31, 2022 and 2021 the Company held a restricted investment of $1,401, which represents a certificate of deposit that is classified as Level 2 in the fair value hierarchy.

4. Investments

Investments by security type consisted of the following at December 31, 2022 and 2021 (in thousands):

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Investments:				
Commercial paper	$ 2,465	$ —	$ —	$ 2,465
Corporate bonds	2,958	—	(1)	2,957
Government securities	12,898	3	(12)	12,889
	$ 18,321	$ 3	$ (13)	$ 18,311

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Investments:				
Commercial paper	$ 6,250	$ —	$ —	$ 6,250
Corporate bonds	40,123	—	(28)	40,095
Government securities	64,885	—	(31)	64,854
	$ 111,258	$ —	$ (59)	$ 111,199

Investments with original maturities of less than 90 days are included in cash and cash equivalents on the consolidated balance sheets and are not included in the table above. Investments with maturities of less than twelve months are considered current assets and those investments with maturities greater than twelve months are considered non-current assets.

Excluded from the tables above at December 31, 2022 and 2021 are restricted investments of $1,401, as the cost approximates current fair value.

The amortized cost and fair value of investments in commercial paper, corporate bonds, and government securities by contractual maturity, as of December 31, 2022 and were as follows (in thousands):

	Available-for-Sale	
	Cost	Fair Value
Due in 1-year or less	$ 18,321	$ 18,311
Due after 1-year through 5-years	—	—
	$ 18,321	$ 18,311

The amortized cost and fair value of investments in commercial paper, corporate bonds, and government securities by contractual maturity, as of December 31, 2021 were as follows (in thousands):

	Available-for-Sale	
	Cost	Fair Value
Due in 1-year or less	$ 110,762	$ 110,704
Due after 1-year through 5-years	496	495
	$ 111,258	$ 111,199

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

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2022	2021
Laboratory equipment	$ 24,533	$ 19,137
Computer equipment	3,557	3,255
Furniture and office equipment	3,491	1,219
Leasehold improvements	32,474	32,925
Construction in progress	3,970	1,670
	68,025	58,206
Less: Accumulated depreciation and amortization	(45,040)	(40,268)
	$ 22,985	$ 17,938

Depreciation and amortization expense was $6,629, $5,947 and $6,578 for the years ended December 31, 2022, 2021 and 2020, respectively. During the year ended December 31, 2022, the Company disposed of certain fully-depreciated assets with a cost basis of $1,857.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2022	2021
Development and manufacturing costs	$ 6,717	$ 11,147
Payroll and payroll-related costs	14,709	9,216
Liability related to 2021 License Agreement (Note 11)	34,770	21,098
Facility and other	3,644	3,633
	$ 59,840	$ 45,094

7. Leases

The Company leases real estate, primarily laboratory, office and manufacturing space. The Company's leases have remaining terms ranging from approximately two to ten years. Certain leases include one or more options to renew, exercisable at the Company's sole discretion, with renewal terms that can extend the lease from approximately one year to five years. The Company evaluated the renewal options in its leases to determine if it was reasonably certain that the renewal option would be exercised, given the Company's current business structure, uncertainty of future growth, and the associated impact to real estate, the Company concluded that it is not reasonably certain that any renewal options would be exercised. Therefore, the operating lease assets and operating lease liabilities only contemplate the initial lease terms. All the Company's leases qualify as operating leases.

In July 2021, the Company entered into a lease agreement for a donor collection facility in Tempe, Arizona with a lease term of ten years, commencing in March 2022, subject to certain renewal options, which are not deemed reasonably certain. Minimum lease payments total $4,052, net of tenant improvement allowance of $770, through the lease term. At lease commencement, the Company recorded a right-of-use asset of $5,900, which consists of the lease liability of $2,327 and $3,573 of leasehold improvements that revert back to the lessor at the termination of the lease.

In August 2021, the Company entered into a lease for additional office and laboratory space in Waltham, Massachusetts with a lease term of ten years, commencing in two phases in October 2021 and March 2022, respectively, with a third and final phase for laboratory space, not yet commenced at December 31, 2022. Minimum lease payments for the two phases that commenced in 2022 total $12,125 and $2,449, respectively, net of tenant improvement allowance of $767 for the laboratory space, through the lease term. At each lease commencement, the Company recorded right-of-use assets of $7,602 and $2,662, respectively, which consist of the lease liability of $7,602 for the office space, and the lease liability of $1,273 and $1,389 of leasehold improvements that revert back to the lessor at the termination of the lease for the laboratory space. The lease is subject to certain renewal options, which are not deemed reasonably certain at commencement of the first two phases.

In September 2021, the Company entered into a lease for additional laboratory and office space in Cambridge, Massachusetts with a lease term of ten years and a renewal option for an additional seven-year term. The lease commenced in December 2022, and the

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

renewal option was not deemed reasonably certain of exercise. Minimum lease payments total $101,548 throughout the lease term. At lease commencement, the Company recorded a right-of-use asset of $56,065, which consists of the lease liability of $54,206 and $1,859 of leasehold improvements that revert back to the lessor at the termination of the lease.

In April 2022, the Company entered into a lease for additional laboratory and office space in Spring House, Pennsylvania, with a lease term of ten years and a renewal option, subject to certain conditions, for an additional five-year term. The undiscounted minimum lease payments are $2,980, net of a tenant improvement allowance of $1,223, over the original ten-year term. As of December 31, 2022, the lease has not yet commenced, and accordingly the Company has not recorded a right-of-use asset or a lease liability with respect thereto.

In December 2022, the Company amended its lease of its corporate headquarters in Cambridge, Massachusetts (the "Lease Amendment"). The Lease Amendment reduced the office space subject to the lease while maintaining the laboratory and manufacturing space and extended the term to begin in November 2023, when the term of the original lease concludes, and continue through January 2030. The Company accounted for the Lease Amendment as a modification to the existing lease and not a new contract separate from the existing contract, and accordingly increased the associated lease liability and right-of-use asset by $32,837. Minimum lease payments total $60,022 throughout the term of the Lease Amendment, net of a tenant improvement allowance of $1,000.

The Company has committed to restore the leased space subject to the Lease Amendment to the condition specified in the original lease, and the Company updated its estimate of the costs required to fulfill this obligation in accordance with ASC 410, *Asset Retirement Obligations*, at the effective date of the modification. Based on current estimates, the Company recorded an additional asset retirement obligation of $452 in December 2022.

The following table summarizes the presentation in the Company's consolidated balance sheets of its operating leases:

	December 31,	
	2022	2021
Assets:		
Operating lease assets	$ 110,984	$ 18,208
Liabilities:		
Operating lease liabilities	$ 3,601	$ 6,610
Operating lease liabilities, net of current portion	107,942	17,958
Total operating lease liabilities	$ 111,543	$ 24,568

The following table summarizes the effect of lease costs in the Company's consolidated statement of operations and comprehensive loss:

	Year Ended December 31,		
	2022	2021	2020
Operating lease costs	$ 8,830	$ 5,170	$ 4,163
Short-term lease costs	1,375	1,452	1,457
Variable lease costs	4,547	3,300	2,890
Sublease income	—	(1,575)	(1,813)
Total lease costs	$ 14,752	$ 8,347	$ 6,697

During the years ended December 31, 2022, 2021, and 2020, the Company made cash payments for operating leases of $7,809, $6,821 and $6,302, respectively.

As of December 31, 2022, future payments of operating lease liabilities are as follows (in thousands):

	As of December 31, 2022
2023	$ 16,815
2024	19,055
2025	21,164
2026	21,755
2027 and thereafter	108,383
Total future payments of operating lease liabilities	$ 187,172
Less: imputed interest	(75,629)
Present value of operating lease liabilities	$ 111,543

As of December 31, 2022, the weighted average remaining lease term was 8.92 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 13%. As of December 31, 2021, the weighted average remaining lease term was 6.12 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 10%.

8. Notes Payable

On October 29, 2019 (the “Closing Date”), the Company entered into the Loan Agreement with Hercules pursuant to which a term loan in an aggregate principal amount of up to $50,000 (the “Original Credit Facility”) was available to the Company in three tranches, subject to certain terms and conditions. The first tranche of $25,000 was advanced to the Company on the Closing Date. The Company did not meet the milestone requirements for the second tranche under the Original Credit Facility, and as such, the additional amount of up to $12,500 was not available for the Company to borrow. The Company elected not to borrow the third tranche of $12,500, which was available upon Hercules’ approval until June 30, 2021. Advances under the Original Credit Facility will bear interest at a rate equal to the greater of either (i) the Prime Rate (as reported in The Wall Street Journal) plus 4.40%, and (ii) 9.65%. Following an interest-only period of 24 months, principal payments are due in 24 equal monthly installments commencing December 1, 2021 and ending November 1, 2023.

Effective as of February 24, 2022 (the “Effective Date”), the Company entered into an Amendment to the Loan and Security Agreement (the “Amendment”), with the lenders party thereto (the “Lenders”), and Hercules in its capacity as the administrative agent and the collateral agent for the Lenders, which amended the Original Credit Facility. Pursuant to the Amendment, term loans in an aggregate principal amount of up to $100,000 (the “New Credit Facility”) became available to the Company in five tranches, subject to certain terms and conditions.

The first tranche in an aggregate principal amount of $25,000 was outstanding as of the Effective Date, after taking into account reborrowing by the Company on the Effective Date of a previously-repaid principal amount of approximately $2,900. The second tranche in an aggregate principal amount of $12,500 and the third tranche in an aggregate principal amount of $12,500 have been advanced to the Company and were outstanding as of the Effective Date. The fourth tranche in an aggregate principal amount of $25,000 is available upon satisfaction of certain conditions, including the approval by the FDA of a biologics license application in respect of SER-109 (the "Regulatory Approval Milestone") by no later than December 15, 2023. The fifth tranche in an aggregate principal amount of up to $25,000 is available through the Amortization Date (as defined below) upon satisfaction of certain conditions, including the Lenders’ investment committee approval.

All advances outstanding under the New Credit Facility will bear interest at a rate equal to the greater of either (i) the Prime Rate (as reported in The Wall Street Journal) plus 6.40%, and (ii) 9.65%. For all advances outstanding under the New Credit Facility, the Company will make interest only payments through December 31, 2023, extendable to December 31, 2024 upon satisfaction of certain conditions (such applicable date, the “Amortization Date”). The principal balance and interest of the advances will be repaid in equal monthly installments after the Amortization Date and continuing through October 1, 2024, extendable to October 1, 2025, upon satisfaction of certain conditions (such applicable date, the “Maturity Date”).

The Company may prepay advances under the New Credit Facility, in whole or in part, at any time subject to a prepayment charge equal to: (a) 2.0% of amounts so prepaid, if such prepayment occurs during the first year following the Effective Date; (b) 1.5% of the amount so prepaid, if such prepayment occurs during the second year following the Effective Date, and (c) 1.0% of the amount so prepaid, if such prepayment occurs during the third year following the Effective Date.

The Company will pay an end of term charge of 4.85% of the aggregate amount of the advances made under the Original Credit Facility on the earliest date of (i) November 1, 2023; (ii) the date that the Company prepays all of the outstanding principal in full, or (iii) the date the loan payments are accelerated due to an event of default. The Company will pay an additional end of term charge of 1.75% of the aggregate amount of the advances under the New Credit Facility (including the first tranche of $25,000) on the earliest

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

date of (i) the Maturity Date; (ii) the date that the Company prepays all of the outstanding principal in full, or (iii) the date the loan payments are accelerated due to an event of default.

Other terms of the New Credit Facility remain generally identical to those under the Original Credit Facility, with certain covenants amended by the Amendment to provide the Company with additional operational flexibility, including the ability for the Company to issue up to $350,000 in convertible notes. The New Credit Facility includes a conditional liquidity covenant commencing on June 15, 2023, which ceases to apply if certain conditions are satisfied.

The New Credit Facility is secured by substantially all of the Company's assets, other than the Company's intellectual property. The Company has agreed to not pledge or secure its intellectual property to others.

The Company accounted for the New Credit Facility as a modification in accordance with the guidance in ASC 470-50, *Debt*. Amounts paid to the lenders were recorded as debt discount and a new effective interest rate was established. Upon issuance, the New Credit Facility was recorded as a liability with an initial carrying value of $50,586, net of debt issuance costs. The initial carrying value will be accreted to the repayment amount, which includes the outstanding principal plus the end of term charge, through interest expense using the effective interest rate method over the term of the Loan Agreement. As of December 31, 2022, the carrying value of the New Credit Facility is $51,047 and the effective interest rate in effect is 15.01%. As of December 31, 2021, the carrying value of the New Credit Facility was $24,643, and the effective interest rate in effect was 11.47%. The New Credit Facility is classified as a long-term liability on the consolidated balance sheet.

The future principal payments due under the New Credit Facility, excluding interest and the end of term charge, are as follows:

Year Ending December 31,	Principal
2023	—
2024	$ 50,000
Total	$ 50,000

During the years ended December 31, 2022 and 2021, the Company recognized $6,020 and $2,910 of interest expense related to the Loan Agreement, respectively, which is reflected in interest expense on the consolidated statement of operations and comprehensive loss.

9. Convertible Preferred Stock

On July 1, 2015, in connection with the closing of the initial public offering of the Company's common stock ("IPO"), the Company effected its Restated Certificate of Incorporation, which authorizes the Company to issue 10,000,000 shares of preferred stock, $0.001 par value per share.

10. Common Stock and Stock-Based Awards

On July 1, 2015, in connection with the closing of the IPO, the Company effected its Restated Certificate of Incorporation, which authorizes the Company to issue 200,000,000 shares of common stock, $0.001 par value per share.

In November 2019, the Company entered into a common stock sales agreement, or the 2019 Sales Agreement, with Cowen to sell shares of the Company's common stock with aggregate gross sales proceeds of up to $25,000, from time to time, through an "at the market" equity offering program, or ATM, under which Cowen acts as sales agent. In March 2020, in connection with filing an updated registration statement on Form S-3 (File No. 333-237033), the Company entered into a new common stock sales agreement, or the 2020 Sales Agreement, with Cowen on substantially the same terms as the 2019 Sales Agreement and terminated the 2019 Sales Agreement. In May 2021, the Company entered into a new common stock sales agreement, or the 2021 Sales Agreement, with Cowen to sell shares of its common stock with aggregate gross sales proceeds of up to $150,000, from time to time, through an ATM under which Cowen acts as sales agent, and terminated the 2020 Sales Agreement. During the year ended December 31, 2022, the Company sold approximately 655,000 shares of common stock under the 2021 Sales Agreement, at an average price of approximately $7.26 per share, raising aggregate net proceeds of approximately $4,447 after deducting an aggregate commission of approximately 3% and other issuance costs. During the year ended December 31, 2021, the Company did not sell any shares of common stock under the 2020 Sales Agreement or the 2021 Sales Agreement. During the year ended December 31, 2020, the Company sold approximately 5,788,000 shares of common stock under the 2019 Sales Agreement and the 2020 Sales Agreement, as applicable, at an average price of approximately

$4.40 per share, raising aggregate net proceeds of approximately $24,773 after deducting an aggregate commission of approximately 3% and other issuance costs.

On August 12, 2020, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Cowen and Company, LLC and Piper Sandler & Co., as representatives of the several underwriters named therein (collectively, the "Underwriters"), in connection with the issuance and sale by the Company in a public offering of 10,500,000 shares of the Company's common stock at a public offering price of $21.50 per share, less underwriting discounts and commissions, pursuant to an effective shelf registration statement on Form S-3 (Registration No. 333-244401) and a related prospectus supplement filed with the SEC (such public offering, the "offering"). Under the terms of the Underwriting Agreement, the Company granted the Underwriters an option exercisable for 30 days to purchase up to an additional 1,575,000 shares of its common stock at the public offering price, less underwriting discounts and commissions, which the underwriters exercised in full. The Company received aggregate net proceeds from the offering of approximately $243,748 after deducting underwriting discounts and commissions and offering expenses payable by the Company.

Additionally on August 12, 2020, the Company entered into a Securities Purchase Agreement (the "Securities Agreement") with Nestlé for the sale by the Company of 959,002 shares of the Company's common stock at a purchase price of $20.855 per share (the "concurrent placement"). The Company received aggregate net proceeds from the concurrent placement of approximately $19,900 after deducting offering expenses payable by the Company. The consummation of the concurrent placement was contingent upon the closing of the offering and the satisfaction of certain other customary conditions. The shares were offered and sold to Nestlé pursuant to an effective registration statement on Form S-3 (File No. 333-237033) and a related prospectus supplement filed with the SEC.

On June 29, 2022, the Company entered into securities purchase agreements with new and existing investors and certain directors and officers in a registered direct offering, or the Registered Direct Offering, of an aggregate of 31,746,030 shares of its common stock at a purchase price of $3.15 per share for total net proceeds of approximately $96,721, after deducting placement agent's fees and other estimated offering expenses. Net proceeds included an aggregate of $27,525 received from Flagship Pioneering Fund VII, L.P. and Nutritional Health LTP Fund, L.P., affiliates of Flagship Pioneering, or Flagship, one of its significant stockholders, in exchange for 8,738,243 shares. The closing date of the Registered Direct Offering was July 5, 2022.

2012 Stock Incentive Plan

The Company's 2012 Stock Incentive Plan, as amended, (the "2012 Plan") provided 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 of directors. 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 granted 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. As of December 31, 2022, there were no shares available for future grant under the 2012 Plan.

2015 Incentive Award Plan

On June 16, 2015, the Company's stockholders approved the 2015 Incentive Award Plan (the "2015 Plan"), which became effective on June 25, 2015. The 2015 Plan was subsequently amended on December 14, 2022, and provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares initially reserved for issuance under the 2015 Plan was the sum of (i) 2,200,000 shares of common stock and (ii) the number of shares subject to awards outstanding under the 2012 Plan that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company on or after the effective date of the 2015 Plan. In addition, the number of shares of common stock that may be issued under the 2015 Plan is subject to increase on the first day of each calendar year, beginning in 2016 and ending in 2025, equal to the lesser of (i) 4% of the number of shares of the Company's common stock outstanding on the last day of the preceding applicable calendar year and (ii) an amount determined by the Company's board of directors.

Stock awards granted under the 2015 Plan generally vest over four years and expire after ten years, although options have been granted with vesting terms less than four years. As of December 31, 2022, there were 967,206 shares available for future grant under the 2015 Plan.

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

2015 Employee Stock Purchase Plan

On June 16, 2015, the Company's stockholders approved the 2015 Employee Stock Purchase Plan (the "ESPP"), which became effective on June 25, 2015. A total of 365,000 shares of common stock were reserved for issuance under the ESPP. In addition, the number of shares of common stock that may be issued under the ESPP automatically increase on the first day of each calendar year, beginning in 2016 and ending in 2025, by an amount equal to the lesser of (i) 400,000 shares, (ii) 1% of the number of shares of the Company's common stock outstanding on the last day of the applicable preceding calendar year and (iii) an amount determined by the Company's board of directors. Offering periods under the ESPP will commence when determined by the plan administrator. During the year ended and as of December 31, 2022, there were 322,560 shares issued and 2,469,204 shares were reserved and available for issuance under the ESPP, respectively.

The ESPP provides that eligible employees may contribute up to 15% of their eligible earnings toward the semi-annual purchase of the Company's common stock. The ESPP is qualified under Section 423 of the Internal Revenue Code. The employee's purchase price is derived from a formula based on the closing price of the common stock on the first day of the offering period versus the closing price on the date of purchase (or, if not a trading day, on the immediately preceding trading day). The offering period under the ESPP has a duration of six months, and the purchase price with respect to each offering period beginning on or after such date is, until otherwise amended, equal to 85% of the lesser of (i) the fair market value of the Company's common stock at the commencement of the applicable six-month offering period or (ii) the fair market value of the Company's common stock on the purchase date.

2022 Employment Inducement Award Plan

On December 14, 2022, the Company's board of directors approved the 2022 Employment Inducement Award Plan (the "2022 Plan"), which became effective on such date without stockholder approval pursuant to Rule 5635(c)(4) of The Nasdaq Stock Market LLC listing rules ("Rule 5635(c)(4)"). The 2022 Plan provides for the grant of nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock- or cash-based awards. In accordance with Rule 5635(c)(4), awards under the 2022 Plan may only be made to a newly hired employee who has not previously been a member of our board of directors, or an employee who is being rehired following a bona fide period of non-employment by us as a material inducement to the employee's entering into employment with us. A total of 2,500,000 shares of common stock were reserved for issuance under the 2022 Plan. Any shares subject to awards previously granted under the 2022 Plan that expire, terminate or are otherwise surrendered, canceled, or forfeited in any case, in a manner that results in the Company acquiring the shares covered by the award at a price not greater than the price (as adjusted to reflect any equity restructuring) paid by the Participant for such shares or not issuing any shares covered by the award, the unused shares covered by the award will again be available for award grants under the 2022 Plan.

As of December 31, 2022, there were no awards outstanding and 2,500,000 shares available for future grant under the 2022 Plan.

Stock Options

The following table summarizes the Company's stock option activity for the year ended December 31, 2022:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2021	11,517,189	$ 11.10	7.42	$ 28,007
Granted	4,527,897	6.89		
Exercised	(326,864)	2.96		
Forfeited	(778,188)	10.62		
Outstanding as of December 31, 2022	14,940,034	$ 10.03	7.25	$ 11,608
Options exercisable as of December 31, 2022	7,441,253	$ 10.38	5.88	$ 8,115

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2022, 2021 and 2020 was $5.53, $15.33, and $5.08 per share, respectively. The total intrinsic value of stock options exercised during the years ended December 31, 2022, 2021, and 2020 was $981, $4,727, and $37,255, respectively.

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

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

During the year ended December 31, 2021, the Company granted performance-based stock options to employees for the purchase of an aggregate of 562 thousand shares of common stock with a grant date fair value of $5.53 per share. These stock options are exercisable only upon achievement of specified performance targets. As of December 31, 2022, none of these options were exercisable because none of the specified performance targets had been achieved. Because achievement of the specified performance targets was not deemed probable as of December 31, 2022, the Company did not record any expense for these stock options from the dates of issuance through December 31, 2022.

Restricted Stock Units

The Company has granted restricted stock units ("RSUs") with service-based vesting conditions. RSUs represent the right to receive shares of common stock upon meeting specified vesting requirements. Restricted stock units may not be sold or transferred by the holder and vest according to the vesting conditions of each award. The table below summarizes the Company's RSU activity for the year ended December 31, 2022:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted stock units as of December 31, 2021	734,755	$ 17.68
Granted	1,302,844	$ 6.95
Forfeited	(205,658)	$ 11.82
Vested	(282,401)	$ 18.06
Unvested restricted stock units as of December 31, 2022	1,549,540	$ 9.37

During the years ended December 31, 2022, 2021 and 2020, the Company granted 1,302,844, 768,998 and 6,500 RSUs, respectively. RSUs generally vest over four years, with 25% vesting after one year, and the remaining 75% vesting quarterly over the next 3 years, subject to continued service to the Company through the applicable vesting date.

The aggregate intrinsic value of restricted stock units that vested during the years ended December 31, 2022, 2021 and 2020 was $1,809, $16, and $532, respectively.

During the year ended December 31, 2021, the Company granted performance-based restricted stock awards to two employees for the purchase of an aggregate of 85,000 shares of common stock with a grant date fair value of $9.59 per share and 40,000 shares with a grant date fair value of $20.35 per share. These restricted stock awards vest only upon achievement of specified performance targets. As of December 31, 2021, these awards were not vested because the specified performance targets had not been achieved. In addition, the performance targets were not deemed probable of achievement. Accordingly, the Company did not record any expense for these awards from the dates of issuance through December 31, 2021. In October 2022, 42,500 of the awards with a grant date fair value of $9.59, and 20,000 of the awards with a grant date fair value of $20.35, vested fully, as the associated performance targets were achieved. Accordingly, the Company recorded $815 in compensation expense during the year ended December 31, 2022, with respect to these awards. As of December 31, 2022, the remaining performance-based restricted stock awards in these grants were not vested because the associated targets had not been achieved. In addition, the performance targets were not deemed probable of achievement. Accordingly, the Company did not record any expense for these remaining awards from the dates of issuance through December 31, 2022.

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

Stock-based Compensation Valuation

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

	Year Ended December 31,		
	2022	2021	2020
Risk-free interest rate	1.67%	0.73%	1.26%
Expected term (in years)	6.0	5.4	6.0
Expected volatility	104.0%	106.5%	73.3%
Expected dividend yield	0%	0%	0%

The Company estimates the fair value of rights to acquire common stock under the ESPP using a Black-Scholes valuation model on the date of grant and the straight-line attribution approach to recognize the expense. The assumptions that the Company used to determine the fair value of rights to acquire common stock under the ESPP were as follows, presented on a weighted average basis:

	Year Ended December 31,		
	2022	2021	2020
Risk-free interest rate	2.11%	0.97%	1.20%
Expected term (in years)	0.5	0.5	0.5
Expected volatility	99.0%	123.8%	74.9%
Expected dividend yield	0%	0%	0%

Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options and restricted stock units in the following expense categories of its consolidated statements of operations and comprehensive loss:

	Year Ended December 31,		
	2022	2021	2020
Research and development expenses	$ 13,429	$ 10,146	$ 4,760
General and administrative expenses	12,053	10,076	4,064
	$ 25,482	$ 20,222	$ 8,824

As of December 31, 2022, the Company had an aggregate of $57,005 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 1.8 years.

11. Collaboration Revenue

License Agreement with NHSc Rx License GmbH (Nestlé)

Summary of Agreement

In July 2021, the Company entered into the 2021 License Agreement with NHSc Pharma Partners, succeeded by NHSc Rx License GmbH (together with Société des Produits Nestlé S.A., their affiliates, and their subsidiaries, "Nestlé"). Under the terms of the Agreement, the Company granted Nestlé a co-exclusive, sublicensable (under certain circumstances) license to develop, commercialize and conduct medical affairs activities for (i) therapeutic products based on the Company's microbiome technology (including the Company's SER-109 product candidate) that are developed by the Company or on the Company's behalf for the treatment of CDI and recurrent CDI, as well as any other indications pursued for the products upon mutual agreement of the parties (the “2021 Field”) in the United States and Canada (the “2021 Licensed Territory”), and (ii) the Company's SER-109 product candidate and any improvements and modifications thereto developed pursuant to the terms of the 2021 License Agreement (the "2021 Collaboration Products") for any indications in the 2021 Licensed Territory. The Company is responsible for completing development of SER-109 in the 2021 Field in the United States until first regulatory approval for SER-109 is obtained.

Nestlé has the sole right to commercialize the 2021 Collaboration Products in the 2021 Licensed Territory in accordance with a commercialization plan. Both parties will perform medical affairs activities in the 2021 Licensed Territory in accordance with a medical affairs plan. The Company will be responsible for the manufacturing and supply for commercialization under a supply agreement that will be entered into between the parties. Both parties will perform pre-launch activities of 2021 Collaboration Products prior to the first

commercial sale in the United States. The Company is responsible for funding the pre-launch activities until first commercial sale of 2021 Collaboration Products in the 2021 Licensed Territory and in accordance with a pre-launch plan, up to a specified cap. Following first commercial sale of the first 2021 Collaboration Product, the Company will be entitled to share equally in its commercial profits and losses.

In connection with the 2021 License Agreement, the Company received an upfront payment of $175,000. The Company is eligible to receive additional payments of up to $360,000 if certain regulatory and sales milestones are achieved. The potential future milestone payments include up to $135,000 for the achievement of specified regulatory milestones and up to $225,000 for the achievement of specified net sales milestones.

The 2021 License Agreement continues in effect until all development and commercialization activities for all 2021 Collaboration Products in the 2021 Licensed Territory have permanently ceased. The 2021 License Agreement may be terminated by either party upon sixty days' written notice for the other party's material breach that remains uncured during such sixty-day period, or immediately upon written notice for the other party's insolvency. Nestlé may also terminate the 2021 License Agreement at-will (i) with twelve months' prior written notice, effective only on or after the third anniversary of first commercial sale of the first 2021 Collaboration Product in the 2021 Licensed Territory, (ii) if first commercial sale of the first 2021 Collaboration Product in the 2021 Licensed Territory has not occurred by the fifth anniversary of the effective date of the 2021 License Agreement, with one hundred eighty days' prior written notice, which must be provided during a specified period set forth in the 2021 License Agreement, or (iii) if regulatory approval for SER-109 is not granted after submission by the Company of a filing seeking first regulatory approval as set forth in the development and regulatory activity plan, and the parties fail to agree on further development of SER-109 in accordance with the terms of the 2021 License Agreement, with one hundred eighty days' prior written notice, which must be provided within a specified period set forth in the 2021 License Agreement. The Company may also terminate the 2021 License Agreement immediately upon written notice if Nestlé challenges any licensed patent in the 2021 Licensed Territory. Upon termination of the 2021 License Agreement, all licenses granted to Nestlé by the Company will terminate. If the Company commits a material breach of the 2021 License Agreement, Nestlé may elect not to terminate the 2021 License Agreement but instead apply specified adjustments to the payment terms and other terms and conditions of the 2021 License Agreement.

Accounting Analysis

The 2021 License Agreement represents a separate contract between Nestlé and the Company. The 2021 License Agreement is within the scope of Accounting Standard Update 2018-18, *Collaborative Arrangements* (Topic 808), and has elements that are within the scope of ASC 606 - *Revenue From Contracts with Customers* (Topic 606) and Topic 808.

The Company identified the following promises in the 2021 License Agreement that were evaluated under the scope of Topic 606: (i) delivery of a co-exclusive license for SER-109 to develop, commercialize and conduct medical affairs in the United States and Canada; (ii) services to be performed in accordance with the development and regulatory activity plan to obtain regulatory approval of SER-109 in the United States. The Company also evaluated whether certain options outlined within the 2021 License Agreement represented material rights that would give rise to a performance obligation and concluded that none of the options convey a material right to Nestlé and therefore are not considered separate performance obligations within the 2021 License Agreement.

The Company assessed the above promises and determined that the co-exclusive license for SER-109 and the services to obtain regulatory approval of SER-109 in the United States are reflective of a vendor-customer relationship and therefore represent performance obligations within the scope of Topic 606. The co-exclusive license for SER-109 in the United States and Canada is considered functional intellectual property and distinct from other promises under the contract as Nestlé can benefit from the license on its own or together with other readily available resources. The services performed by the Company to obtain regulatory approval of SER-109 are not complex or specialized, could be performed by another qualified third party, are not expected to significantly modify or customize the license given that SER-109 is late-stage intellectual property that has completed clinical development and the services are expected to be performed over a short period of time. Therefore, the license and the services each represents a separate performance obligation within a contract with a customer under the scope of Topic 606 at contract inception.

The Company considers the collaborative pre-launch activities and commercialization activities to be separate units of account within the scope of Topic 808 and are not deliverables under Topic 606. The Company and Nestlé are both active participants in the pre-launch activities and commercialization activities and are exposed to significant risks and rewards that are dependent on the commercial success of the activities in the arrangement.

The up-front payment of $175,000 compensated the Company for: (i) the co-exclusive license for SER-109 to develop, commercialize and conduct medical affairs in the United States and Canada, (ii) services performed in accordance with the development and regulatory activity plan to obtain regulatory approval of SER-109 in the United States and (iii) pre-launch activities performed by Nestlé and the Company until the first commercial sale of SER-109 in the United States. The commercialization activities, which include the commercial manufacturing, participation on joint steering committees and medical affairs work, that occur after regulatory approval of SER-109 in the United States, are part of the 50/50 sharing of commercial profits. Therefore, the up-front payment of $175,000 does not compensate the Company for these activities.

The Company allocated the $175,000 between the Topic 606 unit of account and the Topic 808 unit of account by determining the standalone selling price (SSP) of each good or service. The selling price of each good or service was determined based on the Company's SSP with the objective of determining the price at which it would sell such an item if it were to be sold regularly on a standalone basis. The Company determined the transaction price under Topic 606 to be $139,500 and the Topic 808 amount to be $35,500 at the inception of the 2021 License Agreement.

The Company determined that any variable consideration related to regulatory milestones is deemed to be fully constrained and therefore excluded from the transaction price due to the high degree of uncertainty and risk associated with these potential payments, as the Company determined that it could not assert that it was probable that a significant reversal in the amount of cumulative revenue recognized will not occur. The Company also determined that sales milestones relate solely to the license of intellectual property and are therefore excluded from the transaction price under the sales- or usage-based royalty exception of Topic 606. Revenue related to these sales milestones will only be recognized when the associated sales occur, and relevant thresholds are met.

The Topic 606 transaction price of $139,500 has been allocated to the co-exclusive license for SER-109 and the services performed in accordance with the development and regulatory activity plan to obtain regulatory approval of SER-109 in the United States based on the Company's SSP. The Company recognized revenue for the license performance obligation at a point in time, that is upon transfer of the license to Nestlé. As control of the license was transferred in July 2021, the Company recognized $131,343 of collaboration revenue - related party during the year ended December 31, 2021 pertaining to the license performance obligation. The remaining amount of the Topic 606 transaction price of $8,157 was allocated to the services performance obligation and is being recognized over time as the services are performed. During the years ended December 31, 2022 and 2021, the Company recognized $4,114 and $2,068, of collaboration revenue - related party, respectively, related to the services performance obligation under the 2021 License Agreement.

The amount allocated to the Topic 808 unit of accounting relates to the pre-launch activities performed prior to the first commercial sale of SER-109 and was determined to be $35,500 based on standalone selling price.

The Company recorded the $35,500 in total liabilities on its consolidated balance sheet at the inception of the arrangement. On a quarterly basis, the Company and Nestlé will provide financial information about the pre-launch activities performed by both parties. The Company reduces the $35,500 liability as the pre-launch activities are performed and it makes payments to Nestlé for the pre-launch costs Nestlé incurs. As of December 31, 2022 and 2021, there is $34,770 and $21,098 included in accrued expenses and other current liabilities and $0 and $10,585 included in other long-term liabilities, respectively.

The cost associated with pre-launch activities performed by the Company is recorded within total operating expenses in the Company's consolidated statements of operations and comprehensive loss. In the years ended December 31, 2022 and 2021, the Company recognized $6,102 and $2,168 in research and development expenses and $8,953 and $3,383 in general and administrative expenses, respectively, associated with pre-launch activities performed.

As the Company and Nestlé are both active participants in the pre-launch activities, the sharing of 50% of the pre-launch costs will be recognized in collaboration (profit) loss sharing - related party in the Company's consolidated statements of operations and comprehensive loss. The Company recorded $1,004 of expense and $1,732 of income in the collaboration (profit) loss sharing line for the years ended December 31, 2022 and 2021, respectively.

Collaboration and License Agreement with Société des Produits Nestlé S.A. (Nestlé)

Summary of Agreement

In January 2016, the Company entered into a collaboration and license agreement with Nestec Ltd., succeeded by Société des Produits Nestlé S.A. (together with NHSc Rx License GmbH, their affiliates and their subsidiaries, "Nestlé") (the "2016 License Agreement") for the development and commercialization of certain product candidates for the treatment and management of CDI and

inflammatory bowel disease ("IBD"), including UC and Crohn's disease. The 2016 License Agreement supports the development of the Company's portfolio of products for CDI and IBD in markets outside of the United States and Canada (the "2016 Licensed Territory").

Under the 2016 License Agreement, the Company granted to Nestlé an exclusive, royalty-bearing license to develop and commercialize, in the 2016 Licensed Territory, certain products based on its microbiome technology that are being developed for the treatment of CDI and IBD, including SER-109, SER-262, SER-287 and SER-301 (collectively, the "2016 Collaboration Products"). The 2016 License Agreement sets forth the Company's and Nestlé's respective obligations for development, commercialization, regulatory and manufacturing and supply activities for the 2016 Collaboration Products with respect to the licensed fields and the 2016 Licensed Territory.

Under the 2016 License Agreement, Nestlé agreed to pay the Company an upfront cash payment of $120,000, which the Company received in February 2016. The Company is eligible to receive up to $285,000 in development milestone payments, $375,000 in regulatory payments and up to an aggregate of $1,125,000 for the achievement of certain commercial milestones related to the sales of the 2016 Collaboration Products. Nestlé also agreed to pay the Company tiered royalties, at percentages ranging from the high single digits to high teens, of net sales of 2016 Collaboration Products in the 2016 Licensed Territory.

Under the 2016 License Agreement, the Company is entitled to receive a $20,000 milestone payment from Nestlé following initiation of a SER-287 Phase 2 study and a $20,000 milestone payment from Nestlé following the initiation of a SER-287 Phase 3 study. In November 2018, the Company entered into a letter agreement with Nestlé which modified the 2016 License Agreement to address the current clinical plans for SER-287. Pursuant to the letter agreement, the Company and Nestlé agreed that following initiation of the SER-287 Phase 2b study, the Company would be entitled to receive $40,000 in milestone payments from Nestlé, which represent the milestone payments due to the Company for the initiation of a SER-287 Phase 2 study and a Phase 3 study. The SER-287 Phase 2b study was initiated and the $40,000 of milestone payments were received in December 2018. The letter agreement also provides scenarios under which Nestlé's reimbursement to the Company for certain Phase 3 development costs would be reduced or delayed depending on the outcomes of the SER-287 Phase 2b study.

The 2016 License Agreement continues in effect until terminated by either party on the following bases: (i) Nestlé may terminate the 2016 License Agreement in the event of serious safety issues related to any of the 2016 Collaboration Products; (ii) the Company may terminate the 2016 License Agreement if Nestlé challenges the validity or enforceability of any of the Company's licensed patents; and (iii) either party may terminate the 2016 License Agreement in the event of the other party's uncured material breach or insolvency. Upon termination of the 2016 License Agreement, all licenses granted to Nestlé by the Company will terminate, and all rights in and to the 2016 Collaboration Products in the 2016 Licensed Territory will revert to the Company. If the Company commits a material breach of the 2016 License Agreement, Nestlé may elect not to terminate the 2016 License Agreement but instead apply specified adjustments to its payment obligations and other terms and conditions of the 2016 License Agreement.

Accounting Analysis

The Company assessed the 2016 License Agreement in accordance with Topic 606 and concluded that Nestlé is a customer. The Company identified the following promises under the contract: (i) a license to develop and commercialize the 2016 Collaboration Products in the 2016 Licensed Territory, (ii) obligation to perform research and development services, (iii) participation on a joint steering committee, and (iv) manufacturing services to provide clinical supply to complete future clinical trials. In addition, the Company identified a contingent obligation to perform manufacturing services to provide commercial supply if commercialization occurs, which is contingent upon regulatory approval. This contingent obligation is not a performance obligation at inception and has been excluded from the initial allocation as it represents a separate buying decision at market rates, rather than a material right in the contract. The Company assessed the promised goods and services to determine if they are distinct. Based on this assessment, the Company determined that Nestlé cannot benefit from the promised goods and services separately from the others as they are highly interrelated and therefore not distinct. Accordingly, the promised goods and services represent one combined performance obligation and the entire transaction price was allocated to that single combined performance obligation.

At contract inception, the Company determined that the $120,000 non-refundable upfront amount constituted the entirety of the consideration to be included in the transaction price as the development, regulatory, and commercial milestones were fully constrained. During the year ended December 31, 2016, the Company received $10,000 from Nestlé in connection with the initiation of the Phase 1b study for SER-262 in CDI. During the year ended December 31, 2017, the Company received $20,000 from Nestlé in connection with the initiation of the Phase 3 study for SER-109. During the year ended December 31, 2018, the Company received $40,000 from Nestlé in connection with the initiation of the Phase 2b study for SER-287. During the year ended December 31, 2020, the Company received

$10,000 from Nestlé in connection with the initiation of the Phase 1b SER-301 study. As of December 31, 2022, the aggregate amount of the transaction price allocated to the performance obligation of the 2016 License Agreement was approximately $200,000.

During the years ended December 31, 2022, 2021, and 2020 using the cost-to-cost method, which best depicts the transfer of control to the customer, the Company recognized $3,014, $10,446, and $11,897 of Collaboration revenue – related party, respectively, relating to the 2016 License Agreement.

As of December 31, 2022 and 2021, there was $96,689, and $103,817 of deferred revenue related to the unsatisfied portion of the performance obligation under the Nestlé agreements. As of December 31, 2022, deferred revenue is classified as current or non-current in the consolidated balance sheets based on the Company's estimate of revenue that will be recognized within the next twelve months, which is determined by the cost-to-cost method which measures the extent of progress towards completion based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the performance obligation. All costs associated with the 2016 License Agreement are recorded in research and development expense in the consolidated statements of operations and comprehensive loss.

AstraZeneca Research Collaboration and Option Agreement

Summary of the Agreement

In March 2019, the Company entered into a Research Collaboration and Option Agreement (the "Research Agreement") with MedImmune, LLC, a wholly owned subsidiary of AstraZeneca Inc. ("AstraZeneca"), to advance the mechanistic understanding of the microbiome in augmenting the efficacy of cancer immunotherapy. Under the Research Agreement, the Company and AstraZeneca would conduct certain research and development activities as set forth on a research plan focused on the role of the microbiome in certain cancers and cancer immunotherapies, including furthering the research program for SER-401, in combination with AstraZeneca compounds targeting various cancers.

Pursuant to the Research Agreement, the Company agreed not to conduct research or development on any microbiome products specifically designed by the Company during the term of the Research Agreement for the treatment of cancer ("Microbiome Oncology Products"), with or on behalf of any third-party without the prior approval of the joint steering committee for the Research Agreement for at least three years after the effective date (the "Exclusivity Period"). Additionally, AstraZeneca was to pay to the Company a total of $20,000 in three equal installments, the first of which the Company received in April 2019, the second of which the Company received in December 2019, and the third of which the Company received in January 2021. Additionally, AstraZeneca was to bear its costs of conducting activities under the research plan and to reimburse the Company for all activities performed under the research plan based on actual full-time employee ("FTE") time and certain third-party costs incurred by the Company in connection therewith.

Under the Research Agreement, the Company granted to AstraZeneca an exclusive option to negotiate a worldwide, sublicensable exclusive license under relevant intellectual property rights controlled by the Company to exploit Microbiome Oncology Products for the treatment of cancer. Additionally, the Company granted to AstraZeneca an additional exclusive option to obtain a worldwide, sublicensable, license under certain intellectual property rights arising out of the Agreement or coming into the control of the Company during the term of the Agreement, which AstraZeneca did not exercise.

In December 2020, the Company received written notice from AstraZeneca that AstraZeneca elected to terminate the Research Agreement by and in accordance with its terms. The termination of the Research Agreement was effective on April 2, 2021 (the "Termination Date"), which was 120 days from the date of the termination notice.

Accounting Analysis

The Company assessed the Research Agreement in accordance with ASC 606 and concluded that AstraZeneca was a customer, and that the promised goods and services in the Research Agreement represented one combined performance obligation to which the entire transaction price was allocated. The Company also concluded that each option does not constitute a performance obligation at inception and was therefore excluded from the initial allocation since each option represents a separate buying decision at market rates, rather than a material right in the contract.

At contract inception, the Company determined that the transaction price was comprised of: (i) the $20,000 fee, which represents fixed consideration, and (ii) the estimated reimbursement of research and development costs incurred, which totaled approximately

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

$13,900, which represents variable consideration. The Company included the variable consideration in the transaction price at contract inception because the Company had determined it was not probable that a significant reversal of cumulative revenue would occur.

The Company determined that revenue under the Research Agreement should be recognized over time, using a cost-to-cost input method, as AstraZeneca simultaneously receives the benefit from the Company as the Company performs under the single performance obligation over time.

In December 2020, the Company received written notice that AstraZeneca elected to terminate the Research Agreement. As a result of AstraZeneca's decision to terminate the Research Agreement, the Company's performance obligations under the Research Agreement ended as of December 31, 2020. The final transaction price of $23,377 is comprised of the $20,000 fixed consideration and $3,376 for the reimbursed research and development costs. The Company recognized its remaining deferred revenue of $15,145 in collaboration revenue in the year ended December 31, 2020. No collaboration revenue was recognized for the years ended December 31, 2022 and 2021, as the Company's performance obligations under the Research Agreement ended December 31, 2020.

Contract Balances from Contracts with Customers

The following tables present changes in the Company's contract liabilities during the year ended December 31, 2022 and 2021:

	Balance as of December 31, 2021	Additions	Deductions	Balance as of December 31, 2022
Year ended December 31, 2022				
Contract liabilities:				
Deferred revenue - related party	$ 103,817	—	(7,128)	$ 96,689

	Balance as of December 31, 2020	Additions	Deductions	Balance as of December 31, 2021
Year ended December 31, 2021				
Contract liabilities:				
Deferred revenue - related party	$ 108,174	8,157	(12,514)	$ 103,817

During the year ended December 31, 2022, the Company recognized the following revenues as a result of changes in the contract liability balances in the respective periods:

	Year Ended December 31,	
	2022	2021
Revenue recognized in the period from:		
Amounts included in the contract liability at the beginning of the period	$ 7,128	$ 10,446

When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded. Revenue is recognized from the contract liability over time using the cost-to-cost method.

12. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Year Ended December 31,		
	2022	2021	2020
Numerator:			
Net loss attributable to common stockholders	$ (250,157)	$ (65,578)	$ (89,127)
Denominator:			
Weighted average common shares outstanding, basic and diluted	108,077,043	91,702,866	79,789,220
Net loss per share attributable to common stockholders, basic and diluted	$ (2.31)	$ (0.72)	$ (1.12)

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

The Company's potential dilutive securities, which include stock options, unvested restricted common stock and shares issuable under the ESPP, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share and therefore been anti-dilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The following potential common shares, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31,		
	2022	2021	2020
Stock options to purchase common stock	14,940,034	11,517,189	10,037,130
Unvested restricted stock units	1,549,540	734,755	6,500
Shares issuable under employee stock purchase plan	89,593	165,047	10,786
	16,579,167	12,416,991	10,054,416

13. Commitments and Contingencies

Leases

Refer to Note 7 "Leases" for discussion of the commitments associated with the Company's lease portfolio.

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 and its officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2022 or 2021.

Legal Contingencies

The Company accrues a liability for legal contingencies when it believes that it is both probable that a liability has been incurred and that the Company can reasonably estimate the amount of the loss. The Company reviews these accruals and adjusts them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and the views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in the Company's accrued liabilities would be recorded in the period in which such determination is made.

In addition, in accordance with the relevant authoritative guidance, for any matters in which the likelihood of material loss is at least reasonably possible, the Company will provide disclosure of the possible loss or range of loss. If a reasonable estimate cannot be made, however, the Company will provide disclosure to that effect. The Company expenses legal costs as they are incurred.

The Company did not accrue any liabilities related to legal contingencies in its consolidated financial statements as of December 31, 2022 and 2021.

Bacthera Long Term Manufacturing Agreement

On November 8, 2021, the Company entered into a Long Term Manufacturing Agreement with BacThera AG ("Bacthera"), a joint venture between Chr. Hansen and a Lonza Group affiliate, which was amended on December 14, 2022 (the "Bacthera Agreement"). The Bacthera Agreement governs the general terms under which Bacthera, or one of its affiliates, will (i) construct a dedicated full-scale production suite for the Company at Bacthera's Microbiome Center of Excellence in Visp, Switzerland, which is currently under construction; and (ii) provide manufacturing services to the Company for its SER-109 product and other products, as agreed to by the parties.

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

Under the terms of the Bacthera Agreement, the Company agreed to pay Bacthera a total of at least 256,000 CHF (or approximately $277,000) for the initial term of the agreement, inclusive of the construction fees and annual operating fees. Bacthera is funding the majority of the construction costs and will own and control the manufacturing suite during construction. The construction fees that the Company is responsible for represent a small percentage of the overall construction costs and are payable upon the achievement of certain milestones related to the construction of the dedicated manufacturing suite. The annual operating fee includes the cost of a baseline annual batch production volume. The Company has also agreed to pay certain other ancillary fees and a per-batch fee in excess of the baseline batches. These fees are subject to adjustment during construction for certain items outside of Bacthera's control and annually against an agreed index. The Company will supply the active pharmaceutical ingredients to Bacthera to enable it to perform the services and pay for certain other raw materials and manufacturing components, which will be acquired by Bacthera.

The Bacthera Agreement has an initial term that continues until the tenth anniversary of the earlier of (a) successful completion of construction and demonstration of Bacthera's readiness for commercial production or (b) the commencement of manufacturing.

The initial term is subject to renewals, which could extend the term to 16 years, and additional three-year terms thereafter. Each party has the ability to terminate the Bacthera Agreement upon the occurrence of certain customary conditions. The Company may also terminate the Bacthera Agreement for convenience after a defined period. In the event of a termination, the Company has certain financial obligations that would apply, and Bacthera has agreed to grant a license to Bacthera-developed manufacturing know how, if any, and provide technical assistance to the Company, so that the Company could transfer the manufacturing operations to itself or a third party. The Bacthera Agreement also contains representations, warranties and indemnity obligations as well as limitations of liability that are customary for agreements of this type.

The Bacthera Agreement represents a lease as the Company will have the right to use the dedicated manufacturing suite for a period of time following completion of the construction of the manufacturing suite and approval by regulatory authorities. As of December 31, 2022, the lease commencement date has not occurred and therefore the Company has not recorded an operating lease asset or an operating lease liability on its consolidated balance sheets. As of December 31, 2022, the Company has paid Bacthera $12,276, of which $3,448 was expensed in the year ended December 31, 2021, and $8,828 relate to the construction of the dedicated manufacturing suite and are included in other non-current assets in the accompanying consolidated balance sheet.

14. Income Taxes

During the years ended December 31, 2022, 2021 and 2020, 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,		
	2022	2021	2020
Federal statutory income tax rate	(21.0)%	(21.0)%	(21.0)%
Research and development tax credits	(3.1)	(16.6)	(6.4)
State taxes, net of federal benefit	(4.3)	(2.8)	(7.8)
Stock-based compensation	0.6	(0.4)	(5.8)
Uncertain tax position reserves	4.6	—	—
Other	0.3	0.4	0.2
Change in deferred tax asset valuation allowance	22.9	40.4	40.8
Effective income tax rate	—%	—%	—%

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

Net deferred tax assets as of December 31, 2022 and 2021 consisted of the following:

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 132,560	$ 108,189
Research and development tax credit carryforwards	48,854	53,133
Section 174 capitalized research and development expenses	38,894	—
Stock-based compensation expense	20,048	16,045
Lease liability	29,717	6,635
Deferred revenue	29,922	36,666
Accrued expenses	4,044	2,475
Section 163(j) limitation	2,303	1,368
Depreciation and amortization	396	247
Other	200	274
Total deferred tax assets	$ 306,938	$ 225,032
Deferred tax liabilities:		
Depreciation and amortization	—	—
Right of use assets	(29,568)	(4,918)
Total deferred tax liabilities	(29,568)	(4,918)
Valuation allowance	$ (277,370)	$ (220,114)
Net deferred tax assets	$ —	$ —

The Tax Cuts and Jobs Act ("TCJA") requires taxpayers to capitalize and amortize research and experimental expenditures under IRC Section 174 for tax years beginning after December 31, 2021. This rule became effective for the Company during the year ended December 31, 2022 and resulted in the capitalization of research and development costs of $160,586. The Company will amortize these costs for tax purposes over five years if the research and development was performed in the U.S. and over 15 years if the research and development was performed outside the U.S.

As of December 31, 2022, the Company had net operating loss carryforwards (“NOLs”) for federal and state income tax purposes of $501,789 and $481,862, respectively. Federal NOLs of $119,800, generated before 2018, will begin expiring in varying amounts in 2035 unless utilized. The remaining federal NOLs of $381,989, generated after 2017, will be carried forward indefinitely and could be used to offset up to 80% of taxable income in future tax years. The Company's state NOLs will expire at various times starting in 2035. As of December 31, 2022, the Company also had available gross research and development tax credit carryforwards for federal and state income tax purposes of $50,248 and $12,925, respectively, which begin to expire in 2031 and 2028, respectively. The federal research and development tax credits include an orphan drug credit carryforward of $25,623.

Utilization of the NOLs and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code ("IRC") 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. Since its formation, the Company has raised capital through the issuance of capital stock on several occasions. These financings, combined with the purchasing shareholders' subsequent disposition of those shares, may have resulted in a change of control or could result in a change of control in the future upon subsequent disposition. The Company conducted an analysis to determine if historical changes in ownership through December 31, 2020 would limit or otherwise restrict its ability to utilize these NOLs and research and development credit carryforwards. As a result of this analysis, the Company does not believe there are any significant limitations on its ability to utilize these carryforwards. However, future changes in ownership after December 31, 2020 could affect the limitation in future years. Any limitation may result in expiration of a portion of the NOLs or research and development credit carryforwards before utilization.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company’s history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against

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

the deferred tax assets as of December 31, 2022 and 2021. 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, 2022, 2021 and 2020 related primarily to the increases in NOLs, research and development tax credit carryforwards and capitalized research and development expenses pursuant to IRC Section 174, and stock-based compensation were as follows:

	Year Ended December 31,		
	2022	2021	2020
Valuation allowance at beginning of year	$ (220,114)	$ (193,736)	$ (157,346)
Decreases recorded as benefit to income tax provision	—	—	—
Increases recorded to income tax provision	(57,256)	(26,378)	(36,390)
Valuation allowance as of end of year	$ (277,370)	$ (220,114)	$ (193,736)

The Company is currently under examination by the Internal Revenue Service ("IRS") for the period ended December 31, 2018 related to its 2018 research and development tax credits ("R&D Credit(s)"). The Company has adjusted its 2018 R&D Credits and its overall federal and state R&D Credit carryforward balance from the Company's inception to December 31, 2022, based on the most recent information received from the IRS regarding the examination. Also, the Company has reviewed each of its overall filing positions since inception and has not identified any additional positions that do not meet the more likely than not threshold. The Company does not anticipate a material change to its uncertain tax position reserves in the next 12 months. The changes in the Company's unrecognized tax benefits for the years ended December 31, 2022, 2021, and 2020 were as follows:

	Year Ended December 31,		
	2022	2021	2020
Balance at beginning of year	$ —	$ —	$ —
Increase in unrecognized tax benefits as a result of tax positions taken during the year	12,528	—	—
Reduction to unrecognized tax benefits	—	—	—
Increases in unrecognized tax benefits as a result of tax positions taken during current period	$ 12,528	$ —	$ —

The Company has not yet conducted a study of its research and development credit carry forwards. This study may result in further adjustment to the Company's R&D Credits; however, a full valuation allowance has been provided against the Company's R&D Credits, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet or statement of operations if an adjustment were required. The Company had no other unrecognized tax benefits accrued for the years ended December 31, 2022 and 2021, or related interest and penalties as of such dates. The Company will recognize any interest and penalties related to uncertain tax positions in income tax expense.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The Company's tax years are still open under statute from 2011 to present. All years may be examined to the extent the tax credit or net operating loss carryforwards are used in future periods.

15. Related Party Transactions

As described in Note 11, in July 2021, the Company entered into the 2021 License Agreement with NHSc Pharma Partners (together with Société des Produits Nestlé S.A., "Nestlé"). NHSc Pharma Partners is an affiliate of two of the Company's significant stockholders, Société des Produits Nestlé S.A. and Nestlé Health Science U.S. Holdings, Inc. During the years ended December 31, 2022 and 2021, the Company recognized $4,114 and $133,411 of related party revenue, respectively, associated with the 2021 License Agreement. As of the years ended December 31, 2022 and 2021, there was $1,976 and $6,089 of deferred revenue related to the 2021 License Agreement, which is classified as current or non-current in the consolidated balance sheets. As of December 31, 2022 and 2021 there was $34,770 and $21,098 included in accrued expenses and other liabilities and $0 and $10,585 included in other long term liabilities, respectively, related to the 2021 License Agreement. The Company has made no payments to Nestlé during the years ended December 31, 2022 and 2021. There was no amount due from Nestlé as of December 31, 2022 and 2021.

As described in Note 11, in January 2016, the Company entered into the 2016 License Agreement with Société des Produits Nestlé S.A. (successor in interest to Nestec, Ltd.) for the development and commercialization of certain product candidates in development for the treatment and management of CDI and IBD, including UC and Crohn's disease. Société des Produits Nestlé S.A. and its affiliate Nestlé Health Science U.S. Holdings, Inc. are two of the Company's significant stockholders. During the years ended December 31, 2022, 2021, and 2020, the Company recognized $3,014, $10,446, and $11,897, respectively, of related party revenue associated with the 2016 License Agreement. As of December 31, 2022 and 2021, there was $94,713 and $97,728, respectively, of deferred revenue related to the 2016 License Agreement, which is classified as current or non-current in the consolidated balance sheets. The Company has made no payments to Nestlé during the years ended December 31, 2022 and 2021. There was no amount due from Nestlé as of December 31, 2022 and 2021.

As described in Note 10, the Company entered into a securities purchase agreement with Flagship Pioneering Fund VII, L.P. and Nutritional Health LTP Fund, L.P., affiliates of Flagship, one of the Company's significant stockholders, for the sale of 8,738,243 shares of its common stock at a purchase price of $3.15 per share as part of the Registered Direct Offering, which closed on July 5, 2022. The Company received proceeds from Flagship of $27,525.

In July 2022, the Company entered into a Pledge and Utilization Agreement with Flagship Pioneering Labs TPC, Inc., an affiliate of Flagship, for an option to lease certain manufacturing space. The Company paid $833 for this option which is classified in other non-current assets on the Company's condensed consolidated balance sheet as of December 31, 2022.

In July 2019, the Company entered into a sublease agreement with Flagship to sublease a portion of its office and laboratory space in Cambridge, Massachusetts. The term of the sublease agreement commenced in July 2019 and ended in November 2021. Under this agreement, the Company recorded other income of $0 and $1,575 during the years ended December 31, 2022 and 2021. The Company received cash payments of $0 and $1,575 during the years ended December 31, 2022 and 2021.

16. 401(k) Savings Plan

The Company has a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Effective January 1, 2016, the Company elected to match 50% of the first 6% of an employee's deferral. Company contributions are expensed in the year for which they are declared. During the years ended December 31, 2022, 2021, and 2020 the Company recorded expense of $1,921, $1,087, and $586, respectively, for 401(k) match contributions.

SERES THERAPEUTICS, INC.

2015 INCENTIVE AWARD PLAN

(AS AMENDED AND RESTATED EFFECTIVE DECEMBER 14, 2022)

I. PURPOSE

The Plan's purpose is to enhance the Company's ability to attract, retain and motivate persons who make (or are expected to make) important contributions to the Company by providing these individuals with equity ownership opportunities. Capitalized terms used in the Plan are defined in Section XI. This Plan constitutes an amendment and restatement of the Seres Therapeutics, Inc. 2015 Incentive Award Plan.

II. ELIGIBILITY

Service Providers are eligible to be granted Awards under the Plan, subject to the limitations described herein.

III. ADMINISTRATION AND DELEGATION

(a) Administration. The Plan is administered by the Administrator. The Administrator has authority to determine which Service Providers receive Awards, grant Awards and set Award terms and conditions, subject to the conditions and limitations in the Plan. The Administrator also has the authority to take all actions and make all determinations under the Plan, to interpret the Plan and Award Agreements and to adopt, amend and repeal Plan administrative rules, guidelines and practices as it deems advisable. The Administrator may correct defects and ambiguities, supply omissions and reconcile inconsistencies in the Plan or any Award as it deems necessary or appropriate to administer the Plan and any Awards. The Administrator's determinations under the Plan are in its sole discretion and will be final and binding on all persons having or claiming any interest in the Plan or any Award.

(b) Appointment of Committees. To the extent Applicable Laws permit, the Board may delegate any or all of its powers under the Plan to one or more Committees. The Board may abolish any Committee or re-vest in itself any previously delegated authority at any time.

IV. STOCK AVAILABLE FOR AWARDS

(a) Number of Shares. Subject to adjustment under Section VIII and the terms of this Section IV, Awards may be made under the Plan covering up to the Overall Share Limit. As of the Plan's effective date under Section X(c), the Company will cease granting awards under the Prior Plans; however, Prior Plan Awards will remain subject to the terms of the applicable Prior Plan. Shares issued under the Plan may consist of authorized but unissued Shares, Shares purchased on the open market or treasury Shares.

(b) Share Recycling. If all or any part of an Award or Prior Plan Award expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, in any case, in a manner that results in the Company acquiring Shares covered by the Award or Prior Plan Award at a price not greater than the price (as adjusted to reflect any Equity Restructuring) paid by the Participant for such Shares or not issuing any Shares covered by the Award or Prior Plan Award, the unused Shares covered by the Award or Prior Plan Award will, as applicable, become or again be available for Award grants under the Plan. Further, Shares delivered (either by actual delivery or attestation) to the Company by a Participant to satisfy the applicable exercise or purchase price of an Award or Prior Plan Award and/or to satisfy any applicable tax withholding obligation (including Shares retained by the

Company from the Award or Prior Plan Award being exercised or purchased and/or creating the tax obligation) will, as applicable, become or again be available for Award grants under the Plan. The payment of Dividend Equivalents in cash in conjunction with any outstanding Awards or Prior Plan Awards shall not count against the Overall Share Limit.

(c) Incentive Stock Option Limitations. Notwithstanding anything to the contrary herein, no more than 17,200,000 Shares may be issued pursuant to the exercise of Incentive Stock Options.

(d) Substitute Awards. In connection with an entity's merger or consolidation with the Company or the Company's acquisition of an entity's property or stock, the Administrator may grant Awards in substitution for any options or other stock or stock-based awards granted before such merger or consolidation by such entity or its affiliate. Substitute Awards may be granted on such terms as the Administrator deems appropriate, notwithstanding limitations on Awards in the Plan. Substitute Awards will not count against the Overall Share Limit, except that Shares acquired by exercise of substitute Incentive Stock Options will count against the maximum number of Shares that may be issued pursuant to the exercise of Incentive Stock Options under the Plan.

(e) Non-Employee Director Compensation. Notwithstanding any provision to the contrary in the Plan, the Administrator may establish compensation for non-employee Directors from time to time, subject to the limitations in the Plan. The Administrator will from time to time determine the terms, conditions and amounts of all such non-employee Director compensation in its discretion and pursuant to the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, provided that the sum of any cash compensation, or other compensation, and the value (determined as of the grant date in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, or any successor thereto) of Awards granted to a non-employee Director as compensation for services as a non-employee Director during any fiscal year of the Company may not exceed $700,000. The Administrator may make exceptions to this limit for individual non-employee Directors in extraordinary circumstances, as the Administrator may determine in its discretion, provided that the non-employee Director receiving such additional compensation may not participate in the decision to award such compensation or in other compensation decisions involving non-employee Directors.

V. Stock Options and Stock Appreciation Rights

(a) General. The Administrator may grant Options or Stock Appreciation Rights to Service Providers subject to the limitations in the Plan, including Section IX(i) with respect to Incentive Stock Options. The Administrator will determine the number of Shares covered by each Option and Stock Appreciation Right, the exercise price of each Option and Stock Appreciation Right and the conditions and limitations applicable to the exercise of each Option and Stock Appreciation Right. A Stock Appreciation Right will entitle the Participant (or other person entitled to exercise the Stock Appreciation Right) to receive from the Company upon exercise of the exercisable portion of the Stock Appreciation Right an amount determined by multiplying the excess, if any, of the Fair Market Value of one Share on the date of exercise over the exercise price per Share of the Stock Appreciation Right by the number of Shares with respect to which the Stock Appreciation Right is exercised, subject to any limitations of the Plan or that the Administrator may impose and payable in cash, Shares valued at Fair Market Value or a combination of the two as the Administrator may determine or provide in the Award Agreement.

(b) Exercise Price. The Administrator will establish each Option's and Stock Appreciation Right's exercise price and specify the exercise price in the Award Agreement. The exercise price will not be less than 100% of the Fair Market Value on the grant date of the Option or Stock Appreciation Right.

(c) Duration of Options. Each Option or Stock Appreciation Right will be exercisable at such times and as specified in the Award Agreement, provided that the term of an Option or Stock Appreciation Right will not exceed ten years.

(d) Exercise. Options and Stock Appreciation Rights may be exercised by delivering to the Company a written notice of exercise, in a form the Administrator approves (which may be electronic), signed by the person authorized to exercise the Option or Stock Appreciation Right, together with, as applicable, payment in full (i) as specified in Section V(e) for the number of Shares for which the Award is exercised and (ii) as specified in Section IX(e) for any applicable taxes. Unless the Administrator otherwise determines, an Option or Stock Appreciation Right may not be exercised for a fraction of a Share.

(e) Payment Upon Exercise. The exercise price of an Option must be paid in cash, wire transfer of immediately available funds or by check payable to the order of the Company or, subject to Section X(h), any Company insider trading policy (including blackout periods) and Applicable Laws, by:

(i) if there is a public market for Shares at the time of exercise, unless the Administrator otherwise determines, (A) delivery (including telephonically to the extent permitted by the Company) of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to pay the exercise price, or (B) the Participant's delivery to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to pay the exercise price; provided that such amount is paid to the Company at such time as may be required by the Administrator;

(ii) to the extent permitted by the Administrator, delivery (either by actual delivery or attestation) of Shares owned by the Participant valued at their Fair Market Value;

(iii) to the extent permitted by the Administrator, surrendering Shares then issuable upon the Option's exercise valued at their Fair Market Value on the exercise date;

(iv) to the extent permitted by the Administrator, delivery of a promissory note or any other property that the Administrator determines is good and valuable consideration; or

(v) any combination of the above permitted payment forms (including cash, wire transfer or check).

VI. Restricted Stock; Restricted Stock Units

(a) General. The Administrator may grant Restricted Stock, or the right to purchase Restricted Stock, to any Service Provider, subject to the Company's right to repurchase all or part of such shares at their issue price or other stated or formula price from the Participant (or to require forfeiture of such shares) if conditions the Administrator specifies in the Award Agreement are not satisfied before the end of the applicable restriction period or periods that the Administrator establishes for such Award. In addition, the Administrator may grant to Service Providers Restricted Stock Units, which may be subject to vesting and forfeiture conditions during the applicable restriction period or periods, as set forth in an Award Agreement. The Administrator will determine and set forth in the Award Agreement the terms and conditions for each Restricted Stock and Restricted Stock Unit Award, subject to the conditions and limitations contained in the Plan.

(b) Restricted Stock.

(i) *Dividends*. Participants holding shares of Restricted Stock will be entitled to all ordinary cash dividends paid with respect to such shares, unless the Administrator provides otherwise in the Award Agreement. In addition, unless the Administrator provides otherwise, if any dividends or distributions are paid in Shares, or consist of a dividend or distribution to holders of Common Stock of property other than an ordinary cash dividend, the Shares or other property will be subject to the same restrictions on transferability and forfeitability as the shares of Restricted Stock with respect to which they were paid.

(ii) *Stock Certificates.* The Company may require that the Participant deposit in escrow with the Company (or its designee) any stock certificates issued in respect of shares of Restricted Stock, together with a stock power endorsed in blank.

(c) Restricted Stock Units.

(i) *Settlement.* The Administrator may provide that settlement of Restricted Stock Units will occur upon or as soon as reasonably practicable after the Restricted Stock Units vest or will instead be deferred, on a mandatory basis or at the Participant's election, in a manner intended to comply with Section 409A.

(ii) *Stockholder Rights.* A Participant will have no rights of a stockholder with respect to Shares subject to any Restricted Stock Unit unless and until the Shares are delivered in settlement of the Restricted Stock Unit.

(iii) *Dividend Equivalents.* If the Administrator provides, a grant of Restricted Stock Units may provide a Participant with the right to receive Dividend Equivalents. Dividend Equivalents may be paid currently or credited to an account for the Participant, settled in cash or Shares and subject to the same restrictions on transferability and forfeitability as the Restricted Stock Units with respect to which the Dividend Equivalents are granted and subject to other terms and conditions as set forth in the Award Agreement.

VII. Other Stock or Cash Based Awards

Other Stock or Cash Based Awards may be granted to Participants, including Awards entitling Participants to receive Shares to be delivered in the future and including annual or other periodic or long-term cash bonus awards (whether based on specified Performance Criteria or otherwise), in each case subject to any conditions and limitations in the Plan. Such Other Stock or Cash Based Awards will also be available as a payment form in the settlement of other Awards, as standalone payments and as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock or Cash Based Awards may be paid in Shares, cash or other property, as the Administrator determines. Subject to the provisions of the Plan, the Administrator will determine the terms and conditions of each Other Stock or Cash Based Award, including any purchase price, performance goal (which may be based on the Performance Criteria), transfer restrictions, and vesting conditions, which will be set forth in the applicable Award Agreement.

VIII. Adjustments for Changes in Common Stock and Certain Other Events

(a) Equity Restructuring. In connection with any Equity Restructuring, notwithstanding anything to the contrary in this Section VIII, the Administrator will equitably adjust each outstanding Award as it deems appropriate to reflect the Equity Restructuring, which may include adjusting the number and type of securities subject to each outstanding Award and/or the Award's exercise price or grant price (if applicable), granting new Awards to Participants, and making a cash payment to Participants. The adjustments provided

under this Section VIII(a) will be nondiscretionary and final and binding on the affected Participant and the Company; provided that the Administrator will determine whether an adjustment is equitable.

(b) Corporate Transactions. In the event of any dividend or other distribution (whether in the form of cash, Common Stock, other securities, or other property), reorganization, merger, consolidation, combination, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of all or substantially all of the assets of the Company, or sale or exchange of Common Stock or other securities of the Company, Change in Control, issuance of warrants or other rights to purchase Common Stock or other securities of the Company, other similar corporate transaction or event, other unusual or nonrecurring transaction or event affecting the Company or its financial statements or any change in any Applicable Laws or accounting principles, the Administrator, on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event (except that action to give effect to a change in Applicable Law or accounting principles may be made within a reasonable period of time after such change) and either automatically or upon the Participant's request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to (x) prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any Award granted or issued under the Plan, (y) to facilitate such transaction or event or (z) give effect to such changes in Applicable Laws or accounting principles:

(i) To provide for the cancellation of any such Award in exchange for either an amount of cash or other property with a value equal to the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights under the vested portion of such Award, as applicable; provided that, if the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights, in any case, is equal to or less than zero, then the Award may be terminated without payment;

(ii) To provide that such Award shall vest and, to the extent applicable, be exercisable as to all shares covered thereby, notwithstanding anything to the contrary in the Plan or the provisions of such Award;

(iii) To provide that such Award be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by awards covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and/or applicable exercise or purchase price, in all cases, as determined by the Administrator;

(iv) To make adjustments in the number and type of shares of Common Stock (or other securities or property) subject to outstanding Awards and/or with respect to which Awards may be granted under the Plan (including, but not limited to, adjustments of the limitations in Section IV hereof on the maximum number and kind of shares which may be issued) and/or in the terms and conditions of (including the grant or exercise price), and the criteria included in, outstanding Awards;

(v) To replace such Award with other rights or property selected by the Administrator; and/or

(vi) To provide that the Award will terminate and cannot vest, be exercised or become payable after the applicable event.

(c) Administrative Stand Still. In the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other extraordinary transaction or change affecting the Shares or the share price of Common Stock, including any Equity Restructuring or any securities offering or other

similar transaction, for administrative convenience, the Administrator may refuse to permit the exercise of any Award for up to sixty days before or after such transaction.

(d) General. Except as expressly provided in the Plan or the Administrator's action under the Plan, no Participant will have any rights due to any subdivision or consolidation of Shares of any class, dividend payment, increase or decrease in the number of Shares of any class or dissolution, liquidation, merger, or consolidation of the Company or other corporation. Except as expressly provided with respect to an Equity Restructuring under Section VIII(a) above or the Administrator's action under the Plan, no issuance by the Company of Shares of any class, or securities convertible into Shares of any class, will affect, and no adjustment will be made regarding, the number of Shares subject to an Award or the Award's grant or exercise price. The existence of the Plan, any Award Agreements and the Awards granted hereunder will not affect or restrict in any way the Company's right or power to make or authorize (i) any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, (ii) any merger, consolidation dissolution or liquidation of the Company or sale of Company assets or (iii) any sale or issuance of securities, including securities with rights superior to those of the Shares or securities convertible into or exchangeable for Shares. The Administrator may treat Participants and Awards (or portions thereof) differently under this Section VIII.

(e) Change in Control. Notwithstanding Section VIII(b) above, if a Change in Control occurs and Awards are not continued, converted, assumed, or replaced with a comparable award (as determined by the Administrator) by (i) the Company or (ii) a successor entity or its parent or subsidiary (an "***Assumption***"), and provided that the Participant has not had a Termination of Service, then immediately prior to the Change in Control, such Awards (other than any Award that is regularly scheduled to vest based on the attainment of Performance Criteria or other performance-based vesting conditions) will become fully vested, exercisable and/or payable, as applicable, and all forfeiture, repurchase and other restrictions on such Awards will lapse, in which case, such Awards will be canceled upon the consummation of the Change in Control in exchange for the right to receive the Change in Control consideration payable to other holders of Shares, which may be on such terms and conditions as apply generally to holders of Shares under the Change in Control documents (including, without limitation, any escrow, earn-out or other deferred consideration provisions) or such other terms and conditions as the Administrator may provide, and determined by reference to the number of Shares subject to such Awards and net of any applicable exercise price; provided that to the extent that any Awards constitute "nonqualified deferred compensation" that may not be paid upon the Change in Control under Section 409A without the imposition of taxes thereon under Section 409A, the timing of such payments shall be governed by the applicable Award Agreement (subject to any deferred consideration provisions applicable under the Change in Control documents); and provided, further, that if the amount to which a Participant would be entitled upon the settlement or exercise of such Award at the time of the Change in Control is equal to or less than zero, then such Award may be terminated without payment. An Award will be considered replaced with a comparable award if the Award is exchanged for an amount of cash or other property with a value equal to the amount that could have been obtained upon the settlement of such Award in such Change in Control (as determined by the Administrator), even if such cash or other property payable with respect to the unvested portion of such Award remains subject to similar vesting provisions following such Change in Control. Notwithstanding the foregoing, the Administrator will have full and final authority to determine whether an Assumption of an Award has occurred in connection with a Change in Control.

IX. General Provisions Applicable to Awards.

(a) Transferability. Except as the Administrator may determine or provide in an Award Agreement or otherwise for Awards other than Incentive Stock Options, Awards may not be sold, assigned, transferred, pledged or otherwise encumbered, either voluntarily or by operation of law, except by will or the laws of descent and distribution, or, subject to the Administrator's consent, pursuant to a domestic relations order,

and, during the life of the Participant, will be exercisable only by the Participant. References to a Participant, to the extent relevant in the context, will include references to a Participant's authorized transferee that the Administrator specifically approves.

(b) Documentation. Each Award will be evidenced in an Award Agreement, which may be written or electronic, as the Administrator determines. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) Discretion. Except as the Plan otherwise provides, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award to a Participant need not be identical, and the Administrator need not treat Participants or Awards (or portions thereof) uniformly.

(d) Termination of Status. The Administrator will determine how the disability, death, retirement, authorized leave of absence or any other change or purported change in a Participant's Service Provider status affects an Award and the extent to which, and the period during which, the Participant, the Participant's legal representative, conservator, guardian or Designated Beneficiary may exercise rights under the Award, if applicable.

(e) Withholding. Each Participant must pay the Company, or make provision satisfactory to the Administrator for payment of, any taxes required by law to be withheld in connection with such Participant's Awards by the date of the event creating the tax liability. The Company may deduct an amount sufficient to satisfy such tax obligations based on the minimum statutory withholding rates from any payment of any kind otherwise due to a Participant. Participants may satisfy such tax obligations in cash, by wire transfer of immediately available funds, by check made payable to the order of the Company, or subject to Section X(h) and any Company insider trading policy (including blackout periods), (i) to the extent permitted by the Administrator, in whole or in part by delivery of Shares, including Shares retained from the Award creating the tax obligation, valued at their Fair Market Value, (ii) if there is a public market for Shares at the time the tax obligations are satisfied, unless the Administrator otherwise determines, (A) delivery (including telephonically to the extent permitted by the Company) of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to satisfy the tax obligations, or (B) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to satisfy the tax withholding; provided that such amount is paid to the Company at such time as may be required by the Administrator, or (iii) any combination of the foregoing permitted payment forms (including cash, wire transfer or check). If any tax withholding obligation will be satisfied under clause (i) of the immediately preceding sentence by the Company's retention of Shares from the Award creating the tax obligation and there is a public market for Shares at the time the tax obligation is satisfied, the Company may elect to instruct any brokerage firm determined acceptable to the Company for such purpose to sell on the applicable Participant's behalf some or all of the Shares retained and to remit the proceeds of the sale to the Company or its designee, and each Participant's acceptance of an Award under the Plan will constitute the Participant's authorization to the Company and instruction and authorization to such brokerage firm to complete the transactions described in this sentence.

(f) Amendment of Award; Repricing. The Administrator may amend, modify or terminate any outstanding Award, including by substituting another Award of the same or a different type, changing the exercise or settlement date, and converting an Incentive Stock Option to a Non-Qualified Stock Option. The Participant's consent to such action will be required unless (i) the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Award, or (ii) the change is permitted under Section VIII or pursuant to Section X(f). Notwithstanding the foregoing or anything in the Plan to the contrary, the Administrator may, without the approval of the stockholders of the Company, reduce the exercise price per share of outstanding Options or Stock Appreciation Rights or cancel

outstanding Options or Stock Appreciation Rights in exchange for cash, other Awards or Options or Stock Appreciation Rights with an exercise price per share that is less than the exercise price per share of the original Options or Stock Appreciation Rights.

(g) Conditions on Delivery of Stock. The Company will not be obligated to deliver any Shares under the Plan or remove restrictions from Shares previously delivered under the Plan until (i) all Award conditions have been met or removed to the Company's satisfaction, (ii) as determined by the Company, all other legal matters regarding the issuance and delivery of such Shares have been satisfied, including any applicable securities laws and stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Administrator deems necessary or appropriate to satisfy any Applicable Laws. The Company's inability to obtain authority from any regulatory body having jurisdiction, which the Administrator determines is necessary to the lawful issuance and sale of any securities, will relieve the Company of any liability for failing to issue or sell such Shares as to which such requisite authority has not been obtained.

(h) Acceleration. The Administrator may at any time provide that any Award will become immediately vested and fully or partially exercisable, free of some or all restrictions or conditions, or otherwise fully or partially realizable.

(i) Additional Terms of Incentive Stock Options. The Administrator may grant Incentive Stock Options only to employees of the Company, any of its present or future parent or subsidiary corporations, as defined in Sections 424(e) or (f) of the Code, respectively, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code. If an Incentive Stock Option is granted to a Greater Than 10% Stockholder, the exercise price will not be less than 110% of the Fair Market Value on the Option's grant date, and the term of the Option will not exceed five years. All Incentive Stock Options will be subject to and construed consistently with Section 422 of the Code. By accepting an Incentive Stock Option, the Participant agrees to give prompt notice to the Company of dispositions or other transfers (other than in connection with a Change in Control) of Shares acquired under the Option made within (i) two years from the grant date of the Option or (ii) one year after the transfer of such Shares to the Participant, specifying the date of the disposition or other transfer and the amount the Participant realized, in cash, other property, assumption of indebtedness or other consideration, in such disposition or other transfer. Neither the Company nor the Administrator will be liable to a Participant, or any other party, if an Incentive Stock Option fails or ceases to qualify as an "incentive stock option" under Section 422 of the Code . Any Incentive Stock Option or portion thereof that fails to qualify as an "incentive stock option" under Section 422 of the Code for any reason, including becoming exercisable with respect to Shares having a fair market value exceeding the $100,000 limitation under Treasury Regulation Section 1.422-4, will be a Non-Qualified Stock Option.

X. **Miscellaneous.**

(a) No Right to Employment or Other Status. No person will have any claim or right to be granted an Award, and the grant of an Award will not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan or any Award, except as expressly provided in an Award Agreement.

(b) No Rights as Stockholder; Certificates. Subject to the Award Agreement, no Participant or Designated Beneficiary will have any rights as a stockholder with respect to any Shares to be distributed under an Award until becoming the record holder of such Shares. Notwithstanding any other provision of the Plan, unless the Administrator otherwise determines or Applicable Laws require, the Company will not be required to deliver to any Participant certificates evidencing Shares issued in connection with any Award

and instead such Shares may be recorded in the books of the Company (or, as applicable, its transfer agent or stock plan administrator). The Company may place legends on stock certificates issued under the Plan that the Administrator deems necessary or appropriate to comply with Applicable Laws.

(c) Effective Date and Term of Plan. The Plan, as amended and restated, shall become effective as of the Amendment Date. The Plan will remain in effect until the tenth anniversary of the day prior to the Public Trading Date, unless earlier terminated by the Board. No Awards may be granted under the Plan during any suspension period or after Plan termination. Notwithstanding anything in the Plan to the contrary, an Incentive Stock Option may not be granted under the Plan after ten years from the earlier of (i) the date the Board adopted the Plan or (ii) the date the Company's stockholders approved the Plan, but Awards previously granted may extend beyond that date in accordance with the Plan.

(d) Amendment of Plan. The Administrator may amend, suspend or terminate the Plan at any time; provided that no amendment, other than an increase to the Overall Share Limit, may materially and adversely affect any Award outstanding at the time of such amendment without the affected Participant's consent. Awards outstanding at the time of any Plan suspension or termination will continue to be governed by the Plan and the Award Agreement, as in effect before such suspension or termination. The Board will obtain stockholder approval of any Plan amendment to the extent necessary to comply with Applicable Laws.

(e) Provisions for Foreign Participants. The Administrator may modify Awards granted to Participants who are foreign nationals or employed outside the United States or establish subplans or procedures under the Plan to address differences in laws, rules, regulations or customs of such foreign jurisdictions with respect to tax, securities, currency, employee benefit or other matters.

(f) Section 409A.

(i) *General.* The Company intends that all Awards be structured to comply with, or be exempt from, Section 409A, such that no adverse tax consequences, interest, or penalties under Section 409A apply. Notwithstanding anything in the Plan or any Award Agreement to the contrary, the Administrator may, without a Participant's consent, amend this Plan or Awards, adopt policies and procedures, or take any other actions (including amendments, policies, procedures and retroactive actions) as are necessary or appropriate to preserve the intended tax treatment of Awards, including any such actions intended to (A) exempt this Plan or any Award from Section 409A, or (B) comply with Section 409A, including regulations, guidance, compliance programs and other interpretative authority that may be issued after an Award's grant date. The Company makes no representations or warranties as to an Award's tax treatment under Section 409A or otherwise. The Company will have no obligation under this Section X(f) or otherwise to avoid the taxes, penalties or interest under Section 409A with respect to any Award and will have no liability to any Participant or any other person if any Award, compensation or other benefits under the Plan are determined to constitute noncompliant "nonqualified deferred compensation" subject to taxes, penalties or interest under Section 409A.

(ii) *Separation from Service.* If an Award constitutes "nonqualified deferred compensation" under Section 409A, any payment or settlement of such Award upon a termination of a Participant's Service Provider relationship will, to the extent necessary to avoid taxes under Section 409A, be made only upon the Participant's "separation from service" (within the meaning of Section 409A), whether such "separation from service" occurs upon or after the termination of the Participant's Service Provider relationship. For purposes of this Plan or any Award Agreement relating to any such payments or benefits, references to a "termination," "termination of employment" or like terms means a "separation from service."

(iii) *Payments to Specified Employees.* Notwithstanding any contrary provision in the Plan or any Award Agreement, any payment(s) of "nonqualified deferred compensation" required to be made under an Award to a "specified employee" (as defined under Section 409A and as the Administrator determines) due to his or her "separation from service" will, to the extent necessary to avoid taxes under Section 409A(a)(2)(B)(i) of the Code, be delayed for the six-month period immediately following such "separation from service" (or, if earlier, until the specified employee's death) and will instead be paid (as set forth in the Award Agreement) on the day immediately following such six-month period or as soon as administratively practicable thereafter (without interest). Any payments of "nonqualified deferred compensation" under such Award payable more than six months following the Participant's "separation from service" will be paid at the time or times the payments are otherwise scheduled to be made.

(g) Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, other employee or agent of the Company or any Subsidiary will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan or any Award, and such individual will not be personally liable with respect to the Plan because of any contract or other instrument executed in his or her capacity as an Administrator, director, officer, other employee or agent of the Company or any Subsidiary. The Company will indemnify and hold harmless each director, officer, other employee and agent of the Company or any Subsidiary that has been or will be granted or delegated any duty or power relating to the Plan's administration or interpretation, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Administrator's approval) arising from any act or omission concerning this Plan unless arising from such person's own fraud or bad faith.

(h) Lock-Up Period. The Company may, at the request of any underwriter representative or otherwise, in connection with registering the offering of any Company securities under the Securities Act, prohibit Participants from, directly or indirectly, selling or otherwise transferring any Shares or other Company securities during a period of up to one hundred eighty days following the effective date of a Company registration statement filed under the Securities Act, or such longer period as determined by the underwriter.

(i) Data Privacy. As a condition for receiving any Award, each Participant explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of personal data as described in this paragraph by and among the Company and its Subsidiaries and affiliates exclusively for implementing, administering and managing the Participant's participation in the Plan. The Company and its Subsidiaries and affiliates may hold certain personal information about a Participant, including the Participant's name, address and telephone number; birthdate; social security, insurance number or other identification number; salary; nationality; job title(s); any Shares held in the Company or its Subsidiaries and affiliates; and Award details, to implement, manage and administer the Plan and Awards (the "***Data***"). The Company and its Subsidiaries and affiliates may transfer the Data amongst themselves as necessary to implement, administer and manage a Participant's participation in the Plan, and the Company and its Subsidiaries and affiliates may transfer the Data to third parties assisting the Company with Plan implementation, administration and management. These recipients may be located in the Participant's country, or elsewhere, and the Participant's country may have different data privacy laws and protections than the recipients' country. By accepting an Award, each Participant authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, to implement, administer and manage the Participant's participation in the Plan, including any required Data transfer to a broker or other third party with whom the Company or the Participant may elect to deposit any Shares. The Data related to a Participant will be held only as long as necessary to implement, administer, and manage the Participant's participation in the Plan. A Participant may, at any time, view the Data that the Company holds regarding such Participant, request additional information about the storage and processing of the Data regarding such Participant, recommend any necessary corrections to the Data regarding the Participant or refuse or

withdraw the consents in this Section X(i) in writing, without cost, by contacting the local human resources representative. The Company may cancel Participant's ability to participate in the Plan and, in the Administrator's discretion, the Participant may forfeit any outstanding Awards if the Participant refuses or withdraws the consents in this Section X(i). For more information on the consequences of refusing or withdrawing consent, Participants may contact their local human resources representative.

(j) Severability. If any portion of the Plan or any action taken under it is held illegal or invalid for any reason, the illegality or invalidity will not affect the remaining parts of the Plan, and the Plan will be construed and enforced as if the illegal or invalid provisions had been excluded, and the illegal or invalid action will be null and void.

(k) Governing Documents. If any contradiction occurs between the Plan and any Award Agreement or other written agreement between a Participant and the Company (or any Subsidiary) that the Administrator has approved, the Plan will govern, unless it is expressly specified in such Award Agreement or other written document that a specific provision of the Plan will not apply.

(l) Governing Law. The Plan and all Awards will be governed by and interpreted in accordance with the laws of the State of Delaware, disregarding any state's choice-of-law principles requiring the application of a jurisdiction's laws other than the State of Delaware.

(m) Claw-back Provisions. All Awards (including any proceeds, gains or other economic benefit the Participant actually or constructively receives upon receipt or exercise of any Award or the receipt or resale of any Shares underlying the Award) will be subject to any Company claw-back policy, including any claw-back policy adopted to comply with Applicable Laws (including the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder) as set forth in such claw-back policy or the Award Agreement.

(n) Titles and Headings. The titles and headings in the Plan are for convenience of reference only and, if any conflict, the Plan's text, rather than such titles or headings, will control.

(o) Conformity to Securities Laws. Participant acknowledges that the Plan is intended to conform to the extent necessary with Applicable Laws. Notwithstanding anything herein to the contrary, the Plan and all Awards will be administered only in conformance with Applicable Laws. To the extent Applicable Laws permit, the Plan and all Award Agreements will be deemed amended as necessary to conform to Applicable Laws.

(p) Relationship to Other Benefits. No payment under the Plan will be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare or other benefit plan of the Company or any Subsidiary except as expressly provided in writing in such other plan or an agreement thereunder.

(q) Broker-Assisted Sales. In the event of a broker-assisted sale of Shares in connection with the payment of amounts owed by a Participant under or with respect to the Plan or Awards, including amounts to be paid under the final sentence of Section IX(e): (a) any Shares to be sold through the broker-assisted sale will be sold on the day the payment first becomes due, or as soon thereafter as practicable; (b) such Shares may be sold as part of a block trade with other Participants in the Plan in which all participants receive an average price; (c) the applicable Participant will be responsible for all broker's fees and other costs of sale, and by accepting an Award, each Participant agrees to indemnify and hold the Company harmless from any losses, costs, damages, or expenses relating to any such sale; (d) to the extent the Company or its designee receives proceeds of such sale that exceed the amount owed, the Company will pay such excess in cash to the applicable Participant as soon as reasonably practicable; (e) the Company

and its designees are under no obligation to arrange for such sale at any particular price; and (f) in the event the proceeds of such sale are insufficient to satisfy the Participant's applicable obligation, the Participant may be required to pay immediately upon demand to the Company or its designee an amount in cash sufficient to satisfy any remaining portion of the Participant's obligation.

XI. DEFINITIONS

As used in the Plan, the following words and phrases will have the following meanings:

(a) "***Administrator***" means the Board or a Committee to the extent that the Board's powers or authority under the Plan have been delegated to such Committee.

(b) "***Amendment Date***" means December 14, 2022.

(c) "***Applicable Laws***" means the requirements relating to the administration of equity incentive plans under U.S. federal and state securities, tax and other applicable laws, rules and regulations, the applicable rules of any stock exchange or quotation system on which the Common Stock is listed or quoted and the applicable laws and rules of any foreign country or other jurisdiction where Awards are granted.

(d) "***Award***" means, individually or collectively, a grant under the Plan of Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units or Other Stock or Cash Based Awards.

(e) "***Award Agreement***" means a written agreement evidencing an Award, which may be electronic, that contains such terms and conditions as the Administrator determines, consistent with and subject to the terms and conditions of the Plan.

(f) "***Board***" means the Board of Directors of the Company.

(g) "***Change in Control***" means and includes each of the following:

(i) A transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission or a transaction or series of transactions that meets the requirements of clauses (A) and (B) of subsection (iii) below) whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than the Company, any of its Subsidiaries, an employee benefit plan maintained by the Company or any of its Subsidiaries or a "person" that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company's securities outstanding immediately after such acquisition; or

(ii) During any period of two consecutive years, individuals who, at the beginning of such period, constitute the Board together with any new Director(s) (other than a Director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in subsections (i) or (iii)) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the Directors then still in office who either were Directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or

(iii) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization,

or business combination or (y) a sale or other disposition of all or substantially all of the Company's assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:

(A) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the "***Successor Entity***")) directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction, and

(B) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be treated for purposes of this clause (B) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction.

Notwithstanding the foregoing, if a Change in Control constitutes a payment event with respect to any Award (or portion of any Award) that provides for the deferral of compensation that is subject to Section 409A, to the extent required to avoid the imposition of additional taxes under Section 409A, the transaction or event described in subsection (i), (ii) or (iii) with respect to such Award (or portion thereof) shall only constitute a Change in Control for purposes of the payment timing of such Award if such transaction also constitutes a "change in control event," as defined in Treasury Regulation Section 1.409A-3(i)(5).

The Administrator shall have full and final authority, which shall be exercised in its discretion, to determine conclusively whether a Change in Control has occurred pursuant to the above definition, the date of the occurrence of such Change in Control and any incidental matters relating thereto; provided that any exercise of authority in conjunction with a determination of whether a Change in Control is a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.

(h) "***Code***" means the Internal Revenue Code of 1986, as amended, and the regulations issued thereunder.

(i) "***Committee***" means one or more committees or subcommittees of the Board, which may include one or more Company directors or executive officers, to the extent Applicable Laws permit. To the extent required to comply with the provisions of Rule 16b-3, it is intended that each member of the Committee will be, at the time the Committee takes any action with respect to an Award that is subject to Rule 16b-3, a "non-employee director" within the meaning of Rule 16b-3; however, a Committee member's failure to qualify as a "non-employee director" within the meaning of Rule 16b-3 will not invalidate any Award granted by the Committee that is otherwise validly granted under the Plan.

(j) "***Common Stock***" means the common stock of the Company.

(k) "***Company***" means Seres Therapeutics, Inc., a Delaware corporation, or any successor.

(l) "***Consultant***" means any person, including any adviser, engaged by the Company or its parent or Subsidiary to render services to such entity if the consultant or adviser: (i) renders *bona fide* services to the Company; (ii) renders services not in connection with the offer or sale of securities in a capital-raising

transaction and does not directly or indirectly promote or maintain a market for the Company's securities; and (iii) is a natural person.

(m) "***Designated Beneficiary***" means the beneficiary or beneficiaries the Participant designates, in a manner the Administrator determines, to receive amounts due or exercise the Participant's rights if the Participant dies or becomes incapacitated. Without a Participant's effective designation, "Designated Beneficiary" will mean the Participant's estate.

(n) "***Director***" means a Board member.

(o) "***Disability***" means a permanent and total disability under Section 22(e)(3) of the Code, as amended.

(p) "***Dividend Equivalents***" means a right granted to a Participant under the Plan to receive the equivalent value (in cash or Shares) of dividends paid on Shares.

(q) "***Employee***" means any employee of the Company or its Subsidiaries.

(r) "***Equity Restructuring***" means a nonreciprocal transaction between the Company and its stockholders, such as a stock dividend, stock split, spin-off or recapitalization through a large, nonrecurring cash dividend, that affects the number or kind of Shares (or other Company securities) or the share price of Common Stock (or other Company securities) and causes a change in the per share value of the Common Stock underlying outstanding Awards.

(s) "***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

(t) "***Fair Market Value***" means, as of any date, the value of Common Stock determined as follows: (i) if the Common Stock is listed on any established stock exchange, its Fair Market Value will be the closing sales price for such Common Stock as quoted on such exchange for such date, or if no sale occurred on such date, the last day preceding such date during which a sale occurred, as reported in *The Wall Street Journal* or another source the Administrator deems reliable; (ii) if the Common Stock is not traded on a stock exchange but is quoted on a national market or other quotation system, the closing sales price on such date, or if no sales occurred on such date, then on the last date preceding such date during which a sale occurred, as reported in *The Wall Street Journal* or another source the Administrator deems reliable; or (iii) without an established market for the Common Stock, the Administrator will determine the Fair Market Value in its discretion.

(u) "***Greater Than 10% Stockholder***" means an individual then owning (within the meaning of Section 424(d) of the Code) more than 10% of the total combined voting power of all classes of stock of the Company or its parent or subsidiary corporation, as defined in Section 424(e) and (f) of the Code, respectively.

(v) "***Incentive Stock Option***" means an Option intended to qualify as an "incentive stock option" as defined in Section 422 of the Code.

(w) "***Non-Qualified Stock Option***" means an Option not intended or not qualifying as an Incentive Stock Option.

(x) "***Option***" means an option to purchase Shares.

(y) "***Other Stock or Cash Based Awards***" means cash awards, awards of Shares, and other awards valued wholly or partially by referring to, or are otherwise based on, Shares or other property.

(z) "***Overall Share Limit***" means the sum of (i) 2,200,000 Shares; (ii) any shares of Common Stock which are subject to Prior Plan Awards which become available for issuance under the Plan pursuant to Section IV(b) and (iii) an annual increase on the first day of each calendar year beginning January 1, 2016 and ending on and including January 1, 2025, equal to the lesser of (A) 4% of the aggregate number of shares of Common Stock outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of Shares as is determined by the Board.

(aa) "***Participant***" means a Service Provider who has been granted an Award.

(bb) "***Performance Criteria***" mean the criteria (and adjustments) that the Administrator may select for an Award to establish performance goals for a performance period, which may include the following: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization, and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including but not limited to gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on stockholders' equity; total stockholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease, peer group results, or market performance indicators or indices.

(cc) "***Plan***" means this 2015 Incentive Award Plan, as amended or restated from time to time.

(dd) "***Prior Plans***" means, collectively, the Seres Therapeutics, Inc. 2012 Stock Incentive Plan and any prior equity incentive plans of the Company or its predecessor.

(ee) "***Prior Plan Award***" means an award outstanding under the Prior Plans as of the Plan's effective date in Section X(c).

(ff) "***Public Trading Date***" means the first date upon which the Common Stock is listed (or approved for listing) upon notice of issuance on any securities exchange or designated (or approved for designation) upon notice of issuance as a national market security on an interdealer quotation system, or, if earlier, the date on which the Company becomes a "publicly held corporation" for purposes of Treasury Regulation Section 1.162-27(c)(1).

(gg) "***Restricted Stock***" means Shares awarded to a Participant under Section VI subject to certain vesting conditions and other restrictions.

(hh) "***Restricted Stock Unit***" means an unfunded, unsecured right to receive, on the applicable settlement date, one Share or an amount in cash or other consideration determined by the Administrator to be of equal value as of such settlement date, subject to certain vesting conditions and other restrictions.

(ii) "***Rule 16b-3***" means Rule 16b-3 promulgated under the Exchange Act.

(jj) "***Section 409A***" means Section 409A of the Code and all regulations, guidance, compliance programs and other interpretative authority thereunder.

(kk) "***Securities Act***" means the Securities Act of 1933, as amended.

(ll) "***Service Provider***" means an Employee, Consultant or Director.

(mm) "***Shares***" means shares of Common Stock.

(nn) "***Stock Appreciation Right***" means a stock appreciation right granted under Section V.

(oo) "***Subsidiary***" means any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities beginning with the Company if each of the entities other than the last entity in the unbroken chain beneficially owns, at the time of the determination, securities or interests representing at least 50% of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

(pp) "***Termination of Service***" means the date the Participant ceases to be a Service Provider.

* * * * *

SERES THERAPEUTICS, INC.
2015 INCENTIVE AWARD PLAN

STOCK OPTION GRANT NOTICE

Capitalized terms not specifically defined in this Stock Option Grant Notice (the "***Grant Notice***") have the meanings given to them in the 2015 Incentive Award Plan (as amended from time to time, the "***Plan***") of Seres Therapeutics, Inc. (the "***Company***").

The Company hereby grants to the participant listed below ("***Participant***") the stock option described in this Grant Notice (the "***Option***"), subject to the terms and conditions of the Plan and the Stock Option Agreement attached hereto as **Exhibit A** (the "***Agreement***"), both of which are incorporated into this Grant Notice by reference.

Participant:

Grant Date:

Exercise Price per Share:

Shares Subject to the Option:

Final Expiration Date:

Vesting Commencement Date:

Vesting Schedule: [To be specified in individual award agreements]

Type of Option ☐ Incentive Stock Option ☐ Non-Qualified Stock Option

By Participant's signature below, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

SERES THERAPEUTICS, INC.	**PARTICIPANT**
By: _____	
Print Name: _____	_____
Title: _____	

STOCK OPTION AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

ARTICLE I.
GENERAL

1.1 Grant of Option. Pursuant to the Grant Notice to which this Agreement is attached, the Company has granted to Participant the Option effective as of the grant date set forth in the Grant Notice (the "***Grant Date***").

1.2 Incorporation of Terms of Plan. The Option is subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

ARTICLE II.
PERIOD OF EXERCISABILITY

2.1 Commencement of Exercisability. The Option will vest and become exercisable according to the vesting schedule in the Grant Notice (the "***Vesting Schedule***") except that any fraction of a Share as to which the Option would be vested or exercisable will be accumulated and will vest and become exercisable only when a whole Share has accumulated. Notwithstanding anything in the Grant Notice, the Plan or this Agreement to the contrary, unless the Administrator otherwise determines, the Option will immediately expire and be forfeited as to any portion that is not vested and exercisable as of Participant's Termination of Service for any reason.

2.2 Duration of Exercisability. The Vesting Schedule is cumulative. Any portion of the Option which vests and becomes exercisable will remain vested and exercisable until the Option expires. The Option will be forfeited immediately upon its expiration.

2.3 Expiration of Option. The Option may not be exercised to any extent by anyone after, and will expire on, the first of the following to occur:

(a) The final expiration date in the Grant Notice;

(b) Except as the Administrator may otherwise approve, the expiration of three (3) months from the date of Participant's Termination of Service, unless Participant's Termination of Service is for Cause or by reason of Participant's death or Disability;

(c) Except as the Administrator may otherwise approve, the expiration of one (1) year from the date of Participant's Termination of Service by reason of Participant's death or Disability; and

(d) Except as the Administrator may otherwise approve, Participant's Termination of Service for Cause.

As used in this Agreement, "***Cause***" means (i) if Participant is a party to a written employment or consulting agreement with the Company or its Subsidiary in which the term "cause" is defined (a "***Relevant Agreement***"), "Cause" as defined in the Relevant Agreement, and (ii) if no Relevant Agreement exists, (A) the Administrator's determination that Participant failed to substantially perform Participant's duties (other than a failure resulting from Participant's Disability); (B) the Administrator's determination that Participant failed to carry out, or comply with any lawful and reasonable directive of the Board or Participant's immediate supervisor; (C) Participant's conviction, plea of no contest, plea of nolo contendere, or imposition of unadjudicated probation for any felony or indictable offense or crime involving moral turpitude; (D) Participant's unlawful use (including being under the influence) or possession of illegal drugs on the premises of the Company or any of its Subsidiaries or while performing

Participant's duties and responsibilities for the Company or any of its Subsidiaries; or (E) Participant's commission of an act of fraud, embezzlement, misappropriation, misconduct, or breach of fiduciary duty against the Company or any of its Subsidiaries.

ARTICLE III.
EXERCISE OF OPTION

3.1 Person Eligible to Exercise. During Participant's lifetime, only Participant may exercise the Option. After Participant's death, any exercisable portion of the Option may, prior to the time the Option expires, be exercised by Participant's Designated Beneficiary as provided in the Plan.

3.2 Partial Exercise. Any exercisable portion of the Option or the entire Option, if then wholly exercisable, may be exercised, in whole or in part, according to the procedures in the Plan at any time prior to the time the Option or portion thereof expires, except that the Option may only be exercised for whole Shares.

3.3 Tax Withholding.

(a) The Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the Option as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise issuable under the Option.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the Option, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the Option. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or exercise of the Option or the subsequent sale of Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure the Option to reduce or eliminate Participant's tax liability.

ARTICLE IV.
OTHER PROVISIONS

4.1 Adjustments. Participant acknowledges that the Option is subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.

4.2 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant (or, if Participant is then deceased, to the person entitled to exercise the Option) at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

4.3 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

4.4 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

4.5 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the

Company. Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

4.6 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement and the Option will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

4.7 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

4.8 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

4.9 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the Option, and rights no greater than the right to receive the Shares as a general unsecured creditor with respect to the Option, as and when exercised pursuant to the terms hereof.

4.10 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

4.11 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

4.12 Incentive Stock Options. If the Option is designated as an Incentive Stock Option:

(a) Participant acknowledges that to the extent the aggregate fair market value of shares (determined as of the time the option with respect to the shares is granted) with respect to which stock options intended to qualify as "incentive stock options" under Section 422 of the Code, including the Option, are exercisable for the first time by Participant during any calendar year exceeds $100,000 or if for any other reason such stock options do not qualify or cease to qualify for treatment as "incentive stock options" under Section 422 of the Code, such stock options (including the Option) will be treated as non-qualified stock options. Participant further acknowledges that the rule set forth in the preceding sentence will be applied by taking the Option and other stock options into account in the order in which they were granted, as determined under Section 422(d) of the Code. Participant also acknowledges that if the Option is exercised more than three (3) months after Participant's Termination of Service, other than by reason of death or disability, the Option will be taxed as a Non-Qualified Stock Option.

(b) Participant will give prompt written notice to the Company of any disposition or other transfer of any Shares acquired under this Agreement if such disposition or other transfer is made (a) within two (2) years from the Grant Date or (b) within one (1) year after the transfer of such Shares to Participant. Such notice will specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by Participant in such disposition or other transfer.

* * * * *

SERES THERAPEUTICS, INC.
2015 INCENTIVE AWARD PLAN

RESTRICTED STOCK UNIT GRANT NOTICE

Capitalized terms not specifically defined in this Restricted Stock Unit Grant Notice (the "***Grant Notice***") have the meanings given to them in the 2015 Incentive Award Plan (as amended from time to time, the "***Plan***") of Seres Therapeutics, Inc. (the "***Company***").

The Company hereby grants to the participant listed below ("***Participant***") the Restricted Stock Units described in this Grant Notice (the "***RSUs***"), subject to the terms and conditions of the Plan and the Restricted Stock Unit Agreement attached hereto as **Exhibit A** (the "***Agreement***"), both of which are incorporated into this Grant Notice by reference.

Participant:

Grant Date:

Number of RSUs:

Vesting Commencement Date:

Vesting Schedule: [To be specified in individual award agreements]

By Participant's signature below, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

SERES THERAPEUTICS, INC.	**PARTICIPANT**
By: _____	
Print Name: _____	_____
Title: _____	

RESTRICTED STOCK UNIT AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

ARTICLE I.
GENERAL

1.1 Award of RSUs and Dividend Equivalents.

(a) The Company has granted the RSUs to Participant effective as of the grant date set forth in the Grant Notice (the "***Grant Date***"). Each RSU represents the right to receive one Share or, at the option of the Company, an amount of cash, in either case, as set forth in this Agreement. Participant will have no right to the distribution of any Shares or payment of any cash until the time (if ever) the RSUs have vested.

(b) The Company hereby grants to Participant, with respect to each RSU, a Dividend Equivalent for ordinary cash dividends paid to substantially all holders of outstanding Shares with a record date after the Grant Date and prior to the date the applicable RSU is settled, forfeited or otherwise expires. Each Dividend Equivalent entitles Participant to receive the equivalent value of any such ordinary cash dividends paid on a single Share. The Company will establish a separate Dividend Equivalent bookkeeping account (a "***Dividend Equivalent Account***") for each Dividend Equivalent and credit the Dividend Equivalent Account (without interest) on the applicable dividend payment date with the amount of any such cash paid.

1.2 Incorporation of Terms of Plan. The RSUs are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

1.3 Unsecured Promise. The RSUs and Dividend Equivalents will at all times prior to settlement represent an unsecured Company obligation payable only from the Company's general assets.

ARTICLE II.
VESTING; FORFEITURE AND SETTLEMENT

2.1 Vesting; Forfeiture. The RSUs will vest according to the vesting schedule in the Grant Notice except that any fraction of an RSU that would otherwise be vested will be accumulated and will vest only when a whole RSU has accumulated. In the event of Participant's Termination of Service for any reason, all unvested RSUs will immediately and automatically be cancelled and forfeited, except as otherwise determined by the Administrator or provided in a binding written agreement between Participant and the Company. Dividend Equivalents (including any Dividend Equivalent Account balance) will vest or be forfeited, as applicable, upon the vesting or forfeiture of the RSU with respect to which the Dividend Equivalent (including the Dividend Equivalent Account) relates.

2.2 Settlement.

(a) RSUs and Dividend Equivalents (including any Dividend Equivalent Account balance) will be paid in Shares or cash at the Company's option as soon as administratively practicable after the vesting of the applicable RSU, but in no event more than sixty (60) days after the RSU's vesting date. Notwithstanding the foregoing, the Company may delay any payment under this Agreement that the Company reasonably determines would violate Applicable Law until the earliest date the Company reasonably determines the making of the payment will not cause such a violation (in accordance with Treasury Regulation Section 1.409A-2(b)(7)(ii)), provided the Company reasonably believes the delay will not result in the imposition of excise taxes under Section 409A.

(b) If an RSU is paid in cash, the amount of cash paid with respect to the RSU will equal the Fair Market Value of a Share on the day immediately preceding the payment date. If a Dividend Equivalent is paid

in Shares, the number of Shares paid with respect to the Dividend Equivalent will equal the quotient, rounded down to the nearest whole Share, of the Dividend Equivalent Account balance divided by the Fair Market Value of a Share on the day immediately preceding the payment date.

Article III.
TAXATION AND TAX WITHHOLDING

3.1 Representation. Participant represents to the Company that Participant has reviewed with Participant's own tax advisors the tax consequences of this Award and the transactions contemplated by the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

3.2 Tax Withholding.

(a) The Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the RSUs or Dividend Equivalents as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise issuable under the Award.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the RSUs and the Dividend Equivalents, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the RSUs or Dividend Equivalents. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the RSUs or the Dividend Equivalents or the subsequent sale of Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure the RSUs or Dividend Equivalents to reduce or eliminate Participant's tax liability.

(c) Mandatory Sell to Cover

(i) By accepting this Award, Participant understands and agrees that as a condition of the grant of the RSUs hereunder, Participant is required to, and hereby affirmatively elects to (the "Sell to Cover Election"), (1) sell that number of Shares determined in accordance with this Section 3.2(c) as may be necessary to satisfy all applicable withholding obligations with respect to any taxable event arising in connection with the RSUs and similarly sell such number of Shares as may be necessary to satisfy all applicable withholding obligations with respect to any other awards of restricted stock units granted to Participant under the Plan or any other equity incentive plans of the Company or its predecessor, and (2) to allow the transfer agent (together with any other party the Company determines necessary to execute the Sell to Cover Election, the "Agent") to remit the cash proceeds of such sale(s) to the Company. Furthermore, Participant directs the Company to make a cash payment equal to the required tax withholding from the cash proceeds of such sale(s) directly to the appropriate taxing authorities.

(ii) Participant hereby appoints the Agent as Participant's agent and authorizes the Agent to (1) sell on the open market at the then prevailing market price(s), on the Participant's behalf, as soon as practicable on or after the date the Shares are issued upon the vesting of the RSUs, that number (rounded up to the next whole number) of the Shares so issued necessary to generate proceeds to cover (x) any tax withholding obligations incurred with respect to such vesting or issuance and (y) all applicable fees and commissions due to, or required to be collected by, the Agent with respect thereto and (2) apply any remaining funds to Participant's tax withholding obligations hereunder. Participant hereby authorizes the Company and the Agent to cooperate and communicate with one another to determine the number of Shares that must be sold pursuant to this Section 3.2(c)(ii). Participant understands that the Agent may effect sales as provided in this Section 3.2(c)(ii) in one or more sales and that the average price for executions resulting from bunched orders will be assigned to Participant's account. In addition, Participant acknowledges that it may not be possible to sell Shares as provided by this Section 3.2(c)(ii) due to (1) a legal or contractual restriction applicable to Participant or the Agent, (2) a market disruption, or (3) rules

governing order execution priority on the national exchange where the Shares may be traded. Participant further agrees and acknowledges that in the event the sale of Shares would result in material adverse harm to the Company, as determined by the Company in its sole discretion, the Company may instruct the Agent not to sell Shares as provided by this Section 3.2(c)(ii). In the event of the Agent's inability to sell Shares, the Participant will continue to be responsible for the timely payment to the Company and/or its affiliates of all federal, state, local and foreign taxes that are required by applicable laws and regulations to be withheld, including but not limited to those amounts specified in this Section 3.2(c)(ii). Participant acknowledges that regardless of any other term or condition of this Section 3.2(c), the Agent will not be liable to Participant for (1) special, indirect, punitive, exemplary, or consequential damages, or incidental losses or damages of any kind, or (2) any failure to perform or for any delay in performance that results from a cause or circumstance that is beyond its reasonable control. Participant hereby agrees to execute and deliver to the Agent any other agreements or documents as the Agent reasonably deems necessary or appropriate to carry out the purposes and intent of this Section 3.2(c). The Agent is a third-party beneficiary of this Section 3.2(c). This Section 3.2(c) shall terminate not later than the date on which all tax withholding obligations arising in connection with the Award have been satisfied.

(iii) Participant has carefully reviewed this Section 3.2(c) and Participant hereby represents and warrants that on the date hereof he or she is not aware of any material, nonpublic information with respect to the Company or any securities of the Company, is not subject to any legal, regulatory or contractual restriction that would prevent the Agent from conducting sales, does not have, and will not attempt to exercise, authority, influence or control over any sales of Shares effected by the Agent pursuant to the Agreement, and is entering into the Agreement and this election to "sell to cover" in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1 (regarding trading of the Company's securities on the basis of material nonpublic information) under the Exchange Act. It is Participant's intent that this election to "sell to cover" comply with the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act and be interpreted to comply with the requirements of Rule 10b5-1(c) under the Exchange Act.

ARTICLE IV.
OTHER PROVISIONS

4.1 Adjustments. Participant acknowledges that the RSUs, the Shares subject to the RSUs and the Dividend Equivalents are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.

4.2 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

4.3 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

4.4 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

4.5 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company.

Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

4.6 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement, the RSUs and the Dividend Equivalents will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

4.7 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

4.8 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

4.9 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the RSUs and Dividend Equivalents, and rights no greater than the right to receive cash or the Shares as a general unsecured creditor with respect to the RSUs and Dividend Equivalents, as and when settled pursuant to the terms of this Agreement.

4.10 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

4.11 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

* * * * *

SERES THERAPEUTICS, INC.
2022 EMPLOYMENT INDUCEMENT AWARD PLAN

1.***Purpose***

The Plan's purpose is to enhance the Company's ability to attract, retain and motivate persons who are expected to make important contributions to the Company by providing these individuals with equity ownership opportunities. Capitalized terms used in the Plan are defined in Section 11.

2.***Eligibility***

Eligible Individuals are eligible to be granted Awards under the Plan, subject to the limitations described herein.

3.***Administration and Delegation***

(a) Administration. The Plan is administered by the Administrator. The Administrator has authority to determine which Eligible Individuals receive Awards, grant Awards and set Award terms and conditions, subject to the conditions and limitations in the Plan. The Administrator also has the authority to take all actions and make all determinations under the Plan, to interpret the Plan and Award Agreements and to adopt, amend and repeal Plan administrative rules, guidelines and practices as it deems advisable. The Administrator may correct defects and ambiguities, supply omissions and reconcile inconsistencies in the Plan or any Award as it deems necessary or appropriate to administer the Plan and any Awards. The Administrator may adopt procedures from time to time that are intended to ensure that an individual is an Eligible Individual prior to the granting of any Awards to such individual (including without limitation a requirement that each such individual certify to the Company prior to the receipt of an Award that he or she is not currently employed by the Company or a Subsidiary and, if previously so employed, has had a bona fide period of interruption of employment, and that the grant of Awards is an inducement material to the Eligible Individual's agreement to enter into employment with the Company or a Subsidiary). The Administrator's determinations under the Plan are in its sole discretion and will be final and binding on all persons having or claiming any interest in the Plan or any Award.

(b) Appointment of Committees. To the extent Applicable Laws permit, the Board may delegate any or all of its powers under the Plan to one or more Committees. The Board may abolish any Committee or re-vest in itself any previously delegated authority at any time.

4.***Stock Available for Awards***

(a) Number of Shares. Subject to adjustment under Section 8 and the terms of this Section 4, Awards may be made under the Plan covering up to the Overall Share Limit. Shares issued under the Plan may consist of authorized but unissued Shares, Shares purchased on the open market or treasury Shares.

(b) Share Recycling. If all or any part of an Award expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, in any case, in a manner that results in the Company acquiring Shares covered by the Award at a price not greater than the price (as adjusted to reflect any Equity Restructuring) paid by the Participant for such Shares or not issuing any Shares covered by the Award, the unused Shares covered by the Award will again be available for Award grants under the Plan. Further, Shares delivered (either by actual delivery or attestation) to the Company by a Participant to satisfy the applicable exercise or purchase price of an Award and/or to satisfy any applicable tax withholding obligation (including Shares retained by the Company from the Award being exercised or purchased and/or creating the tax obligation) will again be available for Award grants

under the Plan. The payment of Dividend Equivalents in cash in conjunction with any outstanding Awards shall not count against the Overall Share Limit.

5. ***Stock Options and Stock Appreciation Rights***

(a) General. The Administrator may grant Non-Qualified Options or Stock Appreciation Rights to Eligible Individuals subject to the conditions and limitations in the Plan. The Administrator will determine the number of Shares covered by each Option and Stock Appreciation Right, the exercise price of each Option and Stock Appreciation Right and the conditions and limitations applicable to the exercise of each Option and Stock Appreciation Right. A Stock Appreciation Right will entitle the Participant (or other person entitled to exercise the Stock Appreciation Right) to receive from the Company upon exercise of the exercisable portion of the Stock Appreciation Right an amount determined by multiplying the excess, if any, of the Fair Market Value of one Share on the date of exercise over the exercise price per Share of the Stock Appreciation Right by the number of Shares with respect to which the Stock Appreciation Right is exercised, subject to any limitations of the Plan or that the Administrator may impose and payable in cash, Shares valued at Fair Market Value or a combination of the two as the Administrator may determine or provide in the Award Agreement.

(b) Exercise Price. The Administrator will establish each Option's and Stock Appreciation Right's exercise price and specify the exercise price in the Award Agreement. The exercise price will not be less than 100% of the Fair Market Value on the grant date of the Option or Stock Appreciation Right.

(c) Duration of Options. Each Option or Stock Appreciation Right will be exercisable at such times and as specified in the Award Agreement, provided that the term of an Option or Stock Appreciation Right will not exceed ten years.

(d) Exercise. Options and Stock Appreciation Rights may be exercised by delivering to the Company a written notice of exercise, in a form the Administrator approves (which may be electronic), signed by the person authorized to exercise the Option or Stock Appreciation Right, together with, as applicable, payment in full (i) as specified in Section 5(e) for the number of Shares for which the Award is exercised and (ii) as specified in Section 9(e) for any applicable taxes. Unless the Administrator otherwise determines, an Option or Stock Appreciation Right may not be exercised for a fraction of a Share.

(e) Payment Upon Exercise. The exercise price of an Option must be paid in cash, wire transfer of immediately available funds or by check payable to the order of the Company or, subject to Section 10(i), any Company insider trading policy (including blackout periods) and Applicable Laws, by:

(i) if there is a public market for Shares at the time of exercise, unless the Administrator otherwise determines, (A) delivery (including telephonically to the extent permitted by the Company) of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to pay the exercise price, or (B) the Participant's delivery to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to pay the exercise price; provided that such amount is paid to the Company at such time as may be required by the Administrator;

(ii) to the extent permitted by the Administrator, delivery (either by actual delivery or attestation) of Shares owned by the Participant valued at their Fair Market Value;

(iii) to the extent permitted by the Administrator, surrendering Shares then issuable upon the Option's exercise valued at their Fair Market Value on the exercise date;

(iv) to the extent permitted by the Administrator, delivery of a promissory note or any other property that the Administrator determines is good and valuable consideration; or

(v) any combination of the above permitted payment forms (including cash, wire transfer or check).

6.***Restricted Stock; Restricted Stock Units***

(a) General. The Administrator may grant Restricted Stock, or the right to purchase Restricted Stock, to any Eligible Individual, subject to the Company's right to repurchase all or part of such shares at their issue price or other stated or formula price from the Participant (or to require forfeiture of such shares) if conditions the Administrator specifies in the Award Agreement are not satisfied before the end of the applicable restriction period or periods that the Administrator establishes for such Award and subject to the conditions and limitations in the Plan. In addition, subject to the conditions and limitations in the Plan, the Administrator may grant to Eligible Individuals Restricted Stock Units, which may be subject to vesting and forfeiture conditions during the applicable restriction period or periods, as set forth in an Award Agreement. The Administrator will determine and set forth in the Award Agreement the terms and conditions for each Restricted Stock and Restricted Stock Unit Award, subject to the conditions and limitations contained in the Plan.

(b) Restricted Stock.

(i) *Dividends*. Participants holding shares of Restricted Stock will be entitled to all ordinary cash dividends paid with respect to such shares, unless the Administrator provides otherwise in the Award Agreement. In addition, unless the Administrator provides otherwise, if any dividends or distributions are paid in Shares, or consist of a dividend or distribution to holders of Common Stock of property other than an ordinary cash dividend, the Shares or other property will be subject to the same restrictions on transferability and forfeitability as the shares of Restricted Stock with respect to which they were paid.

(ii) *Stock Certificates.* The Company may require that the Participant deposit in escrow with the Company (or its designee) any stock certificates issued in respect of shares of Restricted Stock, together with a stock power endorsed in blank.

(c) Restricted Stock Units.

(i) *Settlement.* The Administrator may provide that settlement of Restricted Stock Units will occur upon or as soon as reasonably practicable after the Restricted Stock Units vest or will instead be deferred, on a mandatory basis or at the Participant's election, in a manner intended to comply with Section 409A.

(ii) *Stockholder Rights.* A Participant will have no rights of a stockholder with respect to Shares subject to any Restricted Stock Unit unless and until the Shares are delivered in settlement of the Restricted Stock Unit.

(iii) *Dividend Equivalents.* If the Administrator provides, a grant of Restricted Stock Units may provide a Participant with the right to receive Dividend Equivalents. Dividend Equivalents may be paid currently or credited to an account for the Participant, settled in cash or Shares and

subject to the same restrictions on transferability and forfeitability as the Restricted Stock Units with respect to which the Dividend Equivalents are granted and subject to other terms and conditions as set forth in the Award Agreement.

7.***Other Stock or Cash Based Awards***

Other Stock or Cash Based Awards may be granted to Participants, including Awards entitling Participants to receive Shares to be delivered in the future and including annual or other periodic or long-term cash bonus awards (whether based on specified Performance Criteria or otherwise), in each case subject to any conditions and limitations in the Plan. Such Other Stock or Cash Based Awards will also be available as a payment form in the settlement of other Awards, as standalone payments and as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock or Cash Based Awards may be paid in Shares, cash or other property, as the Administrator determines. Subject to the provisions of the Plan, the Administrator will determine the terms and conditions of each Other Stock or Cash Based Award, including any purchase price, performance goal (which may be based on the Performance Criteria), transfer restrictions, and vesting conditions, which will be set forth in the applicable Award Agreement.

8.***Adjustments for Changes in Common Stock and Certain Other Events***

(a) Equity Restructuring. In connection with any Equity Restructuring, notwithstanding anything to the contrary in this Section 8, the Administrator will equitably adjust each outstanding Award as it deems appropriate to reflect the Equity Restructuring, which may include adjusting the number and type of securities subject to each outstanding Award and/or the Award's exercise price or grant price (if applicable), granting new Awards to Participants (subject to Section 10(d)), and making a cash payment to Participants. The adjustments provided under this Section 8(a) will be nondiscretionary and final and binding on the affected Participant and the Company; provided that the Administrator will determine whether an adjustment is equitable.

(b) Corporate Transactions. In the event of any dividend or other distribution (whether in the form of cash, Common Stock, other securities, or other property), reorganization, merger, consolidation, combination, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of all or substantially all of the assets of the Company, or sale or exchange of Common Stock or other securities of the Company, Change in Control, issuance of warrants or other rights to purchase Common Stock or other securities of the Company, other similar corporate transaction or event, other unusual or nonrecurring transaction or event affecting the Company or its financial statements or any change in any Applicable Laws or accounting principles, the Administrator, on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event (except that action to give effect to a change in Applicable Law or accounting principles may be made within a reasonable period of time after such change) and either automatically or upon the Participant's request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to (x) prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any Award granted or issued under the Plan, (y) to facilitate such transaction or event or (z) give effect to such changes in Applicable Laws or accounting principles:

(i) to provide for the cancellation of any such Award in exchange for either an amount of cash or other property with a value equal to the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights under the vested portion of such Award, as applicable; provided that, if the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the

Participant's rights, in any case, is equal to or less than zero, then the Award may be terminated without payment;

(ii) to provide that such Award shall vest and, to the extent applicable, be exercisable as to all shares covered thereby, notwithstanding anything to the contrary in the Plan or the provisions of such Award;

(iii) to provide that such Award be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by awards covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and/or applicable exercise or purchase price, in all cases, as determined by the Administrator;

(iv) to make adjustments in the number and type of shares of Common Stock (or other securities or property) subject to outstanding Awards and/or with respect to which Awards may be granted under the Plan (including, but not limited to, adjustments of the limitations in Section 4 hereof on the maximum number and kind of shares which may be issued) and/or in the terms and conditions of (including the grant or exercise price), and the criteria included in, outstanding Awards;

(v) to replace such Award with other rights or property selected by the Administrator; and/or

(vi) to provide that the Award will terminate and cannot vest, be exercised or become payable after the applicable event.

(c) Administrative Stand Still. In the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other extraordinary transaction or change affecting the Shares or the share price of Common Stock, including any Equity Restructuring or any securities offering or other similar transaction, for administrative convenience, the Administrator may refuse to permit the exercise of any Award for up to sixty days before or after such transaction.

(d) General. Except as expressly provided in the Plan or the Administrator's action under the Plan, no Participant will have any rights due to any subdivision or consolidation of Shares of any class, dividend payment, increase or decrease in the number of Shares of any class or dissolution, liquidation, merger, or consolidation of the Company or other corporation. Except as expressly provided with respect to an Equity Restructuring under Section 8(a) above or the Administrator's action under the Plan, no issuance by the Company of Shares of any class, or securities convertible into Shares of any class, will affect, and no adjustment will be made regarding, the number of Shares subject to an Award or the Award's grant or exercise price. The existence of the Plan, any Award Agreements and the Awards granted hereunder will not affect or restrict in any way the Company's right or power to make or authorize (i) any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, (ii) any merger, consolidation dissolution or liquidation of the Company or sale of Company assets or (iii) any sale or issuance of securities, including securities with rights superior to those of the Shares or securities convertible into or exchangeable for Shares. The Administrator may treat Participants and Awards (or portions thereof) differently under this Section 8.

(e) Change in Control. Notwithstanding Section 8(b) above, if a Change in Control occurs and Awards are not continued, converted, assumed, or replaced with a comparable award (as determined by the Administrator) by (i) the Company or (ii) a successor entity or its parent or subsidiary (an "***Assumption***"), and provided that the Participant has not had a Termination of Service, then immediately

prior to the Change in Control, such Awards (other than any Award that is regularly scheduled to vest based on the attainment of Performance Criteria or other performance-based vesting conditions) will become fully vested, exercisable and/or payable, as applicable, and all forfeiture, repurchase and other restrictions on such Awards will lapse, in which case, such Awards will be canceled upon the consummation of the Change in Control in exchange for the right to receive the Change in Control consideration payable to other holders of Shares, which may be on such terms and conditions as apply generally to holders of Shares under the Change in Control documents (including, without limitation, any escrow, earn-out or other deferred consideration provisions) or such other terms and conditions as the Administrator may provide, and determined by reference to the number of Shares subject to such Awards and net of any applicable exercise price; provided that to the extent that any Awards constitute "nonqualified deferred compensation" that may not be paid upon the Change in Control under Section 409A without the imposition of taxes thereon under Section 409A, the timing of such payments shall be governed by the applicable Award Agreement (subject to any deferred consideration provisions applicable under the Change in Control documents); and provided, further, that if the amount to which a Participant would be entitled upon the settlement or exercise of such Award at the time of the Change in Control is equal to or less than zero, then such Award may be terminated without payment. An Award will be considered replaced with a comparable award if the Award is exchanged for an amount of cash or other property with a value equal to the amount that could have been obtained upon the settlement of such Award in such Change in Control (as determined by the Administrator), even if such cash or other property payable with respect to the unvested portion of such Award remains subject to similar vesting provisions following such Change in Control. Notwithstanding the foregoing, the Administrator will have full and final authority to determine whether an Assumption of an Award has occurred in connection with a Change in Control.

9. ***General Provisions Applicable to Awards.***

(a) Transferability. Except as the Administrator may determine or provide in an Award Agreement or otherwise, Awards may not be sold, assigned, transferred, pledged or otherwise encumbered, either voluntarily or by operation of law, except by will or the laws of descent and distribution, or, subject to the Administrator's consent, pursuant to a domestic relations order, and, during the life of the Participant, will be exercisable only by the Participant. References to a Participant, to the extent relevant in the context, will include references to a Participant's authorized transferee that the Administrator specifically approves.

(b) Documentation. Each Award will be evidenced in an Award Agreement, which may be written or electronic, as the Administrator determines. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) Discretion. Except as the Plan otherwise provides, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award to a Participant need not be identical, and the Administrator need not treat Participants or Awards (or portions thereof) uniformly.

(d) Termination of Status. The Administrator will determine how the disability, death, retirement, authorized leave of absence or any other change or purported change in a Participant's Service Provider status affects an Award and the extent to which, and the period during which, the Participant, the Participant's legal representative, conservator, guardian or Designated Beneficiary may exercise rights under the Award, if applicable.

(e) Withholding. Each Participant must pay the Company, or make provision satisfactory to the Administrator for payment of, any taxes required by law to be withheld in connection with such Participant's Awards by the date of the event creating the tax liability. The Company may deduct an

amount sufficient to satisfy such tax obligations based on the minimum statutory withholding rates from any payment of any kind otherwise due to a Participant. Participants may satisfy such tax obligations in cash, by wire transfer of immediately available funds, by check made payable to the order of the Company, or subject to Section 10(i) and any Company insider trading policy (including blackout periods), (i) to the extent permitted by the Administrator, in whole or in part by delivery of Shares, including Shares retained from the Award creating the tax obligation, valued at their Fair Market Value, (ii) if there is a public market for Shares at the time the tax obligations are satisfied, unless the Administrator otherwise determines, (A) delivery (including telephonically to the extent permitted by the Company) of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to satisfy the tax obligations, or (B) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to satisfy the tax withholding; provided that such amount is paid to the Company at such time as may be required by the Administrator, or (iii) any combination of the foregoing permitted payment forms (including cash, wire transfer or check). If any tax withholding obligation will be satisfied under clause (i) of the immediately preceding sentence by the Company's retention of Shares from the Award creating the tax obligation and there is a public market for Shares at the time the tax obligation is satisfied, the Company may elect to instruct any brokerage firm determined acceptable to the Company for such purpose to sell on the applicable Participant's behalf some or all of the Shares retained and to remit the proceeds of the sale to the Company or its designee, and each Participant's acceptance of an Award under the Plan will constitute the Participant's authorization to the Company and instruction and authorization to such brokerage firm to complete the transactions described in this sentence.

(f) Amendment of Award; Repricing. The Administrator may amend, modify or terminate any outstanding Award, including by substituting another Award of the same or a different type or changing the exercise or settlement date. The Participant's consent to such action will be required unless (i) the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Award, or (ii) the change is permitted under Section 8 or pursuant to Section 10(g). Notwithstanding the foregoing or anything in the Plan to the contrary, the Administrator may, without the approval of the stockholders of the Company, reduce the exercise price per share of outstanding Options or Stock Appreciation Rights or cancel outstanding Options or Stock Appreciation Rights in exchange for cash, other Awards or Options or Stock Appreciation Rights with an exercise price per share that is less than the exercise price per share of the original Options or Stock Appreciation Rights.

(g) Conditions on Delivery of Stock. The Company will not be obligated to deliver any Shares under the Plan or remove restrictions from Shares previously delivered under the Plan until (i) all Award conditions have been met or removed to the Company's satisfaction, (ii) as determined by the Company, all other legal matters regarding the issuance and delivery of such Shares have been satisfied, including any applicable securities laws and stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Administrator deems necessary or appropriate to satisfy any Applicable Laws. The Company's inability to obtain authority from any regulatory body having jurisdiction, which the Administrator determines is necessary to the lawful issuance and sale of any securities, will relieve the Company of any liability for failing to issue or sell such Shares as to which such requisite authority has not been obtained.

(h) Acceleration. The Administrator may at any time provide that any Award will become immediately vested and fully or partially exercisable, free of some or all restrictions or conditions, or otherwise fully or partially realizable.

(i) Action Required Upon Grant of Award. Promptly following the grant of an Award, the Company shall, in accordance with NASDAQ Rule 5635(c), (a) issue a press release disclosing the

material terms of the Award, including the recipient(s) of the Award and the number of Shares involved and(b) provide written notice to the NASDAQ of the grant.

10.***Miscellaneous.***

(a) No Right to Employment or Other Status. No person will have any claim or right to be granted an Award, and the grant of an Award will not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan or any Award, except as expressly provided in an Award Agreement.

(b) No Rights as Stockholder; Certificates. Subject to the Award Agreement, no Participant or Designated Beneficiary will have any rights as a stockholder with respect to any Shares to be distributed under an Award until becoming the record holder of such Shares. Notwithstanding any other provision of the Plan, unless the Administrator otherwise determines or Applicable Laws require, the Company will not be required to deliver to any Participant certificates evidencing Shares issued in connection with any Award and instead such Shares may be recorded in the books of the Company (or, as applicable, its transfer agent or stock plan administrator). The Company may place legends on stock certificates issued under the Plan that the Administrator deems necessary or appropriate to comply with Applicable Laws.

(c) Effective Date and Term of Plan. Unless earlier terminated by the Board, the Plan will become effective on the date it is approved by the Board and will remain in effect until the tenth anniversary of such date, but Awards previously granted may extend beyond that date in accordance with the Plan. No Awards may be granted under the Plan during any suspension period or after Plan termination.

(d) Stockholder Approval Not Required. It is expressly intended that approval of the Company's stockholders not be required as a condition of the effectiveness of the Plan, and the Plan's provisions shall be interpreted in a manner consistent with such intent for all purposes. Specifically, NASDAQ Rule 5635(c) generally requires stockholder approval for equity compensation plans adopted by companies whose securities are listed on the NASDAQ Stock Market that provide for the delivery of equity securities to any employees, directors or other service providers of such companies as compensation for services. NASDAQ Rule 5635(c)(4) provides an exemption in certain circumstances for employment inducement awards. Notwithstanding anything to the contrary herein, in accordance with NASDAQ Rule 5635(c)(4), Awards may only be granted as material inducements to Eligible Individuals being hired or rehired as Employees, as applicable, and must be approved by (a) the Board, acting through a majority of the Company's Independent Directors or (b) the independent Compensation Committee of the Board. Accordingly, pursuant to NASDAQ Rule 5635(c)(4), the issuance of Awards and the Shares issuable upon exercise or vesting of such Awards pursuant to the Plan is not subject to the approval of the Company's stockholders.

(e) Amendment of Plan. The Administrator may amend, suspend or terminate the Plan at any time; provided that no amendment, other than an increase to the Overall Share Limit, may materially and adversely affect any Award outstanding at the time of such amendment without the affected Participant's consent. Awards outstanding at the time of any Plan suspension or termination will continue to be governed by the Plan and the Award Agreement, as in effect before such suspension or termination. The Board will obtain stockholder approval of any Plan amendment to the extent necessary to comply with Applicable Laws.

(f) Provisions for Foreign Participants. The Administrator may modify Awards granted to Participants who are foreign nationals or employed outside the United States or establish subplans or

procedures under the Plan to address differences in laws, rules, regulations or customs of such foreign jurisdictions with respect to tax, securities, currency, employee benefit or other matters.

(g) Section 409A.

(i) *General.* The Company intends that all Awards be structured to comply with, or be exempt from, Section 409A, such that no adverse tax consequences, interest, or penalties under Section 409A apply. Notwithstanding anything in the Plan or any Award Agreement to the contrary, the Administrator may, without a Participant's consent, amend this Plan or Awards, adopt policies and procedures, or take any other actions (including amendments, policies, procedures and retroactive actions) as are necessary or appropriate to preserve the intended tax treatment of Awards, including any such actions intended to (A) exempt this Plan or any Award from Section 409A, or (B) comply with Section 409A, including regulations, guidance, compliance programs and other interpretative authority that may be issued after an Award's grant date. The Company makes no representations or warranties as to an Award's tax treatment under Section 409A or otherwise. The Company will have no obligation under this Section 10(g) or otherwise to avoid the taxes, penalties or interest under Section 409A with respect to any Award and will have no liability to any Participant or any other person if any Award, compensation or other benefits under the Plan are determined to constitute noncompliant "nonqualified deferred compensation" subject to taxes, penalties or interest under Section 409A.

(ii) *Separation from Service.* If an Award constitutes "nonqualified deferred compensation" under Section 409A, any payment or settlement of such Award upon a termination of a Participant's Service Provider relationship will, to the extent necessary to avoid taxes under Section 409A, be made only upon the Participant's "separation from service" (within the meaning of Section 409A), whether such "separation from service" occurs upon or after the termination of the Participant's Service Provider relationship. For purposes of this Plan or any Award Agreement relating to any such payments or benefits, references to a "termination," "termination of employment" or like terms means a "separation from service."

(iii) *Payments to Specified Employees.* Notwithstanding any contrary provision in the Plan or any Award Agreement, any payment(s) of "nonqualified deferred compensation" required to be made under an Award to a "specified employee" (as defined under Section 409A and as the Administrator determines) due to his or her "separation from service" will, to the extent necessary to avoid taxes under Section 409A(a)(2)(B)(i) of the Code, be delayed for the six-month period immediately following such "separation from service" (or, if earlier, until the specified employee's death) and will instead be paid (as set forth in the Award Agreement) on the day immediately following such six-month period or as soon as administratively practicable thereafter (without interest). Any payments of "nonqualified deferred compensation" under such Award payable more than six months following the Participant's "separation from service" will be paid at the time or times the payments are otherwise scheduled to be made.

(h) Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, other employee or agent of the Company or any Subsidiary will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan or any Award, and such individual will not be personally liable with respect to the Plan because of any contract or other instrument executed in his or her capacity as an Administrator, director, officer, other employee or agent of the Company or any Subsidiary. The Company will indemnify and hold harmless each director, officer, other employee and agent of the Company or any Subsidiary that has been or will be granted or delegated any duty or power relating to the Plan's administration or interpretation, against any cost or expense (including attorneys' fees) or liability

(including any sum paid in settlement of a claim with the Administrator's approval) arising from any act or omission concerning this Plan unless arising from such person's own fraud or bad faith.

(i) Lock-Up Period. The Company may, at the request of any underwriter representative or otherwise, in connection with registering the offering of any Company securities under the Securities Act, prohibit Participants from, directly or indirectly, selling or otherwise transferring any Shares or other Company securities during a period of up to one hundred eighty days following the effective date of a Company registration statement filed under the Securities Act, or such longer period as determined by the underwriter.

(j) Data Privacy. As a condition for receiving any Award, each Participant explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of personal data as described in this paragraph by and among the Company and its Subsidiaries and affiliates exclusively for implementing, administering and managing the Participant's participation in the Plan. The Company and its Subsidiaries and affiliates may hold certain personal information about a Participant, including the Participant's name, address and telephone number; birthdate; social security, insurance number or other identification number; salary; nationality; job title(s); any Shares held in the Company or its Subsidiaries and affiliates; and Award details, to implement, manage and administer the Plan and Awards (the "***Data***"). The Company and its Subsidiaries and affiliates may transfer the Data amongst themselves as necessary to implement, administer and manage a Participant's participation in the Plan, and the Company and its Subsidiaries and affiliates may transfer the Data to third parties assisting the Company with Plan implementation, administration and management. These recipients may be located in the Participant's country, or elsewhere, and the Participant's country may have different data privacy laws and protections than the recipients' country. By accepting an Award, each Participant authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, to implement, administer and manage the Participant's participation in the Plan, including any required Data transfer to a broker or other third party with whom the Company or the Participant may elect to deposit any Shares. The Data related to a Participant will be held only as long as necessary to implement, administer, and manage the Participant's participation in the Plan. A Participant may, at any time, view the Data that the Company holds regarding such Participant, request additional information about the storage and processing of the Data regarding such Participant, recommend any necessary corrections to the Data regarding the Participant or refuse or withdraw the consents in this Section 10(j) in writing, without cost, by contacting the local human resources representative. The Company may cancel Participant's ability to participate in the Plan and, in the Administrator's discretion, the Participant may forfeit any outstanding Awards if the Participant refuses or withdraws the consents in this Section 10(j). For more information on the consequences of refusing or withdrawing consent, Participants may contact their local human resources representative.

(k) Severability. If any portion of the Plan or any action taken under it is held illegal or invalid for any reason, the illegality or invalidity will not affect the remaining parts of the Plan, and the Plan will be construed and enforced as if the illegal or invalid provisions had been excluded, and the illegal or invalid action will be null and void.

(l) Governing Documents. If any contradiction occurs between the Plan and any Award Agreement or other written agreement between a Participant and the Company (or any Subsidiary) that the Administrator has approved, the Plan will govern, unless it is expressly specified in such Award Agreement or other written document that a specific provision of the Plan will not apply.

(m) Governing Law. The Plan and all Awards will be governed by and interpreted in accordance with the laws of the State of Delaware, disregarding any state's choice-of-law principles requiring the application of a jurisdiction's laws other than the State of Delaware.

(n) Claw-back Provisions. All Awards (including any proceeds, gains or other economic benefit the Participant actually or constructively receives upon receipt or exercise of any Award or the receipt or resale of any Shares underlying the Award) will be subject to any Company claw-back policy, including any claw-back policy adopted to comply with Applicable Laws (including the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder) as set forth in such claw-back policy or the Award Agreement.

(o) Titles and Headings. The titles and headings in the Plan are for convenience of reference only and, if any conflict, the Plan's text, rather than such titles or headings, will control.

(p) Conformity to Securities Laws. Participant acknowledges that the Plan is intended to conform to the extent necessary with Applicable Laws. Notwithstanding anything herein to the contrary, the Plan and all Awards will be administered only in conformance with Applicable Laws. To the extent Applicable Laws permit, the Plan and all Award Agreements will be deemed amended as necessary to conform to Applicable Laws.

(q) Relationship to Other Benefits. No payment under the Plan will be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare or other benefit plan of the Company or any Subsidiary except as expressly provided in writing in such other plan or an agreement thereunder.

(r) Broker-Assisted Sales. In the event of a broker-assisted sale of Shares in connection with the payment of amounts owed by a Participant under or with respect to the Plan or Awards, including amounts to be paid under the final sentence of Section 9(e): (a) any Shares to be sold through the broker-assisted sale will be sold on the day the payment first becomes due, or as soon thereafter as practicable; (b) such Shares may be sold as part of a block trade with other Participants in the Plan in which all participants receive an average price; (c) the applicable Participant will be responsible for all broker's fees and other costs of sale, and by accepting an Award, each Participant agrees to indemnify and hold the Company harmless from any losses, costs, damages, or expenses relating to any such sale; (d) to the extent the Company or its designee receives proceeds of such sale that exceed the amount owed, the Company will pay such excess in cash to the applicable Participant as soon as reasonably practicable; (e) the Company and its designees are under no obligation to arrange for such sale at any particular price; and (f) in the event the proceeds of such sale are insufficient to satisfy the Participant's applicable obligation, the Participant may be required to pay immediately upon demand to the Company or its designee an amount in cash sufficient to satisfy any remaining portion of the Participant's obligation.

11. ***Definitions***

As used in the Plan, the following words and phrases will have the following meanings:

(a) "***Administrator***" means the Board or a Committee to the extent that the Board's powers or authority under the Plan have been delegated to such Committee.

(b) "***Applicable Laws***" means the requirements relating to the administration of equity incentive plans under U.S. federal and state securities, tax and other applicable laws, rules and regulations, the applicable rules of any stock exchange or quotation system on which the Common Stock is listed or quoted and the applicable laws and rules of any foreign country or other jurisdiction where Awards are granted.

(c) "***Award***" means, individually or collectively, a grant under the Plan of Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units or Other Stock or Cash Based Awards.

(d) "***Award Agreement***" means a written agreement evidencing an Award, which may be electronic, that contains such terms and conditions as the Administrator determines, consistent with and subject to the terms and conditions of the Plan.

(e) "***Board***" means the Board of Directors of the Company.

(f) "***Change in Control***" means and includes each of the following:

(i) a transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission or a transaction or series of transactions that meets the requirements of clauses (A) and (B) of subsection (iii) below) whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than the Company, any of its Subsidiaries, an employee benefit plan maintained by the Company or any of its Subsidiaries or a "person" that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company's securities outstanding immediately after such acquisition; or

(ii) during any period of two consecutive years, individuals who, at the beginning of such period, constitute the Board together with any new Director(s) (other than a Director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in subsections (i) or (iii)) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the Directors then still in office who either were Directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or

(iii) the consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of the Company's assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:

(A) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the "***Successor Entity***")) directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction, and

(B) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be treated for purposes of this clause (B) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction.

Notwithstanding the foregoing, if a Change in Control constitutes a payment event with respect to any Award (or portion of any Award) that provides for the deferral of compensation that is subject to Section

409A, to the extent required to avoid the imposition of additional taxes under Section 409A, the transaction or event described in subsection (i), (ii) or (iii) with respect to such Award (or portion thereof) shall only constitute a Change in Control for purposes of the payment timing of such Award if such transaction also constitutes a "change in control event," as defined in Treasury Regulation Section 1.409A-3(i)(5).

The Administrator shall have full and final authority, which shall be exercised in its discretion, to determine conclusively whether a Change in Control has occurred pursuant to the above definition, the date of the occurrence of such Change in Control and any incidental matters relating thereto; provided that any exercise of authority in conjunction with a determination of whether a Change in Control is a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.

(g) "***Code***" means the Internal Revenue Code of 1986, as amended, and the regulations issued thereunder.

(h) "***Committee***" means one or more committees or subcommittees of the Board, which may include one or more Company directors or executive officers, to the extent Applicable Laws permit. To the extent required to comply with the provisions of Rule 16b-3, it is intended that each member of the Committee will be, at the time the Committee takes any action with respect to an Award that is subject to Rule 16b-3, a "non-employee director" within the meaning of Rule 16b-3; however, a Committee member's failure to qualify as a "non-employee director" within the meaning of Rule 16b-3 will not invalidate any Award granted by the Committee that is otherwise validly granted under the Plan.

(i) "***Common Stock***" means the common stock of the Company.

(j) "***Company***" means Seres Therapeutics, Inc., a Delaware corporation, or any successor.

(k) "***Consultant***" means any person, including any adviser, engaged by the Company or its parent or Subsidiary to render services to such entity if the consultant or adviser: (i) renders *bona fide* services to the Company; (ii) renders services not in connection with the offer or sale of securities in a capital-raising transaction and does not directly or indirectly promote or maintain a market for the Company's securities; and (iii) is a natural person.

(l) "***Designated Beneficiary***" means the beneficiary or beneficiaries the Participant designates, in a manner the Administrator determines, to receive amounts due or exercise the Participant's rights if the Participant dies or becomes incapacitated. Without a Participant's effective designation, "Designated Beneficiary" will mean the Participant's estate.

(m) "***Director***" means a Board member.

(n) "***Disability***" means a permanent and total disability under Section 22(e)(3) of the Code, as amended.

(o) "***Dividend Equivalents***" means a right granted to a Participant under the Plan to receive the equivalent value (in cash or Shares) of dividends paid on Shares.

(p) "***Eligible Individual***" means any individual who was not previously an Employee or Director hired as a new Employee or rehired as an Employee following a bona fide period of interruption of employment if such person is granted an Award as a material inducement to his or her entering into employment with the Company or a Subsidiary (within the meaning of the NASDAQ Rule 5635(c)(4)).

(q) "***Employee***" means any employee of the Company or its Subsidiaries.

(r) "***Equity Restructuring***" means a nonreciprocal transaction between the Company and its stockholders, such as a stock dividend, stock split, spin-off or recapitalization through a large, nonrecurring cash dividend, that affects the number or kind of Shares (or other Company securities) or the share price of Common Stock (or other Company securities) and causes a change in the per share value of the Common Stock underlying outstanding Awards.

(s) "***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

(t) "***Fair Market Value***" means, as of any date, the value of Common Stock determined as follows: (i) if the Common Stock is listed on any established stock exchange, its Fair Market Value will be the closing sales price for such Common Stock as quoted on such exchange for such date, or if no sale occurred on such date, the last day preceding such date during which a sale occurred, as reported in *The Wall Street Journal* or another source the Administrator deems reliable; (ii) if the Common Stock is not traded on a stock exchange but is quoted on a national market or other quotation system, the closing sales price on such date, or if no sales occurred on such date, then on the last date preceding such date during which a sale occurred, as reported in *The Wall Street Journal* or another source the Administrator deems reliable; or (iii) without an established market for the Common Stock, the Administrator will determine the Fair Market Value in its discretion.

(u) "***Incentive Stock Option***" means an Option intended to qualify as an "incentive stock option" as defined in Section 422 of the Code.

(v) "***Independent Director***" means a Director who qualifies as "independent" within the meaning of NASDAQ Rule 5635(c)(4), or any successor rule, as such rule may be amended from time to time.

(w) "***NASDAQ Rule 5635(c)(4)***" means NASDAQ Rule 5635(c)(4), or any successor rule, and all guidance and other interpretative authority thereunder, as such rule, guidance and other authority may be amended from time to time.

(x) "***Non-Qualified Stock Option***" means an Option not intended to qualify as an Incentive Stock Option.

(y) "***Option***" means an option to purchase Shares.

(z) "***Other Stock or Cash Based Awards***" means cash awards, awards of Shares, and other awards valued wholly or partially by referring to, or are otherwise based on, Shares or other property.

(aa) "***Overall Share Limit***" means 2,500,000 Shares.

(bb) "***Participant***" means an Eligible Individual who has been granted an Award.

(cc) "***Performance Criteria***" mean the criteria (and adjustments) that the Administrator may select for an Award to establish performance goals for a performance period, which may include the following: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization, and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including but not limited to gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return

on stockholders' equity; total stockholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease, peer group results, or market performance indicators or indices.

(dd) "***Plan***" means this 2022 Employment Inducement Award Plan, as it may be amended and/or restated from time to time.

(ee) "***Restricted Stock***" means Shares awarded to a Participant under Section 6 subject to certain vesting conditions and other restrictions.

(ff) "***Restricted Stock Unit***" means an unfunded, unsecured right to receive, on the applicable settlement date, one Share or an amount in cash or other consideration determined by the Administrator to be of equal value as of such settlement date, subject to certain vesting conditions and other restrictions.

(gg) "***Rule 16b-3***" means Rule 16b-3 promulgated under the Exchange Act.

(hh) "***Section 409A***" means Section 409A of the Code and all regulations, guidance, compliance programs and other interpretative authority thereunder.

(ii) "***Securities Act***" means the Securities Act of 1933, as amended.

(jj) "***Service Provider***" means an Employee, Consultant or Director.

(kk) "***Shares***" means shares of Common Stock.

(ll) "***Stock Appreciation Right***" means a stock appreciation right granted under Section 5.

(mm) "***Subsidiary***" means any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities beginning with the Company if each of the entities other than the last entity in the unbroken chain beneficially owns, at the time of the determination, securities or interests representing at least 50% of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

(nn) "***Termination of Service***" means the date the Participant ceases to be a Service Provider.

* * * * *

SERES THERAPEUTICS, INC.
2022 EMPLOYMENT INDUCEMENT AWARD PLAN

STOCK OPTION GRANT NOTICE

Capitalized terms not specifically defined in this Stock Option Grant Notice (the "***Grant Notice***") have the meanings given to them in the 2022 Employment Inducement Award Plan (as amended from time to time, the "***Plan***") of Seres Therapeutics, Inc. (the "***Company***").

The Company hereby grants to the participant listed below ("***Participant***") the stock option described in this Grant Notice (the "***Option***"), subject to the terms and conditions of the Plan and the Stock Option Agreement attached hereto as **Exhibit A** (the "***Agreement***"), both of which are incorporated into this Grant Notice by reference.

Participant:	[_____]
Grant Date:	[_____]
Exercise Price per Share:	$[_____]
Shares Subject to the Option:	[_____]
Final Expiration Date:	[_____]
Vesting Commencement Date:	[_____]
Vesting Schedule:	[To be specified in individual award agreements]
Type of Option:	Non-Qualified Stock Option

By Participant's signature below, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

SERES THERAPEUTICS, INC.	**PARTICIPANT**
By:	
Name:	
Title:	

STOCK OPTION AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

ARTICLE I.
GENERAL

1.1 Grant of Option. Pursuant to the Grant Notice to which this Agreement is attached, the Company has granted to Participant the Option effective as of the grant date set forth in the Grant Notice (the "***Grant Date***").

1.2 Incorporation of Terms of Plan. The Option is subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

1.3 Employment Inducement Award. The Option is intended to constitute an "employment inducement award" under NASDAQ Rule 5635(c)(4) that is exempt from the requirements of shareholder approval of equity compensation plans under NASDAQ Rule 5635(c)(4). This Agreement and the terms and conditions of the Option will be interpreted consistent with such intent.

ARTICLE II.
PERIOD OF EXERCISABILITY

2.1 Commencement of Exercisability. The Option will vest and become exercisable according to the vesting schedule in the Grant Notice (the "***Vesting Schedule***") except that any fraction of a Share as to which the Option would be vested or exercisable will be accumulated and will vest and become exercisable only when a whole Share has accumulated. Notwithstanding anything in the Grant Notice, the Plan or this Agreement to the contrary, unless the Administrator otherwise determines, the Option will immediately expire and be forfeited as to any portion that is not vested and exercisable as of Participant's Termination of Service for any reason.

2.2 Duration of Exercisability. The Vesting Schedule is cumulative. Any portion of the Option which vests and becomes exercisable will remain vested and exercisable until the Option expires. The Option will be forfeited immediately upon its expiration.

2.3 Expiration of Option. The Option may not be exercised to any extent by anyone after, and will expire on, the first of the following to occur:

(a) the final expiration date in the Grant Notice;

(b) except as the Administrator may otherwise approve, the expiration of three (3) months from the date of Participant's Termination of Service, unless Participant's Termination of Service is for Cause or by reason of Participant's death or Disability;

(c) except as the Administrator may otherwise approve, the expiration of one (1) year from the date of Participant's Termination of Service by reason of Participant's death or Disability; and

(d) except as the Administrator may otherwise approve, Participant's Termination of Service for Cause.

As used in this Agreement, "Cause" means (i) if Participant is a party to a written employment or consulting agreement with the Company or its Subsidiary in which the term "cause" is defined (a "***Relevant Agreement***"), "Cause" as defined in the Relevant Agreement, and (ii) if no Relevant Agreement exists, (A) the Administrator's determination that Participant failed to substantially perform Participant's duties (other than a failure resulting from Participant's Disability); (B) the Administrator's determination that Participant failed to carry out, or comply with any lawful and reasonable directive of the Board or Participant's immediate supervisor; (C) Participant's conviction, plea of no contest, plea of nolo contendere, or imposition of unadjudicated probation for any felony or indictable offense or crime involving moral turpitude; (D) Participant's unlawful use (including being under the influence) or possession of illegal drugs on the premises of the Company or any of its Subsidiaries or while performing Participant's duties and responsibilities for the Company or any of its Subsidiaries; or (E) Participant's commission of an act of fraud, embezzlement, misappropriation, misconduct, or breach of fiduciary duty against the Company or any of its Subsidiaries.

ARTICLE III.
EXERCISE OF OPTION

3.1 Person Eligible to Exercise. During Participant's lifetime, only Participant may exercise the Option. After Participant's death, any exercisable portion of the Option may, prior to the time the Option expires, be exercised by Participant's Designated Beneficiary as provided in the Plan.

3.2 Partial Exercise. Any exercisable portion of the Option or the entire Option, if then wholly exercisable, may be exercised, in whole or in part, according to the procedures in the Plan at any time prior to the time the Option or portion thereof expires, except that the Option may only be exercised for whole Shares.

3.3 Tax Withholding.

(a) The Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the Option as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise issuable under the Option.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the Option, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the Option. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or exercise of the Option or the subsequent sale of Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure the Option to reduce or eliminate Participant's tax liability.

ARTICLE IV.
OTHER PROVISIONS

4.1 Adjustments. Participant acknowledges that the Option is subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.

4.2 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant (or, if Participant is

then deceased, to the person entitled to exercise the Option) at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

4.3 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

4.4 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

4.5 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

4.6 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement and the Option will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

4.7 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

4.8 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

4.9 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the Option, and rights no greater than the right to receive the Shares as a general unsecured creditor with respect to the Option, as and when exercised pursuant to the terms hereof.

4.10 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

4.11 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

* * * * *

SERES THERAPEUTICS, INC.
2022 EMPLOYMENT INDUCEMENT AWARD PLAN

RESTRICTED STOCK UNIT GRANT NOTICE

Capitalized terms not specifically defined in this Restricted Stock Unit Grant Notice (the "***Grant Notice***") have the meanings given to them in the 2022 Employment Inducement Award Plan (as amended from time to time, the "***Plan***") of Seres Therapeutics, Inc. (the "***Company***").

The Company hereby grants to the participant listed below ("***Participant***") the Restricted Stock Units described in this Grant Notice (the "***RSUs***"), subject to the terms and conditions of the Plan and the Restricted Stock Unit Agreement attached hereto as **Exhibit A** (the "***Agreement***"), both of which are incorporated into this Grant Notice by reference.

Participant:	[_____]
Grant Date:	[_____]
Number of RSUs:	[_____]
Vesting Commencement Date:	[_____]
Vesting Schedule:	[To be specified in individual award agreements]

By Participant's signature below, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

SERES THERAPEUTICS, INC.	**PARTICIPANT**
By:	
Print Name:	
Title:	

RESTRICTED STOCK UNIT AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

ARTICLE I.
GENERAL

1.1 Award of RSUs and Dividend Equivalents.

(a) The Company has granted the RSUs to Participant effective as of the grant date set forth in the Grant Notice (the "***Grant Date***"). Each RSU represents the right to receive one Share or, at the option of the Company, an amount of cash, in either case, as set forth in this Agreement. Participant will have no right to the distribution of any Shares or payment of any cash until the time (if ever) the RSUs have vested.

(b) The Company hereby grants to Participant, with respect to each RSU, a Dividend Equivalent for ordinary cash dividends paid to substantially all holders of outstanding Shares with a record date after the Grant Date and prior to the date the applicable RSU is settled, forfeited or otherwise expires. Each Dividend Equivalent entitles Participant to receive the equivalent value of any such ordinary cash dividends paid on a single Share. The Company will establish a separate Dividend Equivalent bookkeeping account (a "***Dividend Equivalent Account***") for each Dividend Equivalent and credit the Dividend Equivalent Account (without interest) on the applicable dividend payment date with the amount of any such cash paid.

1.2 Incorporation of Terms of Plan. The RSUs are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

1.3 Unsecured Promise. The RSUs and Dividend Equivalents will at all times prior to settlement represent an unsecured Company obligation payable only from the Company's general assets.

1.4 Employment Inducement Award. The RSUs are intended to constitute an "employment inducement award" under NASDAQ Rule 5635(c)(4) that is exempt from the requirements of shareholder approval of equity compensation plans under NASDAQ Rule 5635(c)(4). This agreement and the terms and conditions of the RSUS will be interpreted consistent with such intent.

ARTICLE II.
VESTING; FORFEITURE AND SETTLEMENT

2.1 Vesting; Forfeiture. The RSUs will vest according to the vesting schedule in the Grant Notice except that any fraction of an RSU that would otherwise be vested will be accumulated and will vest only when a whole RSU has accumulated. In the event of Participant's Termination of Service for any reason, all unvested RSUs will immediately and automatically be cancelled and forfeited, except as otherwise determined by the Administrator or provided in a binding written agreement between Participant and the Company. Dividend Equivalents (including any Dividend Equivalent Account balance) will vest or be forfeited, as applicable, upon the vesting or forfeiture of the RSU with respect to which the Dividend Equivalent (including the Dividend Equivalent Account) relates.

2.2 Settlement.

(a) RSUs and Dividend Equivalents (including any Dividend Equivalent Account balance) will be paid in Shares or cash at the Company's option as soon as administratively practicable after the vesting of the applicable RSU, but in no event more than sixty (60) days after the RSU's vesting date. Notwithstanding the foregoing, the Company may delay any payment under this Agreement that the Company reasonably determines would violate Applicable Law until the earliest date the Company reasonably determines the making of the payment will not cause such a violation (in accordance with Treasury Regulation Section 1.409A-2(b)(7)(ii)), provided the Company reasonably believes the delay will not result in the imposition of excise taxes under Section 409A.

(b) If an RSU is paid in cash, the amount of cash paid with respect to the RSU will equal the Fair Market Value of a Share on the day immediately preceding the payment date. If a Dividend Equivalent is paid in Shares, the number of Shares paid with respect to the Dividend Equivalent will equal the quotient, rounded down to the nearest whole Share, of the Dividend Equivalent Account balance divided by the Fair Market Value of a Share on the day immediately preceding the payment date.

ARTICLE III.
TAXATION AND TAX WITHHOLDING

3.1 Representation. Participant represents to the Company that Participant has reviewed with Participant's own tax advisors the tax consequences of this Award and the transactions contemplated by the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

3.2 Tax Withholding.

(a) The Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the RSUs or Dividend Equivalents as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise issuable under the Award.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the RSUs and the Dividend Equivalents, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the RSUs or Dividend Equivalents. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the RSUs or the Dividend Equivalents or the subsequent sale of Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure the RSUs or Dividend Equivalents to reduce or eliminate Participant's tax liability.

(c) Mandatory Sell to Cover

(i) By accepting this Award, Participant understands and agrees that as a condition of the grant of the RSUs hereunder, Participant is required to, and hereby affirmatively elects to (the "***Sell to Cover Election***"), (1) sell that number of Shares determined in accordance with this Section 3.2(c) as may be necessary to satisfy all applicable withholding obligations with respect to any taxable event arising in connection with the RSUs and similarly sell such number of Shares as may be necessary to satisfy all applicable withholding obligations with respect to any other awards of restricted stock units granted to Participant under the Plan or any other equity incentive plans of the Company or its predecessor, and (2) to allow the transfer agent (together with any other party

the Company determines necessary to execute the Sell to Cover Election, the "***Agent***") to remit the cash proceeds of such sale(s) to the Company. Furthermore, Participant directs the Company to make a cash payment equal to the required tax withholding from the cash proceeds of such sale(s) directly to the appropriate taxing authorities.

(ii) Participant hereby appoints the Agent as Participant's agent and authorizes the Agent to (1) sell on the open market at the then prevailing market price(s), on the Participant's behalf, as soon as practicable on or after the date the Shares are issued upon the vesting of the RSUs, that number (rounded up to the next whole number) of the Shares so issued necessary to generate proceeds to cover (x) any tax withholding obligations incurred with respect to such vesting or issuance and (y) all applicable fees and commissions due to, or required to be collected by, the Agent with respect thereto and (2) apply any remaining funds to Participant's tax withholding obligations hereunder. Participant hereby authorizes the Company and the Agent to cooperate and communicate with one another to determine the number of Shares that must be sold pursuant to this Section 3.2(c)(ii). Participant understands that the Agent may effect sales as provided in this Section 3.2(c)(ii) in one or more sales and that the average price for executions resulting from bunched orders will be assigned to Participant's account. In addition, Participant acknowledges that it may not be possible to sell Shares as provided by this Section 3.2(c)(ii) due to (1) a legal or contractual restriction applicable to Participant or the Agent, (2) a market disruption, or (3) rules governing order execution priority on the national exchange where the Shares may be traded. Participant further agrees and acknowledges that in the event the sale of Shares would result in material adverse harm to the Company, as determined by the Company in its sole discretion, the Company may instruct the Agent not to sell Shares as provided by this Section 3.2(c)(ii). In the event of the Agent's inability to sell Shares, the Participant will continue to be responsible for the timely payment to the Company and/or its affiliates of all federal, state, local and foreign taxes that are required by applicable laws and regulations to be withheld, including but not limited to those amounts specified in this Section 3.2(c)(ii). Participant acknowledges that regardless of any other term or condition of this Section 3.2(c), the Agent will not be liable to Participant for (1) special, indirect, punitive, exemplary, or consequential damages, or incidental losses or damages of any kind, or (2) any failure to perform or for any delay in performance that results from a cause or circumstance that is beyond its reasonable control. Participant hereby agrees to execute and deliver to the Agent any other agreements or documents as the Agent reasonably deems necessary or appropriate to carry out the purposes and intent of this Section 3.2(c). The Agent is a third-party beneficiary of this Section 3.2(c). This Section 3.2(c) shall terminate not later than the date on which all tax withholding obligations arising in connection with the Award have been satisfied.

(iii) **Participant has carefully reviewed this Section 3.2(c) and Participant hereby represents and warrants that on the date hereof he or she is not aware of any material, nonpublic information with respect to the Company or any securities of the Company, is not subject to any legal, regulatory or contractual restriction that would prevent the Agent from conducting sales, does not have, and will not attempt to exercise, authority, influence or control over any sales of Shares effected by the Agent pursuant to the Agreement, and is entering into the Agreement and this election to "sell to cover" in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1 (regarding trading of the Company's securities on the basis of material nonpublic information) under the Exchange Act. It is Participant's intent that this election to "sell to cover" comply with the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act and be interpreted to comply with the requirements of Rule 10b5-1(c) under the Exchange Act**.

ARTICLE IV.
OTHER PROVISIONS

4.1 Adjustments. Participant acknowledges that the RSUs, the Shares subject to the RSUs and the Dividend Equivalents are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.

4.2 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

4.3 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

4.4 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

4.5 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

4.6 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement, the RSUs and the Dividend Equivalents will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

4.7 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

4.8 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

4.9 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any

underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the RSUs and Dividend Equivalents, and rights no greater than the right to receive cash or the Shares as a general unsecured creditor with respect to the RSUs and Dividend Equivalents, as and when settled pursuant to the terms of this Agreement.

4.10 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

4.11 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

* * * * *

Exhibit 10.5

SERES THERAPEUTICS, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

(as amended effective February 17, 2023)(the "***Effective Date***")

Non-employee members of the board of directors (the "***Board***") of Seres Therapeutics, Inc. (the "***Company***") shall receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program (this "***Program***"). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board (other than the determination by the Compensation and Talent Committee of the number of shares subject to an Initial Award as set forth in Section II(A)), to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "***Non-Employee Director***") who is entitled to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors. No Non-Employee Director shall have any rights hereunder, except with respect to stock options granted pursuant to the Program.

I. CASH COMPENSATION

A. Annual Retainers. Each Non-Employee Director shall receive an annual retainer of $45,000 for service on the Board.

B. Additional Annual Retainers. In addition, each Non-Employee Director shall receive the following annual retainers:

1. *Chairman of the Board or Lead Independent Director*. A Non-Employee Director serving as Chairman of the Board or Lead Independent Director shall receive an additional annual retainer of $35,000 for such service.

2. *Audit Committee*. A Non-Employee Director serving as Chairperson of the Audit Committee shall receive an additional annual retainer of $20,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Audit Committee shall receive an additional annual retainer of $10,000 for such service.

3. *Compensation and Talent Committee*. A Non-Employee Director serving as Chairperson of the Compensation and Talent Committee shall receive an additional annual retainer of $15,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Compensation and Talent Committee shall receive an additional annual retainer of $7,500 for such service.

4. *Nominating and Corporate Governance Committee*. A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of $10,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of $5,000 for such service.

5. *Science and Clinical Development Committee*. A Non-Employee Director serving as Chairperson of the Science and Clinical Development Committee shall receive an additional annual retainer of $15,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Science and Clinical Development Committee shall receive an additional annual retainer of $7,500 for such service.

C. Payment of Retainers. The annual retainers described in Sections I(A) and I(B) shall be earned on a quarterly basis based on a calendar quarter and shall be paid in cash by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section I(B), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

II. Equity Compensation

Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Company's 2015 Incentive Award Plan or any other applicable Company equity incentive plan then-maintained by the Company (the "***Equity Plan***") and shall be granted subject to award agreements, including attached exhibits, in substantially the form previously approved by the Board. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein, and all grants of stock options hereby are subject in all respects to the terms of the Equity Plan and the applicable award agreement. For the avoidance of doubt, the share numbers in Sections II(A) and II(B) shall be subject to adjustment as provided in the Equity Plan, including without limitation with respect to any stock dividend, stock split, reverse stock split or other similar event affecting the Company's common stock that is effected prior to the Effective Date.

A. Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall receive an option to purchase shares of the Company's common stock on the date of such initial election or appointment in an amount determined by the Compensation and Talent Committee prior to such initial election or appointment and subject to the terms and provisions of the Equity Plan, including without limitation Section IV.(e) thereto. The awards described in this Section II(A) shall be referred to as "***Initial Awards***." No Non-Employee Director shall be granted more than one Initial Award.

B. Subsequent Awards. A Non-Employee Director who (i) has been serving as a Non-Employee Director on the Board for at least six months as of the date of any annual meeting of the Company's stockholders after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall be automatically granted an option to purchase 35,000 shares of the Company's common stock on the date of such annual meeting. The awards

described in this Section II(B) shall be referred to as "***Subsequent Awards***." For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an annual meeting of the Company's stockholders shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Award on the date of such meeting as well.

C. Termination of Service of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section II(A) above, but to the extent that they are otherwise entitled, will receive, after termination from service with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section II(B) above.

D. Terms of Awards Granted to Non-Employee Directors

1. *Exercise Price*. The per share exercise price of each option granted to a Non-Employee Director shall equal the Fair Market Value (as defined in the Equity Plan) of a share of common stock on the date the option is granted.

2. *Vesting*. Each Initial Award shall vest and become exercisable in four substantially equal annual installments following the date of grant, such that the Initial Award shall be fully vested on the fourth anniversary of the date of grant, subject to the Non-Employee Director continuing in service as a Non-Employee Director through each such vesting date. Each Subsequent Award shall vest and become exercisable on the earlier of the first anniversary of the date of grant or the day immediately prior to the date of the next annual meeting of the Company's stockholders occurring after the date of grant, in either case subject to the Non-Employee Director continuing in service on the Board as a Non-Employee Director through each such vesting date. Unless the Board otherwise determines, any portion of an Initial Award or Subsequent Award which is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board as a Non-Employee Director shall be immediately forfeited upon such termination of service and shall not thereafter become vested and exercisable. All of a Non-Employee Director's Initial Awards and Subsequent Awards shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.

3. *Term*. The maximum term of each stock option granted to a Non-Employee Director hereunder shall be ten (10) years from the date the option is granted.

* * * * *

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

AMENDMENT TO LONG TERM MANUFACTURING AGREEMENT

THIS AMENDMENT (the "**Amendment**"), to that certain Long Term Manufacturing Agreement by and between Seres Therapeutics, Inc. and BacThera AG, dated as of November 8, 2021 (the "**LTMA**"), is made and entered into as of December 14, 2022 by and between Seres Therapeutics, Inc. ("**Seres**"), a corporation organized and existing under the laws of Delaware, having its principal place of business at 200 Sidney Street, Cambridge, MA 02139, USA; and BacThera AG, a joint venture between Chr. Hansen A/S and Capsugel Belgium NV, a Lonza Group Affiliate, ("**Lonza**"), having a place of business at Hochbergerstrasse 60A, 4057 Basel, Switzerland ("**Bacthera**"). Seres and Bacthera may be referred to herein individually as a "**Party**" or collectively as the "**Parties**."

WHEREAS, pursuant to Section 10.2 of Exhibit 1 to the LTMA, Bacthera has proposed two adjustments to the CapEx Target (defined therein); and

WHEREAS, pursuant to Section 12.1 of Exhibit 1 to the LTMA, Bacthera has proposed certain changes to the Work (defined therein).

NOW, THEREFORE, in consideration of the mutual covenants and obligations set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. **DEFINITIONS**

1.1 The definition of Product(s) in the LTMA shall be revised to "SER-109 and other products, as agreed to by both Parties".

1.2 Capitalized terms not defined in this Amendment shall have the definition ascribed to them in the LTMA.

2. **CHANGE ORDER**

2.1 *Change Order*. The Change Order attached hereto as Exhibit 1, totaling [***], is hereby accepted and agreed to by the Parties.

2.2 *Additional Scope.* Bacthera agrees to complete development of Spray Drying technologies Proof of Concept for Seres at the Hørsholm Facility [***].

3. **CAPEX TARGET ADJUSTMENTS**

3.1 *First Adjustment*. Pursuant to Section 10.2(a)(i) of Exhibit 1 to the LTMA, the Parties hereby agree that the First Adjustment shall not exceed [***]. The Adjusted CapEx Target shall not exceed [***] including the Change Order.

3.2 *Second Adjustment*. Purusant to Section 10.2(a)(ii) of Exhibit 1 to the LTMA, the Parties hereby agree that the Second Adjustment shall not exceed [***][(1)] which is [***].

4. **FINAL CAPEX AMOUNT**

4.1 *Final CapEx Amount.* The Parties agree that following the adjustments to the CapEx Target and the Change Order, the Final CapEx Amount shall not exceed [***][(2)].

4.2 *Reductions*. Consistent with Section 10.2 of Exhibit 1 to the LTMA, Bacthera will [***].

5. **MILESTONE PAYMENTS**

5.1 The table in Section 11.1(a) of Exhibit 1 to the LTMA is hereby replaced with the following:

MILESTONE	MILESTONE PAYMENT (CAPEX TARGET)
Contract Signature	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

6. **BUDGET UPDATES**

6.1 [***].

7. **MISCELLANEOUS**

7.1 *Counterparts*. This Amendment may be executed simultaneously in any number of counterparts, any one of which need not contain the signature of more than one Party but all such counterparts taken together will constitute one and the same agreement.

[Signature page follows]

In Witness Whereof, the Parties have caused this Agreement to be executed by their respective duly authorized officers as of the Effective Date, each copy of which will for all purposes be deemed to be an original.

SIGNED BY:
FOR AND ON BEHALF OF
SERES THERAPEUTICS, INC.

/s/ Eric D. Shaff
NAME ERIC D. SHAFF
TITLE PRESIDENT, CEO
DATE December 17, 2022 | 1:11PM PST

SIGNED BY:
For and on behalf of
BacThera AG

/s/ [***]
Name [***]
Title [***]
Date December 20, 2022

SIGNED BY:
For and on behalf of
BacThera AG

/s/ [***]
Name [***]
Title [***]
Date December 20, 2022

Exhibit 1
Change Order

[***]

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-269081, 333-263134, 333-253776, 333-236824, 333-230092, 333-223514, 333-210171 and 333-205253) and Form S-3 (Nos.333-244401, 333- 237033 and 333-216735) of Seres Therapeutics, Inc. of our report dated March 7, 2023 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/PricewaterhouseCoopers LLP
Boston, Massachusetts
March 7, 2023

Exhibit 31.1

CERTIFICATIONS

I, Eric D. Shaff, certify that:

1. I have reviewed this Annual Report on Form 10-K of Seres Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 7, 2023

By: /s/ Eric D. Shaff

Eric D. Shaff
President and Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 31.2

CERTIFICATIONS

I, David Arkowitz, certify that:

1. I have reviewed this Annual Report on Form 10-K of Seres Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 7, 2023

By: /s/ David Arkowitz

David Arkowitz

Executive Vice President, Chief Financial Officer and Head of Business Development

(*Principal Financial and Accounting Officer*)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Eric D. Shaff, President and Chief Executive Officer of Seres Therapeutics, Inc. (the "Company"), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Annual Report on Form 10-K of the Company for the period ended December 31, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 7, 2023

/s/ Eric D. Shaff
Eric D. Shaff
President and Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, David Arkowitz, Executive Vice President, Chief Financial Officer and Head of Business Development of Seres Therapeutics, Inc. (the "Company"), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Annual Report on Form 10-K of the Company for the period ended December 31, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 7, 2023

/s/ David Arkowitz

David Arkowitz

Executive Vice President, Chief Financial Officer and Head of Business Development
(*Principal Financial and Accounting Officer*)